Measuring Operational Excellence Performance – A Mixed-methods Conceptualization and Application in Pharmaceutical Quality Control Laboratories

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Danksagung

Die vorliegende Dissertation entstand während meiner Zeit als wissenschaftlicher Mitarbeiter im Bereich Produktionsmanagement am Institut für Technologiemanagement an der Universität St.Gallen. In den knapp drei Jahren als wissenschaftlicher Mitarbeiter konnte ich in der Gruppe Operational Excellence zahlreiche internationale Projekterfahrung mit direktem und indirektem Bezug zu meiner Dissertation sammeln. Der Gruppenfokus ermöglichte es mir darüber hinaus, über die vergangenen Jahre eine Mehrzahl an dissertationsbezogenen Industrieprojekten und eine Industrie-Austauschplattform zu realisieren, um einerseits die Empirie sicherzustellen und andererseits meine vorläufigen Forschungsergebnisse zu diskutieren. Die internationale Ausrichtung meiner täglichen Arbeit war besonders gewinnbringend. Die Kooperation mit knapp 30 internationalen Unternehmen, mehreren Forschungsinstituten und der US Food and Drug Administration erlaubte mir einen vielfältigen Einblick, der einige Teile dieser Dissertation bereichert hat.

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St. Gallen, Dezember 2018 Stephan Köhler

Summary

Operational Excellence (OPEX) has been recognized as a major driver for business performance. Despite the importance of an integrated approach to drive business performance, scholars and practitioners have primarily focused on OPEX in manufacturing to create sustainable success. However, in the pharmaceutical industry the quality control (QC) lab constitutes a major bottleneck in the value creation. In recent time OPEX in QC labs has gained increased interest as a driver of the performance of the organization that has been overlooked to date.

Literature contributes with generic excellence models. However, scholars have neglected to show their application in the specific context of QC labs of this research. The diverse performance measurement literature emphasizes that the approach to operational performance depends on the unit of analysis and cannot be transferred one-to-one from other areas. Today, the empirical work from academia and practice that discusses OPEX performance in pharmaceutical QC labs from an integrated perspective is scarce.

Accordingly, this thesis addresses the outlined gap of knowledge with a scientifically conceptualized, practically operationalized, unified, and integrated approach to measure OPEX performance in pharmaceutical QC labs. The research employs a mixed-methods approach combining quantitative and qualitative research. The resource-based view (RBV) constitutes the scientific basis framing the research at hand.

The thesis comprises three research stages. First, OPEX performance in pharmaceutical QC labs is conceptualized and operationalized. This stage concludes in an operationalized performance measurement model (PMM). Additionally, this stage yields in research propositions and hypotheses for the subsequent research stage. Second, a quantitative analysis provides new insight into the relation between the model dimensions and OPEX performance in QC labs. In particular, it focuses on the relation between OPEX performance, OPEX enablers, and the operating context. Some research findings of this stage contradict earlier empirical work in the Operations Management (OM) literature. These contradicting findings build the basis of the third and last research stage, the application of the PMM. Third, three qualitative case studies provide rich context information explaining how and why some QC labs contradict earlier work in OM literature.

The quantitative part of this research contributes new knowledge on the interdependencies of OPEX performance, OPEX enablers, and the operating context of pharmaceutical QC labs. Furthermore, it enables practitioners to compare the research findings with the OPEX state in their QC labs to identify areas of improvement with the highest impact on their OPEX performance eventually driving business performance. The qualitative part of this research discloses and deepens several influencing factors explaining performance and enabler implementation gaps. Additionally, the case studies provide an impulse for practitioners to review their OPEX strategy in QC labs by incorporating lessons learned and successful practices of the analyzed case companies.

To conclude, the developed OPEX performance measurement model allows a comprehensive examination of OPEX performance in QC labs. The quantitative and qualitative research findings serve as a starting point to align current industry practices with successful practices of well performing QC labs.

Zusammenfassung

Operational Excellence (OPEX) ist ein wesentlicher Treiber nachhaltiger Performance von Unternehmen. Bisher haben sich Wissenschaftler und Praktiker besonders auf OPEX in der Produktion konzentriert. Das Qualitätskontrolllabor (QK Labor) stellt in der pharmazeutischen Industrie jedoch einen bedeutenden Engpass in der Wertschöpfung dar. In den letzten Jahren zeigte sich daher ein zunehmendes Interesse an OPEX in QK Laboren als bis dato unausgeschöpfter Performance Treiber.

In der Literatur sind generische Exzellenzmodelle festgehalten, jedoch wurde deren Übertragung auf spezifische Kontexte vernachlässigt. Die Performance Measurement Literatur betont, dass ein Performance Messansatz nicht ohne Anpassungen auf eine neue Untersuchungseinheit übertragen werden kann. Bis heute mangelt es an empirischen Arbeiten in Academia und Praxis, die einen ganzheitlichen Performance Messansatz in pharmazeutischen QK Laboren vertiefen.

Die vorliegende Dissertation adressiert diese Wissenslücke mit der Konzeptualisierung und Operationalisierung eines ganzheitlichen OPEX Messansatzes in pharmazeutischen QK Laboren. Es werden ein quantitativer und ein qualitativer Forschungsansatz kombiniert. Der resource-based view (RBV) dient als Forschungstheorie.

Die Dissertation umfasst drei Forschungsphasen. In Phase 1 wird die Messung von OPEX Performance konzeptualisiert und operationalisiert. Das ganzheitliche OPEX Performance Messmodel ist Ergebnis dieser Forschungsphase. Ausserdem werden anhand des Models Hypothesen formuliert, die die Basis für die nachfolgende Forschungsphase darstellen. Phase 2 umfasst die quantitative Analyse des Zusammenhangs zwischen den Dimensionen des entwickelten Messmodels. Die Analyse vertieft den Zusammenhang von OPEX Performance, OPEX Praktiken und operativem Umfeld. Ein Teil der Analysen weist einen Widerspruch mit früheren empirischen Untersuchungen der Operations Management (OM) Literatur auf. Dieser Widerspruch stellt die Grundlage für die dritte und letzte Phase des Forschungsvorhabens, die Modellanwendung, dar. In Phase 3 ermöglichen drei qualitative Fallstudien die Erklärung des identifizierten Widerspruchs zur OM Literatur mittels umfassender Kontextinformationen.

Der quantitative Teil dieser Dissertation generiert neues Wissen, wie OPEX Performance, OPEX Praktiken und das operative Umfeld von QK Laboren zusammenhängt. Die Forschungsergebnisse ermöglichen es Praktikern, diese mit dem eigenen QK OPEX Reifegrad zu vergleichen, um Verbesserungspotentiale mit dem höchsten Einfluss auf die OPEX Performance der Labore und letztendlich die Unternehmens-Performance zu priorisieren. Der qualitative Teil bringt zahlreiche Einflussfaktoren hervor und vertieft, wie diese auf Performance und Praktiken wirken. Die Fallstudien erlauben Praktikern, die eigene OPEX Strategie in QK Laboren zu überprüfen und die Erkenntnisse und erfolgreichen Praktiken der analysierten Unternehmen zu berücksichtigen.

Das in der vorliegenden Dissertation entwickelte Model ermöglicht eine ganzheitliche Analyse von OPEX Performance in QK Laboren. Die quantitativen und qualitativen Forschungsergebnisse stellen einen Startpunkt dar, um Industriepraktiken kritisch zu reflektieren und diese anhand der Praktiken von erfolgreichen QK Laboren neu auszurichten.

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List of Abbreviations

ANOVA	Analysis of Variance
CAPA	Corrective Action and Preventive Action
CFDA	China Food and Drug Administration
CI	Continuous Improvement
DP	Drug Product
DS	Drug Substance
DV	Dependent Variable
EFQM	European Foundation for Quality Management
EMA	European Medicines Agency
EMS	Effective Management System
FAQ	Frequently Asked Questions
FDA	US Food and Drug Administration
FTE	Full-Time Equivalent
HRM	Human Resource Management
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ISPE	International Society for Pharmaceutical Engineering
IV	Independent Variable
JIT	Just-In-Time
KPI	Key Performance Indicator
OM	Operations Management
OOE	Out-of-Expectation
OPEX	Operational Excellence
OOS	Out-of-Specification
OOT	Out-of-Trend
LM	Lean Manufacturing
LR	Linear Regression
MBNQA	Malcolm Baldrige National Quality Award
MES	Management Enabler System
MLR	Multiple Linear Regression
MRQ	Main-research-question
NIST	National Institute of Standards and Technology
N/A	Not Applicable

NDA	Non-disclosure Agreement
OC	Organizational Culture
PDCA	Plan, Do, Check, Act
PM	Performance Measurement
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Performance Measurement Framework
PMM	Performance Measurement Model
PMS	Performance Measurement System
PQS	Pharmaceutical Quality System
Q&A	Question and Answer
QC	Quality Control
QCHP	Quality Control Lab Effectiveness High Performer
QCLP	Quality Control Lab Effectiveness Low Performer
QM	Quality Management
RBV	Resource-based View
R&D	Research and Development
SRQ	Sub-research-question
TES	Technical Enabler System
TPM	Total Productive Maintenance
TPS	Toyota Production System
TQM	Total Quality Management
UoA	Unit of Analysis
VSM	Value Stream Mapping
VIF	Variance Inflation Factor
WCM	World Class Manufacturing
WHO	World Health Organization

1 Introduction

This chapter outlines the research motivation in chapter 1.1, the conceptual design in chapter 1.2, and the thesis structure in chapter 1.3. The research gap and the research objective are introduced. To frame the research the research questions are raised.

1.1 Research Motivation

This chapter depicts the practical and theoretical relevance of the research. The chapter closes with the research gap and the introduction of the objective of the research at hand.

1.1.1 Practical Relevance

The importance of Operational Excellence (OPEX) has been recognized across industries (Issar & Navon, 2016; Mitchell, 2016; Shanley, 2011). Companies have been striving to achieve OPEX to drive their business performance and to create sustainable growth of their organization (DuPont, 2014, 2015; Mitchell, 2015). Both effectiveness and efficiency have been the focus of interest of Operational Excellence ranging from operational to cultural levers to improve the organization's OPEX performance (Friedli & Bellm, 2013).

Compared to other industries the concept of OPEX has not been adapted for a long time in the pharmaceutical industry (Friedli & Werani, 2013). In recent years the industry faces an increasing cost pressure leading to the necessity to change (EY, 2017; PwC, 2017). In addition, product and manufacturing issues leading to an increased number of recalls and warning letters have gained attention by industry and regulators (McKinsey & Company, 2013). Considering the trend toward an increased number of product recalls and drug shortages Yu and Kopcha (2017) stress the importance of OPEX as a source for a sustainable competitive advantage serving the capability of a pharmaceutical company to produce drugs of high quality leading to direct benefits for the patient. According to an industry study in 2013[1] none of the participants started to implement OPEX before 2000. Only 33 % have already fully rolled-out OPEX to all their sites across the manufacturing network. While 56 % of the participants have started the implementation at some sites, 11 % are still in the pilot phase. The industry study highlights the importance of a structured approach to OPEX to achieve comparability of the success.

In the context of OPEX the major focus in the pharmaceutical industry was and still is limited to the manufacturing function (Friedli, Lembke, Schneider, & Gütter, 2013; Friedli, Tykal, & Gronauer, 2008). To improve the OPEX state of an organization, an end-to-end view of the value chain is needed (Bajaj & Reffell, 2018). May (2014) argues that the quality control (QC) lab has to be incorporated into the border definition of the manufacturing value chain to recognize the critical role of the lab in the value creation of a pharmaceutical company. Timely test results can be seen as their products (Barbarite & Maslaton, 2008; M. May, 2014).

OPEX in quality control (QC) labs has lately gained increased interest by the industry (Barbarite & Maslaton, 2008; Friedli, Ponce, & Köhler, 2018). The QC lab is an integral part of the value chain of a pharmaceutical drug manufacturer and plays a critical role in

[1] Operational excellence in the pharmaceutical industry (Porsche Consulting, 2013)

the effective and efficient release of drugs (FDA, 1993; M. May, 2014). A robust QC lab supports the Pharmaceutical Quality System (PQS) to ensure that patients are provided with safe and effective high quality drugs (Friedli, Köhler, & Buess, 2017).
In their draft and revised draft guidance[2] on quality metrics the US Food and Drug Administration (FDA) incorporated one QC lab quality metric next to two manufacturing quality metrics to identify companies at risk of quality and compliance failures (FDA, 2015, 2016). This acknowledges the critical position of the QC lab within the value chain of a pharmaceutical company.
A QC lab represents a key bottleneck for a pharmaceutical company and is therefore a critical component to achieve OPEX throughout the entire value chain (Barbarite & Maslaton, 2008; Friedli, Köhler, Buess, Calnan, & Basu, 2018; Longden, 2011; Maslaton, 2012). There have been initial approaches to productivity enhancements and improvement programs leveraging lean techniques, but there is no integrated approach to OPEX in QC labs in the pharmaceutical industry until today (Barbarite & Maslaton, 2008; Helfrich, 2006; M. May, 2014).
To ensure lasting success Greulich (2012) underlines the importance to measure OPEX in QC labs using appropriate performance indicators. Pioneers have successfully started to adapt OPEX approaches from other industries to the QC lab environment to enable structured improvement initiatives (Zevitas, 2012). An industry-wide used tool to assess and compare the success of such initiatives in the QC lab does currently not exist. Today, a company has no means to identify its QC lab OPEX capabilities relative to the industry peer-group to learn how to improve the lab OPEX performance.

1.1.2 Theoretical Relevance

To drive the improvement of the organization performance measures have always been a key aspect in scholars' discussions (Digalwar & Sangwan, 2011; Kennerley & Neely, 2003; Skinner, 1969). According to Neely (1999), increased competition across industries has led to an increased importance of business performance measurement lately. The utilization of metrics has been long recognized to translate an organization's strategy into objectives to meet certain targets making success tangible (Melnyk, Stewart, & Swink, 2004). However, traditional financial measures are not sufficient to assess business performance (Neely, 1999, 2007). Liebetrau (2015) emphasizes the fact that operational performance is seen as one of the key performance dimensions by managers, but the author agrees with Neely (2007) that there are certain shortcomings of traditional financial and operational performance measures.

[2] The draft guidance on quality metrics in July 2015 and the revised draft guidance in November 2016 were published by FDA in preparation for a planned reporting program that has the objective to identify companies at risk of quality and compliance failure. The draft guidance and its revision include FDA's intention how to utilize the data submitted by the pharmaceutical companies as part of the program. The documents have the intention to support the industry on how to provide quality metrics to the planned reporting program. The reporting program was supposed to start with a voluntary phase in January 2018. However, the data collection was postponed to a later point in time and has not started until late 2018.

Neely (2005) states an increased interest of scholars in performance measurement and criticizes the narrow focus on single measurement approaches. There is a general understanding that competitive capabilities play a key role in the performance measurement of the operations (Digalwar & Sangwan, 2011; Schiuma, 2009). However, scholars do not agree whether these capabilities are trade-offs (Boyer & Lewis, 2002; Rosenzweig & Easton, 2010), cumulative (C. J. Corbett & van Wassenhove, 1993; Ferdows & De Meyer, 1990), or integrative (Nand, Singh, & Power, 2013; Schmenner & Swink, 1998).

According to Neely (2005), scholars should build on existing frameworks but continue to enhance the research in this field. In addition, Neely (2007) outlines the importance of a multidimensional approach to performance measurement as traditional measures are rarely integrated with each other. Neely, Gregory, and Platts (1995) highlight that a holistic approach to performance measurement addresses the multidimensional character of operational performance.

White (1996) and Melnyk, Stewart, and Swink (2004) emphasize that the benefit of metrics for effective and efficient performance measurement only exists in case of a comparison with a reference point. The authors stress that this supports day-to-day control, communication and improvement efforts (Melnyk et al., 2004).

1.1.3 Research Gap and Objective

Existing research in the field of OPEX in the pharmaceutical industry is primarily focused on the manufacturing function (Friedli, Goetzfried, & Basu, 2010; Schneider, Friedli, Basu, & Werani, 2015). Practitioners have started to contribute approaches to OPEX in QC labs in their company (Barbarite & Maslaton, 2008; Zevitas, 2012). However, an industry-wide used tool to assess and compare the success of OPEX initiatives in the QC lab does currently not exist. Today, a company has no means to identify its QC lab OPEX capabilities relative to the industry peer-group to learn how to improve the lab OPEX performance.

The initial approaches have not yet been complemented with a unified, research-driven, quantitative analysis of OPEX in QC labs with the ability to make an industry-wide comparison. Consequently, the research at hand aims at conceptualizing performance measurement for OPEX in pharmaceutical QC labs. The objective is to develop an integrated model that covers the multidimensional concept of OPEX from operational to behavior aspects. The model is supposed to allow the comparison of the OPEX performance of QC labs in the pharmaceutical industry under consideration of their specific environment. In addition, the model is meant to support to determine how high performing QC labs reach their superior OPEX position by incorporating OPEX enablers.

1.2 Research Design

This chapter outlines the design of the research. The conceptual background is given and a research theory as the theoretical grounding is introduced. The theory provides a framework for the research from a scientific perspective. In addition, the research questions are introduced and an overview of the research methodology and process is provided.

1.2.1 Conceptual Background

According to Ulrich (1984), business studies can be seen as applied social science. The author outlines business studies as a leadership and management theory that deals with the designing, steering, and solving of problems of social systems from practice. The complexity of the social system is acknowledged and total control is abandoned (Ulrich, 1984). Ulrich (1984) proposes a holistic system perspective to avoid isolated solutions that do not concur with the integrated characteristics of the problem. As a result of the system perspective a certain level of abstraction is appropriate to determine the character of the overall system (Ulrich, 1984).

According to Ulrich (1982), the unit of analysis for applied science is always derived from practice. Moreover, the author stresses the difference of research driven by natural science observing an existent reality compared to applied science with its objective to develop and create a new reality (Ulrich, 1982). In addition, Ulrich (1982) emphasizes the fact that in contrast to natural science with its typical focus on one discipline, applied science is usually interdisciplinary and has to incorporate the social context.

Following Ulrich (1982, 1984), the research at hand is based on the practical and scientific interest to generate new knowledge addressing a specific problem from practice and thereby to solve the problem from an integrated system perspective. The linkage of the research to a problem from practice provides the direct benefit of scientific research to inform future actions of practitioners in the field of this research.

1.2.2 Research Theory

The resource-based view (RBV) constitutes the scientific framework for the research at hand. The research theory originates in Selznick's (1957) and Penrose's (1959) early work on internal resources as a driver for organizational success. While Selznick (1957) focuses specifically on leadership, Penrose (1959) emphasizes a broader view on internal resources as the driver of organizational growth. In the 1980s Wernerfelt (1984) reemphasized the relevance of this theory by complementing the traditional product market perspective on corporate strategy with the resource perspective.

The RBV describes the relation between internal resources of a company, competitive advantage, and performance (Peteraf, 1993). According to RBV, superior performance in efficiency and effectiveness of the company is rooted in the company's internal resources (Barney, 1991; Wernerfelt, 1984). The capability to deploy these internal resources plays a key role in RBV to gain a competitive advantage that leads to superior performance (Amit & Schoemaker, 1993; Day, 1994; Zahra & Das, 1993). Teece, Pisano, and Shuen (1997) argue that these capabilities have to be developed internally as they cannot be bought externally. In this context, the term competence can be used interchangeably with capability (Hooley, Broderick, & Möller, 1998). Barney (1991) stresses the importance that sustainable competitive advantage can only be achieved if the benefits of the deployment of the resources cannot be duplicated by others.

In the resource-based theory different definitions for resources of a company exist (Amit & Schoemaker, 1993; Barney, 1991; Wernerfelt, 1984). However, the authors agree that resources can be both tangible and intangible (Amit & Schoemaker, 1993; Barney & Arikan, 2001; Hooley et al., 1998; Wernerfelt, 1984). According to Barney (1991), the

company's resources combine hard and soft assets and can be defined as physical, human, and organizational resources. The author's definition comprises tangible equipment related assets (physical resources), educational aspects (human resources), and intangible cultural aspects (organizational resources) (Barney, 1991). Barney (1986), Wernerfelt (1995), and Zahra and Das (1993) emphasize the importance of culture as an intangible resource to provide a competitive advantage. All resources have to be valuable, rare, imitable, non-substitutable to guarantee sustainable competitive advantage (Barney, 1991).

Barney (1991) and Wernerfelt (1984) describe the theoretical concept of RBV at the company level. Various scholars have applied the theoretical concept at company level, investigating company's performance (Bates & Flynn, 1995; Dutta, Narasimhan, & Rajiv, 1999; Nath, Nachiappan, & Ramanathan, 2010; Song, Di Benedetto, & Nason, 2007). Moreover, RVB has also been applied to other levels of the organization. Scholars have used it in the context of an individual within an organization (Van Rijnsoever, Hessels, & Vandeberg, 2008) and the process level (Ray, Barney, & Muhanna, 2004). In addition, RBV has been applied to analyze an individual function linking its resources with the performance of the function (R. G. Schroeder, Bates, & Junttila, 2002). Thus, RBV can be applied to the research at hand which is focused on the resources of an individual function and the capabilities to deploy these resources to achieve a higher performance of this function.

Hitt, Xu, & Carnes (2016) emphasized RBV as a key to understand effectiveness and efficiency in performance management in Operations Management (OM). Other authors confirm its application in OM (Amundson, 1998; Bates & Flynn, 1995; R. G. Schroeder et al., 2002). To conclude, in the OM context of this research the RBV concept supports the underlying research interest to understand the relation between internal resources, the capability to deploy these resources, sustainable competitive advantage, and performance as an outcome. Consequently, RBV is used as the theoretical grounding of the research at hand.

1.2.3 Research Questions

The research aims at answering the research questions outlined in the following. These questions are based on the twofold theoretical gap derived from literature (cf. chapter 2.3). First, the approach to operational performance depends on the unit of analysis. Consequently, it cannot be transferred one-to-one from other areas. Second, the research questions are also based on the non-existence of an OPEX PM approach in the area of interest. The implications of the OPEX and PM literature (cf. chapter 2.1.4 and chapter 2.2.5) determine the direction of the research. The main-research-question (MRQ) and its sub-research-questions (SRQ) are depicted in table 1.

To answer the MRQ, three SRQ are formulated. The SRQ 1 reflects a literature-driven analysis with the objective to identify which elements need to be addressed for the OPEX performance measurement in QC labs concluding in a measurement model. In SRQ 2 key performance indicators (KPIs), relevant context factors, and enablers are identified. This SRQ aims at operationalizing each element of the performance measurement model (PMM) developed as part of SRQ 1. The SRQ 3 is a twofold question that aims at

identifying relations within the model and factors that influence these relations. The objective is to identify the relation between the model dimensions. Furthermore, the aim of this question is to determine context factors that cause differing OPEX performance and therefore have to be considered when comparing OPEX performance across QC labs.

Table 1: Research questions

No.	Research Question
MRQ	**How can OPEX performance be measured in pharmaceutical QC labs?**
SRQ 1	How can OPEX performance be conceptualized in pharmaceutical QC labs?
SRQ 2	How can OPEX performance in QC labs be operationalized?
SRQ 3	What is the relation between the model dimensions, context factors, and the OPEX performance in QC labs?

1.2.4 Research Methodology and Process

The research aims at generating scientific knowledge. New knowledge has to fulfill the criteria of credibility and plausibility to be regarded as knowledge with scientific relevance (N. Lee & Lings, 2008). To establish credibility and plausibility of the research a suitable research strategy is required and it has to be ensured that the research process is carried out appropriately and transparently (Bryman & Bell, 2015; Easterby-Smith, Thorpe, & Jackson, 2015). In the following the research methodology and process is outlined.

The research can be classified as a mixed-methods approach, more specifically an exploratory sequential approach (Creswell, 2014). According to DeCuir-Gunby's (2008) and Creswell's (2014) research approach, a phenomenon is best understood if different perspectives are considered. Therefore, the research combines qualitative and quantitative research. According to Creswell (2014), the combination of both approaches allows a more complete understanding compared to a single-method approach. Furthermore, the triangulation between the two methods serves the validity of the research findings (Jick, 1979; R. B. Johnson, Onwuegbuzie, & Turner, 2007). The exploratory sequential approach begins with a qualitative phase which is followed by a quantitative phase (Creswell, 2014). The nature of SRQ 1-3 (cf. chapter 1.2.3) follows this sequence of first qualitative and then quantitative research.

Due to its conceptual background of business studies as applied social science the research at hand – in contrast to natural science – does not seek for universal truth but new theoretical and practical knowledge for both academia and practitioners (Friedli, 2006; Ulrich, 1984). To allow a sound understanding of the phenomenon, the exploratory sequential mixed-methods approach is complemented with iterations throughout its phases, resulting in a learning process (cf. figure 1).

The objective of the iterative research process is to reflect the preliminary understanding and involve practitioners to accumulate the preliminary theoretical understanding into theoretical knowledge (Baumbach, 1998; Gassmann, 1999; Kubicek, 1977; Tomczak, 1992). The iterative research process enables to flexible expand the sequential approach of first qualitative and then quantitative research with iterations of the two approaches to reflect preliminary research findings from different perspectives. Consequently, this

research does not follow a strict sequence of first qualitative and then quantitative research but allows flexibility to reflect preliminary research results that need further investigation. Lee and Lings (2008) outline that empirical data serves the credibility of the created scientific knowledge and consequently the research itself. To conclude, the combination of theoretical and empirical work ensures the research to be both scientifically rigor and relevant for practice (Nunamaker, Briggs, Derrick, & Schwabe, 2015).

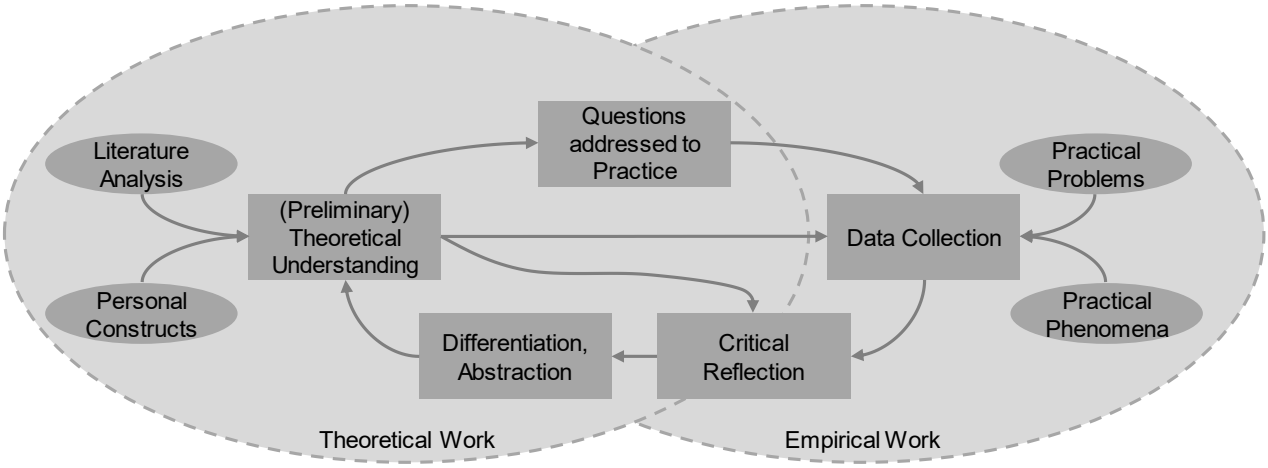

Figure 1: Research process adapted from Tomczak (1992), Baumbach (1998)*, and Gassmann (1999)*

In total, the research comprises four phases. Table 2 depicts the research phases and data sources that form the basis to answer the research questions outlined in chapter 1.2.3. In addition, the intended result is supposed to give a first idea of the research outcome.

Table 2: Research phases, data source, and intended result

Research Phase	Data Source	Intended Result
Phase 0 State of Research	Literature on Operational Excellence and Performance Measurement	Implications for research and theoretical gap
Phase 1 (SRQ 1) Conceptualization of Performance Measurement	Literature, workshop results, and expert interviews with pharmaceutical companies of the St. Gallen QC Lab Exchange Platform[3] and the St. Gallen OPEX Research Group[4]	Performance measurement model

[3] The St. Gallen QC Lab Exchange Platform is an event series organized by the University of St. Gallen with three two-day meetings in the period of 12 months. The platform was initiated in the first half of 2018. It was launched in parallel to this research with the objective to discuss preliminary results with the industry. Sixteen pharmaceutical companies participate in its first edition. The participants are corporate executives and local managers with extensive knowledge related to OPEX in QC labs.

[4] The St. Gallen OPEX Research Group is an event series organized by the University of St. Gallen with four two-day meetings each year. The group was launched in 2014. From 2016 to 2018 between nine and eleven pharmaceutical companies participated each year to discuss industry- and research-topics of OPEX that they have identified as important to the industry. The participants are senior executives with many years of experience in the field of OPEX in the pharmaceutical industry.

Research Phase	Data Source	Intended Result
Phase 2 (SRQ 2) Operationalization of Performance Measurement Model	Literature, workshop results, and expert interviews with pharmaceutical companies of the St. Gallen QC Lab Exchange Platform and the St. Gallen OPEX Research Group	Identification of KPIs, structural factors and enablers
Phase 3 (SRQ 3 part 1) Interrelation and relevant Context Factors	Quantitative analysis of St. Gallen QC Lab OPEX Benchmarking database[5]	Interrelations of model dimensions
Phase 4 (SRQ 3 part 2) Application of Model	Multiple (holistic) case studies including benchmarking data, individual and group interviews, publicly available and confidential company material, workshop results, personal notes and emails, and on-site lab observations	Application of selected phase 3 analysis results

Phase 0: State of Research

The initial phase is focused on a representative review of relevant literature of Operational Excellence and Performance Measurement in Operations Management. The literature review is conducted in accordance to Cooper's (1988) taxonomy which provides a systematic overview of the review approach. As part of the literature review, a definition of OPEX is derived. The definition builds the foundation for the research to define the scope of the PM model that is developed. Furthermore, existing Performance Measurement dimensions are discussed and major PM models are elaborated. In addition, implications for the intended research and the theoretical gap are derived.

Phase 1: Conceptualization of Performance Measurement

The implications of the literature review of OPEX and PM in OM of the initial phase, complemented with expert interviews and workshops, serves as the basis to develop the descriptive OPEX performance measurement model for QC labs. Following an iterative research process (cf. figure 1) offers the chance to reflect the preliminary understanding to accumulate the preliminary theoretical understanding into credible and plausible theoretical knowledge. Furthermore, the triangulation of preliminary conclusions ensures that the model encompasses all relevant dimensions that determine OPEX performance in QC labs.

Phase 2: Operationalization of Performance Measurement Model

In this phase the developed OPEX performance measurement model for QC labs is operationalized. To ensure its relevance for the pharmaceutical industry this phase is conducted in close collaboration with industry partners to determine relevant and meaningful KPIs to assess the OPEX performance. The access to multiple practitioners of a diverse group of pharmaceutical companies, which operate in different environments, allows an operationalization that incorporates different perspectives on meaningful KPIs

[5] The St. Gallen QC Lab OPEX Benchmarking was developed as part of the St. Gallen OPEX Research Group in 2016. In total, the benchmarking comprises 355 different data points, thereof 165 performance-related, 68 enabler-related, and 122 context-related data points. At the point of analysis for this research, the benchmarking database comprised 53 QC labs of 17 different pharmaceutical companies. Additional QC labs are acquired on a continuous basis.

and thus limits the level of bias to a minimum. Furthermore, the suggested enablers of OPEX from literature are consolidated and triangulated with the practitioners to identify a representative set of OPEX enablers for the QC lab.

Phase 3: Interrelation and relevant Context Factors
Based on the St. Gallen QC Lab OPEX Benchmarking database the interrelations and context factors of all labs are analyzed. The aim is to analyze the performance enabler relation in the specific QC lab context. In addition, the objective is to identify factors that determine a differing OPEX performance in QC labs due to structural difference of the labs. Following Kubicek's (1977), Tomczak's (1992), Baumbach's (1998), and Gassmann (1999) iterative research design this phase is primarily focused on quantitative research. Next to the quantitative research the continuous involvement of practitioners to discuss early findings provides a complementary view on both the interrelations and relevant context factors throughout the research process. The continuous iteration with practitioners allows reflecting preliminary research findings regarding scientific and practical relevance.

Phase 4: Application of Model
To ensure credibility and plausibility of the research in the concluding phase the findings of the preceding phases are applied in three representative case studies. The objective of this phase is to apply the OPEX performance measurement model to enhance the quantitative research findings of phase 3. The case studies serve as a complement to explain why a certain pattern occurs in the phase 3 quantitative research that is limited to describe what patterns can be observed. Additionally, the case studies explain what differences and commonalities exist between the patterns. The case study research is employed to deepen the understanding beyond quantitative research results and to understand contradicting findings. This combination of quantitative and qualitative data as a source for each case study serves the credibility and plausibility of the findings of this phase.

1.3 Thesis Structure

To develop an OPEX performance measurement model for QC labs in the pharmaceutical industry the thesis structure follows the intention of the research phases outlined in chapter 1.2.4. First, in chapter 2 an initial literature review is provided. Thereafter, chapter 3 focuses on the model development (SRQ 1 & SRQ 2). A quantitative data analysis (chapter 4) of the model dimensions and the model application (chapter 5) in multiple case studies allowed understanding the interrelations of the model dimensions (SRQ3). The thesis structure is illustrated in figure 2.

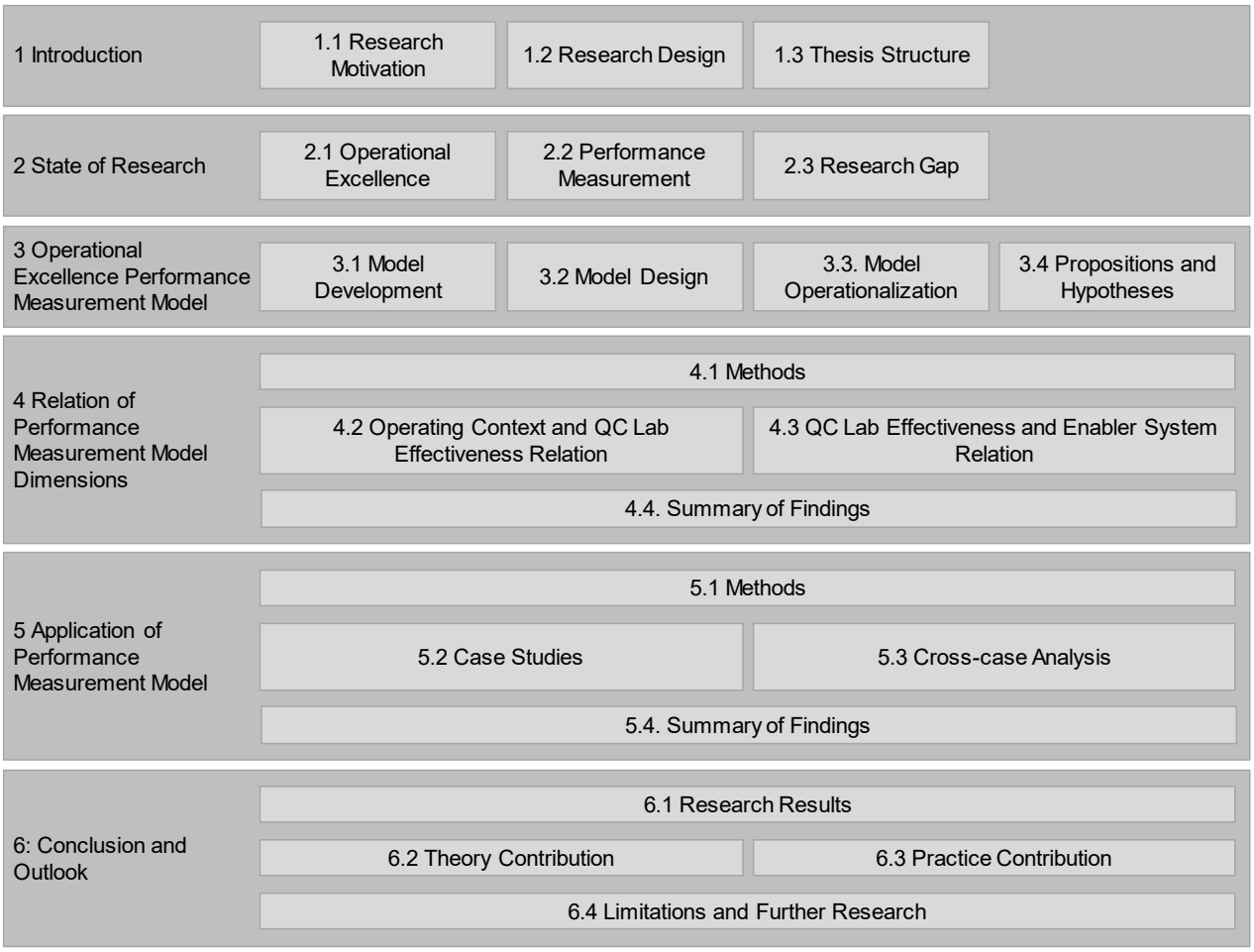

Figure 2: Thesis structure

Chapter 1 – Introduction

Chapter 1 outlines the research motivation, followed by the research design. The research motivation includes an overview of the practical and theoretical relevance. In addition, the research gap and objective are framed. The research design depicts the conceptual background, research theory, research questions, research methodology, and research process.

Chapter 2 – State of Research

Chapter 2 provides an overview of the state of research of the relevant literature. First, the OPEX literature with a special focus on the pharmaceutical industry is discussed. The umbrella term OPEX is analyzed in detail and a definition is derived for this research. Second, the PM literature in OM is analyzed and relevant performance measurement models are introduced. For both literature streams implications for the research are derived.

Chapter 3 – Operational Excellence Performance Measurement Model

Chapter 3 describes the conceptual abstraction of performance measurement in QC labs. First, the model dimensions are derived from comparing existing PMMs. Then, the OPEX performance measurement model for QC labs is introduced. Thereafter, all model

dimensions are operationalized. The chapter concludes with propositions and hypotheses for the quantitative analysis of the subsequent chapter.

Chapter 4 – Relation of Performance Measurement Model Dimensions
Chapter 4 presents a quantitative analysis of the relation between the performance measurement model dimensions. The propositions related to the operating context of QC labs are addressed. Furthermore, the hypotheses related individual model dimensions are tested and the results are discussed in detail. The chapter closes with a summary of conclusions related to each proposition and hypothesis of the quantitative analysis. The research findings of this chapter serve as the basis of the case selection and model application in chapter 5.

Chapter 5 – Application of Performance Measurement Model
Chapter 5 focuses on deepening the findings of the quantitative analysis. The qualitative case study research allows complementing the quantitative results with qualitative findings. In total, three case studies are described. Each of these case study addresses multiple QC labs. In total, 22 QC labs of three different pharmaceutical companies inform the qualitative research. The case studies and cross-case analysis allow understanding why different patterns regarding QC lab performance exist. The chapter closes with a summary of the main findings.

Chapter 6 – Conclusion and Outlook
Chapter 6 summarizes the findings of the previous chapters and provides an outlook on future research in the context of this thesis. First, the model development is summarized. Second, the main conclusions of the quantitative analysis regarding the model dimensions are provided. Third, the findings of the case studies are elaborated. Fourth, the limitations and future research opportunities are described.

2 State of Research

This chapter provides an overview of the state of research regarding OPEX and performance measurement in operations management. As different terminology can be found in literature describing OPEX, a distinct definition is provided in chapter 2.1. This definition is the basis of this research. OPEX in the pharmaceutical industry is introduced, followed by its application in QC labs. Furthermore, the development of performance measurement (PM) is outlined and its dimensions are discussed in chapter 2.2. An overview of performance measurement frameworks is given. At the end of the two literature streams, OPEX and PM, implications for further research are summarized. Based on the implication of both literature streams the chapter concludes with an outline of the theoretical gap in chapter 2.3.

The literature review was conducted in accordance to Cooper's (1988) taxonomy which provides a systematic overview of the review approach. The author distinguishes six characteristics of a literature review, comprising the focus (1), goal (2), perspective (3), coverage (4), organization (5), and audience (6) (Cooper, 1988). While for focus, goal, organization, and audience multiple aspects can be combined, the perspective and coverage are characteristics with mutual exclusive categories. The following literature review on OPEX and PM has a manifold focus, incorporating research outcomes, research methods, theories, and practices or applications. The goal is to integrate and synthesize the literature identifying central issues that allow systematically deriving implications for the research. The perspective is chosen neutral representative. The literature review covers a representative scope that is central to the area of interest. Furthermore, the review is organized in a conceptual and methodological way to allow related topics and similar methods to be grouped together. With a great attention on implications of the literature for the research the audience is in-line with the objective of the research at hand to have theoretical and practical contribution. Thus, the audience incorporates general scholars and practitioners. Table 3 depicts the character of the literature review conducted for this research highlighted in grey.

Table 3: Taxonomy for the literature review (adapted from Cooper, 1988)

Characteristic	Categories			
Focus	Research outcomes	Research method	Theories	Practices or Applications
Goal	Integration	Criticism		Central issues
Perspective	Neutral representative		Espousal of position	
Coverage	Exhaustive	Exhaustive with selective citation	Representative	Central or pivotal
Organization	Historical	Conceptual		Methodological
Audience	Specialized scholars	General scholars	Practitioners/ politicians	General public

2.1 Operational Excellence

The literature on OPEX in operations management investigates how manufacturing operations can enable the competitiveness of the company (Friedli & Bellm, 2013; Friedli

et al., 2008). However, with an overlap of the described scope and targets the terminology varies among authors (Kickuth, 2005). The objective of this literature review is therefore to get a clearer view on OPEX as an umbrella term incorporating the different approaches and terminologies in the context of operations management. OPEX in QC labs is still in the initial phase and the lab can be seen as a manufacturing unit with timely test results as its products (Barbarite & Maslaton, 2008; M. May, 2014). Thus, the literature with a focus on OPEX in manufacturing is appropriate to build a distinct understanding of the concept OPEX for this research.
In the following, first the scope of Operation Excellence is outlined. This leads to a definition that is used for the research at hand. Second, OPEX in the pharmaceutical industry is discussed. Third, details regarding the application of OPEX in pharmaceutical QC labs are provided. The chapter concludes with implications of the OPEX literature for the research.

2.1.1 Scope

To get a distinct view on OPEX as an umbrella term its three main focus areas have to be discussed. Literature suggests that Continuous Improvement (CI) enables Lean Manufacturing (LM) which may lead to World Class Manufacturing (WCM). In the following paragraphs these three focus area are outlined beginning with WCM, followed by LM and CI.

2.1.1.1 World Class Manufacturing

To describe how companies can achieve competitiveness through manufacturing Hayes and Wheelwright (1985) started a structured discussion on OPEX, introducing the term World Class Manufacturing (WCM). The authors argue that persistent effort over a long period of time, transforming traditional manufacturing toward excellent manufacturing, is the source of competitive advantage (Hayes & Wheelwright, 1985). By comparing Japanese and American manufacturing companies, Wheelwright and Hayes (1985) observe that Japanese companies succeed due to their superior production systems[6]. Thus, Wheelwright and Hayes (1985) stress that manufacturing is a major competitive factors of Japanese companies, whereas American companies have traditionally focused on product innovation, marketing capabilities, and financial strength. To achieve a competitive advantage through manufacturing the authors suggest a four-stages-process that allows companies to not only align capabilities with the company's strategy but to influence the strategy facilitating manufacturing capabilities as a competitive weapon (Hayes & Wheelwright, 1985; Voss, 1995).
To achieve WCM Wheelwright and Hayes introduced a set of practices that should be implemented (Flynn, Schroeder, & Flynn, 1999). These practices include workforce skills and capabilities, management of technical capabilities, competing through quality,

[6] A production system is an inter-firm relations management system with the purpose to eliminate non-value adding activities through continuous improvement measures (Monden, 2012). The Toyota Production System (TPS) is often mentioned as the first integrated production system (Fullerton et al., 2014). The TPS combines defined lean elements which include tools and practices not as a fundament but as response to an occurring problem which subject to change over time when improvements can be observed (Spear & Bowen, 1999).

workforce participation, rebuilding manufacturing engineering, and incremental improvement approaches (Flynn et al., 1999). Many authors have built on this approach of practices and enhanced the scope to enable superior performance (Z. Chen & Tan, 2013; Cua, McKone, & Schroeder, 2001; Friedli & Bellm, 2013; Friedli, Goetzfried, & Basu, 2010; Fullerton, Kennedy, & Widener, 2014; Jaeger & Matyas, 2016; Shah & Ward, 2003; Voss, 1995; Wiengarten, Gimenez, Fynes, & Ferdows, 2015).

2.1.1.2 Lean Manufacturing

Lean Manufacturing[7] (LM) is seen as a concept to enable WCM (Feld, 2000; Friedli & Schuh, 2012; Upadhye, Deshmukh, & Garg, 2010). LM follows the pro-active lean philosophy with customer-focus-driven internal improvements through waste reduction, engaging all employees, and empowerment of the workforce, leading to a robust and flexible organization (Brown, Collins, & Edward, 2006; Issar & Navon, 2016; Womack & Jones, 2003; Womack, Jones, & Roos, 1990). The organization is focused on Continuous Improvement (CI) delivering high quality products or services cost efficiently and on-time (Brown et al., 2006; Issar & Navon, 2016; Womack & Jones, 2003; Womack et al., 1990). To successfully implement LM human resources, manufacturing technology, and corporate strategy need to be aligned (Friedli & Schuh, 2012). Feld (2000) outlines the LM needs to have an overall system perspective focusing on manufacturing flow, the organization, process control, metrics, and logistics to allow an organization to achieve WCM.

Gosh (2012) as well as Shah and Ward (2007) outline three levels of LM with a differing degree of abstraction. The first level, the lean philosophy, has the highest abstraction and stresses the importance of waste elimination from the production system while satisfying the customer (Shingo, 1989). The second level with lower abstraction is a rule-driven system (Spear & Bowen, 1999) for designing the production system and targeted problem solving. The third level with the lowest abstraction combines all lean associated tools and techniques that aim at eliminating waste (Shah & Ward, 2003). Pettersen (2009) emphasizes that lean tools are point-in-time centric, whereas the lean philosophy is rather a continuous effort. Shah and Ward (2007) stress that the different levels of abstraction allow a better understanding of the concept LM and does not indicate disagreement between scholars.

According to Hines, Holweg, and Rich (2004), LM has developed over time from a unidimensional approach to a value-driven approach. Womack & Jones (2003) agree and highlight that lean thinking goes beyond *muda* (waste reduction) as this does not directly create value. Addressing m*ura* (unevenness) and *muri* (overburden) builds the foundation to achieve flow and to overcome variability (Imai, 2012; Ramekar, Muneshwar, Kute, & Choube, 2017).

To conclude, LM is a concept with the need to focus on an integrated system perspective beyond manufacturing to avoid optimization of isolated aspects that does not enable WCM

[7] Scholars also refer to Lean Production instead of Lean Manufacturing without stressing fundamental differences (Hines et al., 2004; Krafcik, 1988; Pettersen, 2009; Womack & Jones, 2003). Thus, these terms are interchangeable.

(Friedli & Schuh, 2012; Womack & Jones, 1996). The term Lean Thinking expresses the expanded perspective of LM and is used more recently by authors (Hines et al., 2004; Womack & Jones, 1996, 2003).

2.1.1.3 Continuous Improvement

In Pettersen's (2009) literature review the author identifies Continuous Improvement (CI) as one of the key elements of LM. CI is also known as kaizen, an artificial Japanese term for change (kai) for the better (zen) (Palmer, 2001). Shingo (1988) emphasizes CI is a necessity to remain competitive in a changing market environment. CI programs incorporating employees' involvement, i.e. building on every employees' experience and skills, have been a key element of the competitive advantage of Japan's economic success in the past (Imai, 1986; D. M. Schroeder & Robinson, 1991). Accordingly, scholars agree that the workforce is a fundamental driver of CI (Imai, 1986; D. M. Schroeder & Robinson, 1991; Singh & Singh, 2012; Wickens, 1990).

In contrast to innovation with its focus on disruptive improvements CI is focused on significant but incremental improvements (J. C. Chen, Dugger, & Hammer, 2001; Singh & Singh, 2012). Instead of high investments the success is determined by everyone's continuous effort and commitment (Imai, 2012; Singh & Singh, 2012). Schroeder and Robinson (1991) underline that continuous incremental improvements may lead to higher performance than efforts to achieve technology breakthroughs. From a process angle the Deming Cycle provides a four-stages-process to CI with the phases plan, do, check, and act (C. N. Johnson, 2002). Built on these phases the Deming Cycle is also referred to as Plan-Do-Check-Act (PDCA) Cycle (Basu, 2004). In the long-term application the PDCA Cycle approach aims at permanent corrective actions that enable sustainable CI eliminating root causes of problems (Basu, 2004).

2.1.1.4 Conclusion

Based on the literature review of WCM, LM, and CI an OPEX definition can be derived. The following paragraph highlights the key aspects and authors of the literature review that build the center of the OPEX definition. According to Hayes and Wheelwright (1985) continuous effort over a long period of time leads to excellence operations as a source of competitive advantage. Schroeder and Robinson (1991) as well as Pettersen (2009) emphasize continuity of improving leads to higher performance. Among others Womack, Jones, and Ross (1990) outline the philosophy of continuous engagement of all employees and empowering the workforce leading to an organization delivering high quality and service level as well as cost efficiency. Singh and Singh (2012) add commitment as a key success factor. The following OPEX definition is used for this research:

> Operational Excellence constitutes the achievement of a superior operational system performance state of an organization based on its capability of continuous improvement, management alignment, and employee empowerment leading to and preserving a competitive advantage relative to its peer-group.

2.1.2 Application in the Pharmaceutical Industry

In academia OPEX in the pharmaceutical industry has not been widely discussed by scholars. However, some dedicated journal articles and books have been published with a focus on OPEX in pharmaceutical manufacturing (Chowdary & George, 2011; Friedli, Basu, Calnan, & Mänder, 2018; Friedli, Bellm, Werani, & Basu, 2013; Friedli, Gronauer, & Werani, 2010; Friedli, Kickuth, Stieneker, Thaler, & Werani, 2006; Friedli et al., 2008; Gebauer, Kickuth, & Friedli, 2009; Muse, Njeru, & Waiganjo, 2016; Pavlović & Božanić, 2012; Schneider, Friedli, Basu, & Werani, 2015). In the following paragraphs the major aspects of OPEX in the pharmaceutical industry are provided.

In the highly regulated pharmaceutical industry companies have often been reluctant to change processes and equipment due to regulatory hurdles (FDA, 2004). However, the industry is working on improvement potential in its operations and regarding quality while complying with regulations (Pavlović & Božanić, 2012). The FDA emphasizes the fact that better process understanding enables improvements in quality and productivity, leads to a reduction of variability and creates a beneficial state for both industry and patient (FDA, 2004). Thus, as the regulatory oversight the US Food and Drug Administration (FDA) has worked toward a regulatory framework that encourages companies to make these changes and to work on CI to achieve this state of shared benefits for the industry and patient (Pavlović & Božanić, 2012). This trend toward CI allows efficiency improvements in a current Good Manufacturing Practice environment that is primarily focused to ensure safety, reliability, and quality (Pavlović & Božanić, 2012). The authors conclude that the current Good Manufacturing Practice and Lean Thinking must be merged and anchored in the organizational culture to be successful (Pavlović & Božanić, 2012).

Since the beginning of the 21st century FDA has increased its attention to OPEX and CI with multiple initiatives focusing on product quality, process efficiency, and new technology (Yu & Kopcha, 2017). Friedli and Werani (2013) agree and add that CI and OPEX in the industry have been driven by the increased competition and cost pressure of the industry. In 2009 the FDA adopted the ICH Q10 guideline[8] which promotes CI throughout the entire product lifecycle and stresses the importance of management commitment and communication (FDA, 2009). In addition, the guidance suggests to implement a Corrective Action and Preventive Action (CAPA) system to determine root causes and prevent future issues leading to an improved product and process understanding (FDA, 2009). Considering the trend toward an increased number of product recalls and drug shortages Yu and Kopcha (2017) stress the importance of OPEX as a source for a sustainable competitive advantage to serve the capability of a pharmaceutical company to produce drugs of high quality leading to direct benefits to the patient.

According to Gronauer, Friedli, and Goetzfried (2010), three major phases of OPEX can be distinguished in the pharmaceutical industry. Three years later, Friedli and Werani

[8] The ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) Q 10 guideline has been developed by an ICH expert working group with involvement of regulatory parties. The objective of the guideline is to assist pharmaceutical companies to achieve an effective pharmaceutical quality system leading to enhanced product quality and drug availability. The guideline was suggested for adaption to regulatory bodies from the EU, Japan, and USA in 2008. (ICH, 2008)

(2013) revised the development phases of OPEX in the industry and added a fourth phase. The first phase, which lasted until the late 1990s, is called *pre-OPEX* phase and was followed by the second phase *Best-Practice-Transfer* which led into the phase *Transformation* (Friedli & Werani, 2013; Gronauer et al., 2010). The fourth phase is named *Integrated Operations System*, addressing the importance of an integrated approach to OPEX (Friedli & Werani, 2013). The first phase was mainly focused on isolated improvement projects without a structured approach leading to silo-optimization (Gronauer et al., 2010). During the second phase the industry aimed to transfer methods and tools from other industries to the pharmaceutical industry, but it did not entirely succeed due to lagging employee commitment (Gronauer et al., 2010). Thus, the third phase was focused on change management recognizing the important role of every employee to achieve OPEX (Gronauer et al., 2010). Today, the fourth phase of OPEX in the pharmaceutical industry has started with a stronger focus to further align improvement initiatives throughout the organization, to strengthen the alignment with the top-management level, and to foster proactive OPEX effort (Friedli & Werani, 2013). However, the authors stress that most companies are still in the third phase *Transformation* (Friedli & Werani, 2013).

2.1.3 Application in Pharmaceutical Quality Control Labs

Until today the discussion of OPEX in QC labs is driven by practitioners and has only been published in magazine articles of the pharmaceutical industry. The important role of the QC lab within the value chain driving OPEX of the overall system has not gained attention by scholars. The adaptability of OPEX approaches from other functions and industries has not been discussed in academia from a theoretical perspective or within empirical studies. Thus, the following elaboration of the current state of OPEX in QC labs is derived on the available contributions of practitioners.

According to Mannion (2011), literature suggests that LM principles can be applied to any business process. At the same time the author underlines that these principles have not always been successful outside the manufacturing function as the focus was solely focused on *muda* (reduction of waste) (Mannion, 2011). Zevitas (2012) and Greulich (2012) agree and emphasize the fact that adjustments of the lean practices to the lab environment are required. Following Womack and Jones (2003) that LM goes beyond *muda,* Mannion (2011) agrees and stresses the importance to also consider the foundation of Toyota's production system, *mura* (unevenness) and *muri* (overburden), to address volatility and to achieve LM in QC labs. For a successful application of OPEX principles the organization has to address the special characteristics of the QC lab. Important aspects to consider are the QC lab's workload volatility and variability, lower process reliability and predictability compared to manufacturing, longer cycle times as well as the combination of routine and non-routine work (Greulich, 2012).

There is a general agreement that OPEX in QC labs is needed to meet the increased cost pressure and to achieve overall improvements (Barbarite & Maslaton, 2008). Practitioners acknowledge that OPEX and lean in QC labs is multidimensional, including an effectiveness and efficiency dimension (Barbarite & Maslaton, 2008; Greulich, 2012; Mannion, 2011; Zevitas, 2012). Greulich (2012) underlines fast delivery, cost effectiveness, and better product quality as three pillars of OPEX in the QC lab. Howard

and Bublitsky (2004) define the four dimensions quality and compliance (1), cost consciousness (2), organizational and personnel (3), and customer service (4) to identify best-in-class labs. The involvement and empowerment of lab employees plays a key role for the success (M. May, 2014; Scharton-Kersten, T., Shoel, G., Kimmel, L., Peytremann, C., Reynolds, T., Garay, J., Gazvoda, J., Orombelli, P., Gabardi, F., Dockery, M., Sirovatka, n.d.; Zevitas, 2012). May (2014) outlines two dimensions of lean for QC labs, the outside integration into the value chain and inside the lab with a focus on the lab operations. Peytremann and Moreu (2016) agree and emphasize that stable QC operations and synchronization with the manufacturing function lead to overall success.
To conclude, the integrated approach to OPEX in QC labs in the pharmaceutical industry can be transferred from manufacturing, but it needs to be specified to meet the characteristics of the QC lab.

2.1.4 Operational Excellence Implications for Research

Based on the literature review on World Class Manufacturing, Lean Manufacturing, Continuous Improvement, and OPEX in the pharmaceutical industry as well as in the pharmaceutical QC labs table 4 depicts the implications for the research.

Table 4: Operational Excellence implications for research

No.	Implication
1	OPEX is multidimensional incorporating a technical and a social dimension and needs an integrated system approach.
2	OPEX includes an effectiveness and efficiency dimension.
3	OPEX addresses muda (reduction of waste), mura (unevenness), and muri (overburden).
4	Superior performance is based on the competitive advantage of an organization through internal OPEX capabilities.
5	Internal capabilities of the organization build the basis of OPEX.
6	Involvement and empowerment of each employee enables commitment and drives the continual success.
7	Non-value adding activities should be eliminated to drive OPEX effectiveness.
8	The pharmaceutical industry has a regulatory burden to OPEX.
9	OPEX approaches from other industries need to be revised to drive success in the pharmaceutical industry.
10	OPEX throughout the pharmaceutical value chain enables sustainable success.
11	The OPEX approach from the pharmaceutical manufacturing can be transferred to the QC lab environment, but it needs to be revised to meet special requirements of the lab.
12	The QC lab represents a key bottleneck for a pharmaceutical company and is therefore a critical component to achieve OPEX throughout the entire value chain.
13	QC operations should be synchronized with the operations in manufacturing to enable OPEX.

2.2 Performance Measurement

The Performance Measurement (PM) literature has evolved over the past and researchers have contributed continuously with diverse concepts, approaches, and perspectives (Marr & Schiuma, 2003). This has led to a controversial discussion of PM throughout its past till today. For this research the operations management (OM) perspective is used without

ignoring the existence of other perspectives that can support the understanding of PM. To get a better understanding of the PM scope for this research, the development of PM is outlined in the following. The multidimensional PM approach is highlighted and an overview of the differing standpoints of scholars regarding the interrelation of these dimensions is provided. Furthermore, a number of relevant PM frameworks for the context of this research are discussed and general requirements to performance measures are introduced. The chapter concludes with implications of PM for the research.

2.2.1 Development of the Approach to Performance Measurement

To get a better understanding of today's scope and application of PM from an OM perspective the historical development of PM in this domain is examined in the following. According to Radnor and Barnes (2007), three major phases of PM can be identified. Kennerley and Neely (2003) agree but refer to trends instead of distinct phases. Digalwar and Sangwan (2011) as well as Ghalayini and Noble (1996) only distinguish two phases of PM but confirm the general trend discussed by the other authors. Thus, to have a distinct picture of the development of PM three major development steps are outlined below.

In the early phase the efficiency dimension was determining PM with a focus on cost (Digalwar & Sangwan, 2011; Radnor & Barnes, 2007). Radnor and Barnes (2007) stress that on the shop floor level individual workers were financially incentivized to achieve a higher productivity. The labor intensive mass production during this phase led to the reasonable PM focus on volume and cost (Radnor & Barnes, 2007). Hayes and Abernathy (2007) emphasize that this unidimensional approach to PM has led American managers focus on short-term efficiency gains which led to lagging competitiveness. According to Neely et al. (1995), the traditional PM had further shortcomings beyond the encouragement of short-term thinking, such as local optimization and the incentive to reduce variance instead of CI. Thus, in the second phase of PM the focus shifted from a unidimensional efficiency perspective to an integrated approach combining efficiency with effectiveness (Hayes & Abernathy, 2007; Radnor & Barnes, 2007). Skinner (1969) outlines that the historical focus on efficiency oversimplified manufacturing operations. The author stresses that corporate strategy affects and is affected by manufacturing (Skinner, 1969). Skinner (1974) supports the shift to more criteria to assess performance to have a more balanced approach to PM. In the third phase PM has developed toward a balanced, multidimensional system approach covering the competitive capabilities of an organization (Bourne, Mills, Wilcox, Neely, & Platts, 2000; Radnor & Barnes, 2007). This integrated approach to PM includes financial and non-financial measures and comprises forward- and backward-looking elements (Bourne et al., 2000; Radnor & Barnes, 2007). It is also referred to as Performance Measurement Framework (PMF) describing a comprehensive set of multidimensional measures (Bourne et al., 2000; Digalwar & Sangwan, 2011; Neely, Kennerley, & Adams, 2007; Radnor & Barnes, 2007). In this latest phase scholars also designed processes to implement PMF into an organization (Kennerley & Neely, 2003). The combination of the PMF, its implementation, and application process is referred to as Performance Measurement System (PMS) (Folan & Browne, 2005; Neely, Richards, Mills, Platts, & Bourne, 1997). Digalwar and Sangwan (2011) emphasize that today's PM is a prerequisite for CI of an organization.

2.2.2 Dimensions of Performance Measurement

On the highest abstraction level PM combines the two dimensions efficiency and effectiveness (Neely, 2005; Neely et al., 1995; Radnor & Barnes, 2007). Scholars recognize competitive priorities as a suitable basis to describe the multidimensional approach of PM in more detail (Digalwar & Sangwan, 2011; Ferdows & De Meyer, 1990; Flynn & Flynn, 2004; Gößler & Grübner, 2006; Neely et al., 1995; Noble, 1995). Boyer and Lewis (2002) emphasize that a company needs to build certain capabilities addressing the competitive priorities to gain a competitive advantage to succeed against its competitors. If a company successfully competes with regard to the competitive priorities (planned success factors) turn into competitive capabilities (actual strength) (Boyer & Lewis, 2002; Flynn & Flynn, 2004; Rosenzweig & Easton, 2010). Competitive capabilities are the basis of performance (Gößler & Grübner, 2006). The linkage between competitive priorities, capabilities, advantage, and performance is depicted in figure 3.

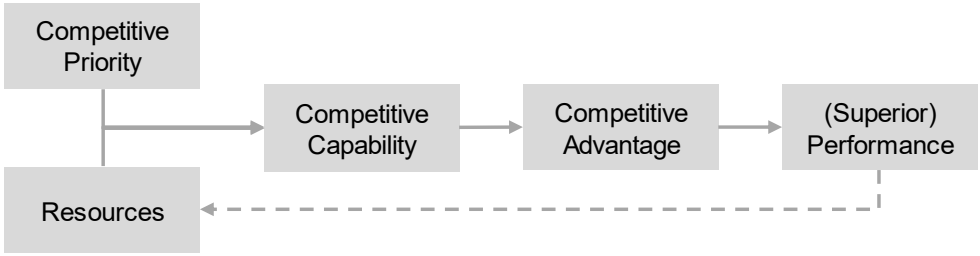

Figure 3: Competitive priorities and performance adapted from Gößler and Grübner (2006)

Most commonly *flexibility, quality, delivery,* and *cost* are referred to as competitive priorities (Gößler & Grübner, 2006; Ward, McCreery, Ritzman, & Sharma, 1998). Flynn and Flynn (2004) stress that the discussion about competitive priorities often leads to confusion because scholars have small but distinct differences in their definition of flexibility, quality, delivery, and cost. Thus, a detailed description of each competitive priority is provided in the following paragraphs. In addition, the less used dimension *innovation* is described.

The traditional definition of *quality* stresses the conformance to specification (Ferdows & De Meyer, 1990; Neely, 2007). However, during the shift to Total Quality Management (TQM) the focus moved from conformance to specification to satisfaction of the customer (Nand et al., 2013; Neely, 2007). Neely (2007) emphasizes that quality combines both product and process quality. Thus, the author underlines that quality is a key dimension for the performance measurement of the operations (Neely, 2007).

Delivery is used interchangeably with dependability and describes more specifically on-time delivery (Ferdows & De Meyer, 1990; Noble, 1995). This dimension describes the reliability of the processes to deliver as scheduled (Ward et al., 1998). Corbett and van Wassenhove (1993) add the aspect of delivery to the right place and in the right quantity to the definition. Some authors also associate delivery speed with this category (Ward et al., 1998). However, not all authors agree delivery speed should define this dimension (L. M. Corbett & Claridge, 2002; Neely, 2007). In the context of LM along with the Just-In-Time (JIT) concept both too early and too late delivery is seen as waste (Neely, 2007).

The dimension *flexibility* is used interchangeably with reaction speed and covers the aspect how quick an organization can respond to occurring changes (Ferdows & De

Meyer, 1990; Neely, 2007). Slack (1983) emphasizes that flexibility is twofold including a range and time aspect. According to Gerwin (1993), seven different dimensions of flexibility exist. The author highlights mix flexibility (handling a range of products/variants) and changeover flexibility (handling a new product introduction) (Gerwin, 1993). In addition, Gerwin (1993) incorporates modification flexibility, volume flexibility, rerouting flexibility, material flexibility, and flexibility responsiveness.

Within the dimension *cost* all direct costs as well as the utilization and inventory level are captured (Ward et al., 1998). However, Neely (2007) argues that indirect costs also play a key role to determine the operations performance. An overview of the competitive priorities that are commonly used to describe the dimensions of PM and key authors are exhibited in table 5.

Although many authors do not include the dimension *innovation* into their definition of competitive priorities some scholars include it as a fifth dimension (cf. table 5). Innovation refers to the development and introduction of new products (L. M. Corbett & Claridge, 2002; Noble, 1995). Corbett and van Wassenhove (1993) stress that the capability of this dimension builds on the speed to innovate faster than the competitors.

Table 5: Competitive priorities overview in literature

Dimension	Authors
Flexibility, Quality, Delivery, and Cost	Adam and Swamidass (1989); Behrouzi and Wong (2011); Boyer and Lewis (2002); Ferdows and De Meyer (1990)[a b]; Flynn and Flynn (2004)[c]; Gößler and Grübner (2006); Kim and Arnold (1996)[c d]; Miller and Roth (1994)[c]; Nand, Singh, and Power (2013); Neely (2007)[b]; Neely, Gregory, and Platts (1995)[a]; Rosenzweig and Easton (2010); Schmenner and Swink (1998);Skinner (1969, 1974); Ward, McCreery, Ritzmann, and Sharma (1998); Wheelwright (1984)[a]; White (1996)[a]
Flexibility, Quality, Delivery, Cost, and Innovation	Noble (1995, 1997)[a]; C. J. Corbett and van Wassenhove (1993)[e]; L. M. Corbett and Claridge (2002)

[a] Delivery interchangeable with dependability and time or dimensions are not aggregated
[b] Flexibility interchangeable with (reaction) speed or dimensions are not aggregated
[c] Higher granularity for one or more dimensions (e.g. product and volume flexibility)
[d] Cost interchangeable with price
[e] Aggregation into fewer categories but including all five dimensions

Although there is broad agreement on the multiple dimensions of the competitive priorities authors have come to different conclusions regarding the relation between the competitive priorities and, consequently, regarding the question how to build superior performance (Boyer & Lewis, 2002; Flynn & Flynn, 2004; Rosenzweig & Easton, 2010). The trade-off approach constitutes the traditional approach to the relationship between the competitive priorities (C. J. Corbett & van Wassenhove, 1993). Skinner (1974) outlines that a company cannot perform well on all four dimensions. The author argues that cost and quality is an explicit trade-off and adds the fact of additional rather implicit trade-offs between the dimensions (Skinner, 1974). However, the author emphasizes that a company does not necessarily perform poorly in one dimension if a trade-off exists but needs to decide which dimension is valued higher (Skinner, 1974). According to the author, the choice needs to

be aligned with the corporate strategy and will lead to successful competition (Skinner, 1969, 1974).

Other authors argue that the competitive capabilities built on competitive priorities are not mutually exclusive but can enhance one another if addressed in sequence (Ferdows & De Meyer, 1990). Schroeder, Shah, and Peng (2011) outline that literature suggests different orders of sequence. The cumulative approach of Ferdows and De Meyer (1990) suggests to start with quality, then to focus on delivery, flexibility, and cost in sequence (Ferdows & De Meyer, 1990). This sequence has broadly been accepted (R. G. Schroeder et al., 2011). Ferdows and De Meyer (1990) emphasize that a company needs to enhance effort on the previous focus once it proceeds to build the next capability to be successful (Ferdows & De Meyer, 1990). Ferdows and De Meyer (1990) refer to their model as the sand cone model which conveys the sequence that can only be built from the basis and not from the top. Flynn and Flynn (2004) analyze the relation of the competitive priorities in different regions of the world and come to the conclusion that there are certain influencing factors that lead to differing cumulative characteristics.

The integrated approach aims at combining the trade-off and cumulative perspective to competitive priorities (Nand et al., 2013). Schmenner and Swink (1998) use the theory of performance frontiers[9] to describe the relation between competitive priorities. The authors argue that a company with competitive capabilities lagging behind typically gains a competitive advantage following the cumulative approach (Schmenner & Swink, 1998). A leading-edge company needs to make trade-off choices (Schmenner & Swink, 1998).

Due to the differing units of analysis (e.g. site level vs. department level) and context (e.g. region) all approaches elaborated above have empirical support and no unified understanding of the relation between the competitive priorities can be derived. Table 6 depicts the three different approaches of the relation between the competitive priorities and key authors.

Table 6: Different approach to the relation of competitive priorities

Approach	Authors
Trade-off	Boyer and Lewis (2002); Buffa (1984); Skinner (1969); Hayes and Wheelwright (1984); Hill (1995)
Cumulative	L. M. Corbett and Claridge (2002); C. J. Corbett and van Wassenhove (1993); Gößler and Grübner (2006); Ferdow and De Meyer (1990); Flynn and Flynn (2004); Miller and Roth (1988); Noble (1995); R. G. Schroeder, Shah, and Peng (2011)
Integrated	Nand, Singh, and Power (2013); Schmenner and Swink (1998)

In addition to the competitive priorities many authors add additional dimensions to the discussion of PM that can be described as enabling factors to achieve superior performance (Negrão, Godinho Filho, & Marodin, 2017). These enabling factors are also

[9] The theory of performance frontiers identifies a company's competitive position based on an operating frontier and an asset frontier. Both are special cases of a performance frontier. The operating frontier describes infrastructural choices that are connected to the operating strategy. The asset frontier comprises all structural choices. If these two frontiers converge a company is leading-edge because it achieved to maximize its returns on the structural choices and investments (Nand et al., 2013).

called practices (Ahmad, Schroeder, & Sinha, 2003; Shah & Ward, 2003; Voss, 1995) or principles (Belekoukias, Garza-Reyes, & Kumar, 2014). In the following a single enabling factor is referred to as an enabler. A group of internally consistent enablers with the same improvement focus are summarized as an enabler dimension. The authors do not agree about the scope and number of enablers mostly due to a certain focus of analysis or a different degree of detail (Negrão et al., 2017).

Flynn, Schroeder, and Sakakibara (1994) apply a process definition to quality management (QM) which underlines the importance to analyze both inputs (enablers) and output (performance). This additional dimension of enablers leads to a broader understanding of how performance is achieved. The process perspective has been transferred implicitly and explicitly to PM (Folan & Browne, 2005; Friedli & Bellm, 2013; Jaeger, Matyas, & Sihn, 2014). According to Cua, McKone-Sweet, and Schroeder (2006), both the technical sub-system as well as the social sub-system need to be considered and enablers should always be implemented systematically as part of an overall program. Jochimsen and Napier (2013) agree and link organizational culture with high performance in manufacturing. The authors argue that the so-called soft enablers need to be considered to enable an organization to implement LM that drives operational performance leading to WCM (Jochimsen & Napier, 2013).

The major enabler dimensions that are discussed in literature are Total Productive Maintenance (TPM)[10], Total Quality Management (TQM), Just-In-Time (JIT), Human Resource Management (HRM), and Organizational Culture (OC) (cf. table 7). Each of the dimensions should represent an internally consistent set of enablers (Shah & Ward, 2003). However, the scope of the definitions in literature differs (Ahmad et al., 2003).

The objective of TPM is to maximize the equipment effectiveness by avoiding unexpected breakdowns through planned maintenance and equipment-related improvement effort (Cua et al., 2001). According to the authors, TPM encompasses enablers such as autonomous maintenance and planned maintenance but also a committed leadership, cross-functional training, and employee involvement to improve the equipment stability (Cua et al., 2001). Friedli and Bellm (2013) outline a short-term and long-term focus of TPM. While the short-term focus is on maintenance itself, the long-term focus incorporates the launch of new technology (Friedli & Bellm, 2013).

The TQM dimension aims at stabilizing both product and process quality to meet or exceed customer expectations (Cua et al., 2001; Furlan, Vinelli, & Dal Point, 2011). Among other enablers Cua, McKone, and Schroeder (2001) stress the importance of supplier, customer and employee involvement, systematic process management, and committed leadership to achieve TQM performance. Furlan, Vinelli, and Dal Point (2011) emphasize to reduce process variance to achieve the objective of TQM.

[10] TPM is sometimes also referred to as Total Productive Management as a synonym for Total Productive Maintenance (Mitchell, 2015). Other authors stress that TPM developed toward a Total Productive Management approach (C. May, 2008). To avoid an overlap of TPM with other enabler dimensions in the context of this research TPM will be referred to as Total Productive Maintenance with its objective of maximizing the equipment effectiveness.

JIT aims at reducing and eliminate all types of waste (Ahmad et al., 2003; Cua et al., 2001). Through the involvement of the leadership team and employees JIT aims at reducing set-up time and inventory and to adhere to the planned schedule (Cua et al., 2001).
All three enabler dimensions TPM, TQM, and JIT emphasize the importance of leadership, strategic planning, cross-functional training, and employee involvement to achieve its objective (Cua et al., 2001). The dimension HRM can be seen as the supporting infrastructure of all three dimensions summarizing employee-related aspects in a separate dimension. According to Shah and Ward (2003), HRM includes enablers such as job rotation, cross-training, formal training programs, teamwork, problem solving in teams, and employee involvement. The OC dimension describes the unique behavioral collectivism of an organization based on the mindset, values, and behavior of its individuals contributing to the way the organization does its business (Barney, 1986; Jochimsen & Napier, 2013; Wiengarten et al., 2015). The term Effective Management System (EMS)[11] includes all aspects of the supporting infrastructure of HRM and OC in one dimension (Friedli & Bellm, 2013).
Multiple analysis have shown that enablers have supported organizations to improve their operational performance (Belekoukias et al., 2014; Ghosh, 2012; Shah & Ward, 2003). Ketokivi and Schroeder (2004) emphasize the fact that operational performance cannot be defined unidimensionally as this leads into an incomplete understanding of the relation between enabler and performance. The author stress that operational performance needs to be defined multidimensionally (Ketokivi & Schroeder, 2004). It has to be noted that the definition of operational performance is not consistent throughout literature[12]. The success measured as performance outcome based on the implementation of the enablers varies between companies (Ahmad et al., 2003; Inman & Brandon, 1992). The organizational context is seen as a decisive factor of differing results (Ketokivi & Schroeder, 2004; R. E. White, Pearson, & Wilson, 1999). Shah and Ward (2003) agree and stress that the size of the site has a significant impact on the result. In addition, the enablers have to be seen as interlinked factors (Ahmad et al., 2003). Cua, McKone, and Schroeder (2001) as well as Shah and Ward (2003) agree and argue that the different enabler dimensions have to be analyzed together as the dimensions are interlinked. The enabler dimensions grouped together and as standalone, which authors directly link to operational performance, are depicted in table 7. Indirect links between enabler dimensions and operational performance are not illustrated. The philosophy kaizan that is used as synonym for CI (cf. chapter 2.1.1.3) was excluded from the overview due to its higher level of aggregation including aspects of a range of dimensions exhibited in table 7. In addition, some aspects such as Value Stream Mapping (VSM) outlined by authors as a dimension are rather

[11] The term Effective Management System (EMS) combines all aspects of HRM and OC in one dimension and will be used in this research to describe this supporting infrastructure of TPM, TQM, and JIT.

[12] Operational performance is defined differently in various studies depicted in table 7. Although competitive capabilities seem to be acknowledged as a good set of proxies not all authors use all dimensions to operationalize performance in their empirical work. This may be partly caused by difficulties to find appropriate measures for each competitive capability and/or access to certain databases with limited measures for their research.

associated with an individual enabler than an enabler dimension and are therefore not illustrated in table 7.

Table 7: Enabler dimensions directly linked to performance in literature

Dimension(s)	Authors
TPM, TQM, JIT, and HRM	Shah and Ward (2003); Friedli and Bellm (2013)[a]
TPM, TQM, JIT	Challis, Samson, and Lawson (2005)[b]; Cua, McKone, and Schroeder (2001); Cua, KcKone-Sweet, and Schroeder (2006); Friedli and Bellm (2013)
TPM	Belekoukias, Garza-Ryes, and Kumar (2014); Challis, Samson, and Lawson (2005)[b]; Cua, McKone, and Schroeder (2001); Cua, KcKone-Sweet, and Schroeder (2006); McKone and Weiss (1998); Shah and Ward (2003); Friedli and Bellm (2013)
TQM	Challis, Samson, and Lawson (2005); Cua, McKone, and Schroeder (2001); Cua, KcKone-Sweet, and Schroeder (2006); Friedli and Bellm (2013); Shah and Ward (2003); Sriparavastu and Gupta (1997); Rahman and Bullock (2005)
JIT	Ahmad, Schroeder, and Sinha (2003); Belekoukias, Garza-Ryes, and Kumar (2014); Challis, Samson, and Lawson (2005); Chen and Tan (2013); Cua, McKone, and Schroeder (2001); Cua, KcKone-Sweet, and Schroeder (2006); Friedli and Bellm (2013); Matsui (2007); Shah and Ward (2003); Sriparavastu and Gupta (1997); White, Pearson, and Wilson (1999)
HRM	Shah and Ward (2003); Challis, Samson, and Lawson (2005); Friedli and Bellm (2013)[a]; Huselid (1995); MacDuffie (1995)
Culture[c]	Barney (1986)[d]; Bortolotti, Boscari, and Danese (2015); Hanson and Voss (1995)[e]; Jochimsen and Napier (2013); Wiengarten, Gimenez, Fynes, and Ferdows (2015)

[a] EMS used instead of HRM to incorporate leadership and culture aspects
[b] AMT used instead of TPM describing the equipment-related dimension
[c] Linked to competitive advantage leading to performance
[d] Focus on financial performance
[e] Focus on business performance

2.2.3 Performance Measurement Framework

In the context of the conceptual abstraction of PM literature suggests different terminologies[13]. Authors refer to frameworks (Dahlgaard-Park & Dahlgaard, 2007; Digalwar & Sangwan, 2011; Hanson & Voss, 1995; Lu, Betts, & Croom, 2011; Neely, Adams, & Crowe, 2001; Neely et al., 2007), models (Dahlgaard-Park & Dahlgaard, 2007; Hanson & Voss, 1995; Lu et al., 2011), or systems (Digalwar & Sangwan, 2011; Folan & Browne, 2005). Many authors use the terms framework and model interchangeably (Dahlgaard-Park & Dahlgaard, 2007; Hanson & Voss, 1995; Lu et al., 2011). The combination of a framework, its implementation, and application process is referred to as Performance Measurement System (PMS) (Folan & Browne, 2005). Following the objective to determine an overall performance there is general agreement that performance measures should not be used in isolation (Digalwar & Sangwan, 2011; Fry & Cox, 1989). Performance Measurement Frameworks (PMF) aim at overcoming the

[13] The terms model and framework are interchangeable in this research. When referring to a Performance Measurement System (PMS) the deployment of the model/framework is incorporated.

disadvantage of an isolated performance perspective by incorporating manifold performance measures from different focus areas of interest (Digalwar & Sangwan, 2011). Table 8 depicts an overview of PMF and their focus used in the context of operational and business excellence. In the following paragraphs selected PMF are exhibited. The PMFs that have few highly aggregated and not significantly different dimensions such as the Performance-Measurement-Matrix (Keegan, Eiler, & Jones, 1989), the Balanced Scorecard (Kaplan & Norton, 1992), and the Performance Prism framework (Neely et al., 2001) are not elaborated any further.

Table 8: Performance measurement frameworks in the context of excellence

Framework	Focus
Balanced Scorecard (1)	- Financial perspective - Internal Business perspective - Innovation and learning perspective - Customer perspective
European Foundation for Quality Management (EFQM) Excellence Model (2)	- Enablers: leadership, people, strategy, partnership & resources, process, products & services - Results: people results, customer results, society results, business results - Learning, creativity, and innovation
Malcolm Baldrige National Quality Award (MBNQA) Performance Excellence Framework (3)	- Leadership - Strategy - Customers - Measurement, analysis, and knowledge management - Workforce - Operations - Results
Performance-Measurement-Matrix (4)	- Internal non-cost - Internal cost - External non-cost - External cost
Performance Prism Framework (5)	- Stakeholder satisfaction - Strategies - Processes - Capabilities - Stakeholder contribution
Performance Pyramid (6)	- Operations - Quality - Delivery - Process Time - Cost - Customer satisfaction - Flexibility - Productivity - Market measures - Financial measures - Vision
St. Gallen Operational Excellence (OPEX) Model (7)	- Enabler: TPM, TQM, JIT, EMS, basic elements - Performance: TPM, TQM, JIT, EMS

(1) Kaplan & Norton (1992), (2) EFQM (2012), (3) MBNQA (2017), (4) Keegan, Eiler, and Jones (1989), (5) Neely, Adams, and Crowe (2001), (6) Cross & Lynch (1988), (7) Kickuth (2005)

European Foundation for Quality Management Excellence Model

The EFQM model has a twofold approach to excellence. It combines the dimension enablers and results to provide a cause-and-effect relationship perspective between the input of on organization and the output that is achieved to drive CI. The model comprises nine elements, thereof five enabler and four result categories. The dimension enablers can be separated into the five sub-dimensions: leadership (1), people (2), strategy (3), partnerships & resources (4), and processes, products & services (5). The result dimension includes four sub-dimensions: people results (1), customer results (2), society results (3), and business results (4). (EFQM, 2012)

To achieve excellence the philosophy of this model is to develop a strong leadership, to define a clear strategy, to train people, to foster partnerships & resources, and to improve processes to develop value-adding products and services. According to the model, sustainable success is based on an effective implementation of the enablers, leading to results that meet or exceed expectations. According to the EFQM model, excellent organizations are able to define a multidimensional set of KPIs. These organizations understand the drivers of their performance and are aware of the underlying reasons that impact the performance in the different areas of the organization. Rusev and Salonitis (2016) argue that due to its complex scoring matrix the EFQM model can only be applied by assessors. However, the model is also widely seen as a self-assessment tool within an organization to understand the current state in each of the nine model dimension (Jaeger & Matyas, 2016; Wongrassamee, Gardiner, & Simmons, 2003). The model does not provide suggestions what measures should be implemented to enable CI (Wongrassamee et al., 2003). Figure 4 shows the EFQM excellence model. (EFQM, 2012)

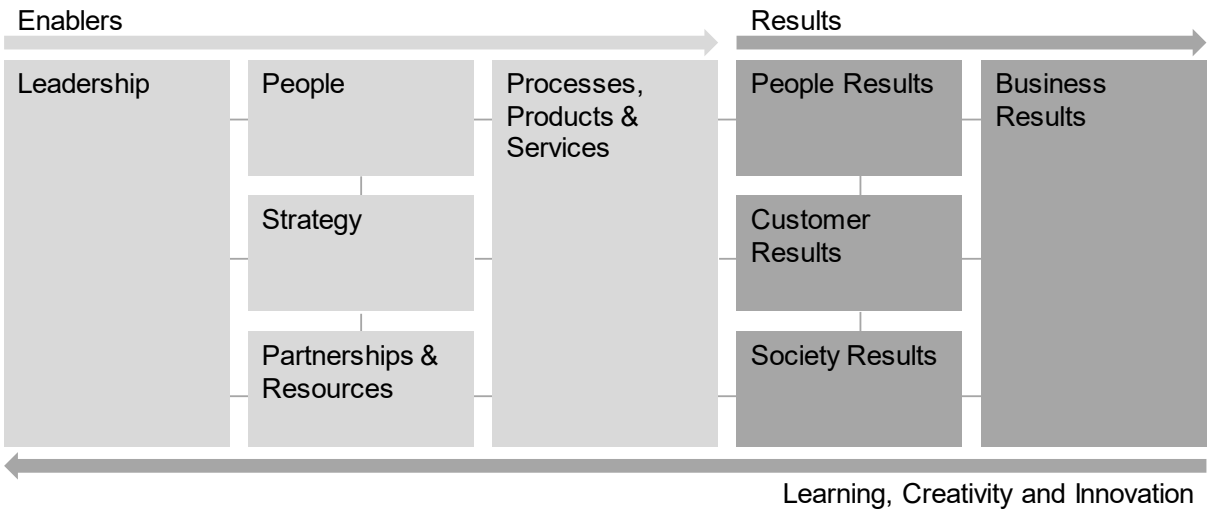

Figure 4: European Foundation for Quality Management Excellence Model (EFQM, 2012)

Malcolm Baldrige Excellence Framework

The Malcolm Baldrige framework is an integrated approach to organizational performance addressing both effectiveness and efficiency aspects. It originates in the field of QM as a quality performance framework and has developed toward an organizational performance framework over time. To reflect this in 2010 the Baldrige National Quality Program was

renamed to Baldrige Performance Excellence Program (Link & Scott, 2011). Embedded in the organizational profile, which incorporates the organizations context, its opportunities, and constraints, the framework comprises seven dimensions. Leadership (1), strategy (2), customer (3), measurement, analysis & knowledge management (4), workforce (5), operations (6), and results (7) are defined as the key criteria for organizational excellence. Each of the criteria is an aggregation of multiple sub-elements. The criteria leadership and strategy emphasize the organizational culture and the learning process to gain long-term success. The customer focus enables the organization to meet and exceed the customers' expectations contributing to long-term success. The criteria measurement, analysis, and knowledge management is central for the alignment between the organization's strategic objectives and its operations. The support of the workforce and operational effectiveness enables the organization to achieve the desired results. In addition to the seven key dimensions of the framework, core values, and concepts are incorporated in the framework to address individual behaviors within the organization. The framework was originally designed to be used by assessors (Rusev & Salonitis, 2016). Nevertheless, it is also seen as a self-assessment tool. The Malcolm Baldrige framework is exhibited in figure 5. (Friedli & Bellm, 2013; MBNQA, 2017; NIST, 2017)

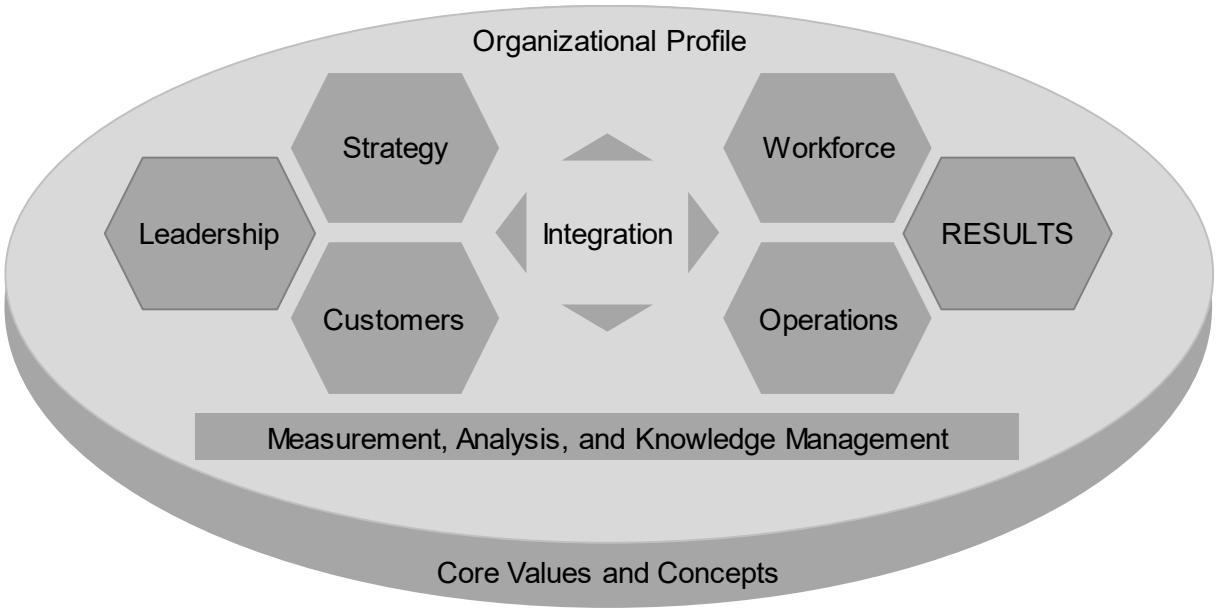

Figure 5: Malcolm Baldrige Excellence Framework (NIST, 2017)

Performance Pyramid

The Performance Pyramid was introduced in the late 1980s to enable decision making that is not based on the unidimensional thinking of the early PM phase anymore. The framework addresses PM as external effectiveness and internal efficiency (Neely et al., 2007). The pyramid encompasses four levels linking operations as the foundation with corporate vision at the top of the pyramid. The first level combines the elements quality, delivery, cycle time, and waste to ensure meeting the objective of the second level which comprises customer satisfaction, flexibility, and productivity. Market and finance build the third level. The top of the pyramid, the fourth level, represents the corporate vision. The framework ensures that objectives of the management are translated top-down into

tangible goals for each element of the pyramid. This is complemented with a bottom-up approach having measures in each element of the pyramid to determine the success. The application of the model enables a strategy-driven PMS. The framework does not explicitly incorporate the concept of CI (Digalwar & Sangwan, 2011; Ghalayini & Noble, 1996). However, with appropriately defined measures it encourages CI. The Performance Pyramid is depicted in figure 6. (Cross & Lynch, 1988)

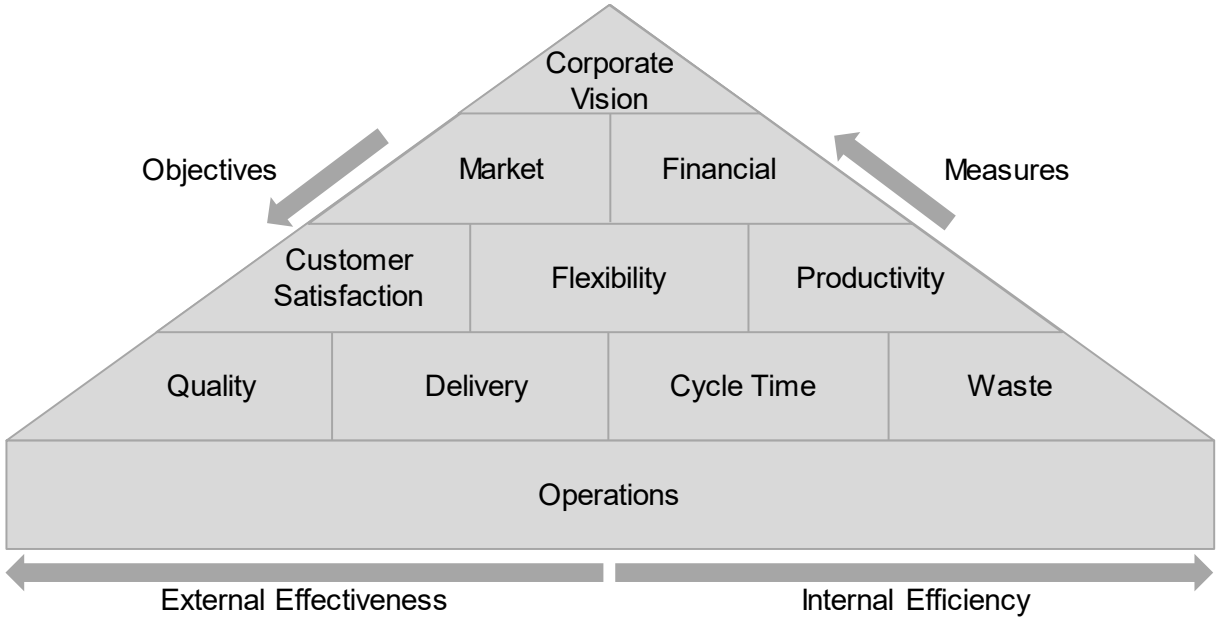

Figure 6: Performance Pyramid adapted from Cross & Lynch (1988) and Neely et al. (2007)

St. Gallen Operational Excellence Model

The St. Gallen OPEX model addresses the need of an integrated system approach to OPEX analyzing effectiveness and efficiency. It has been primarily applied in the manufacturing function of the pharmaceutical industry. However, its conceptual dimensions are independent from the application focus. The underlying logic of this model follows the EFQM excellence model including two major dimensions, enablers as an input and performance as an outcome. On the highest abstraction level the model combines a technical sub-system with a social sub-system. The technical sub-system provides details on the dimensions Total Productive Maintenance (TPM), Total Quality Management (TQM), and Just-In-Time (JIT). This sub-system analyzes the equipment-related (TPM), process-related (TQM), and inventory-related (JIT) aspects in the sequence of first TPM, then TQM, and then JIT. The twofold element standardization and visual management serves as the basis of all three dimensions of the technical sub-system as this element is not only related to one of the dimensions. The social sub-system deepens the understanding of the Effective Management System (EMS). It incorporates aspects that belong to the employee involvement, empowerment, and support of the management. The frame of the St. Gallen OPEX model comprises the dimensions cost and structural factors. The dimension structural factors encompasses constraints that affect the OPEX performance and, therefore, are important for the interpretation of the performance

outcome. The structural factors[14] result from business decisions on the company's value creation focus. According to the St. Gallen OPEX model, a company achieves a high OPEX performance if it performs well in all three technical dimensions TPM, TQM, and JIT. The model is designed to be used by assessors to identify a company's OPEX performance. Furthermore, the application allows a company to identify areas of improvement linking the performance in TPM, TQM, and JIT with the respective enabler dimension. Therefore, the St. Gallen OPEX encourages CI. The model is shown in figure 1. (Friedli & Bellm, 2013)

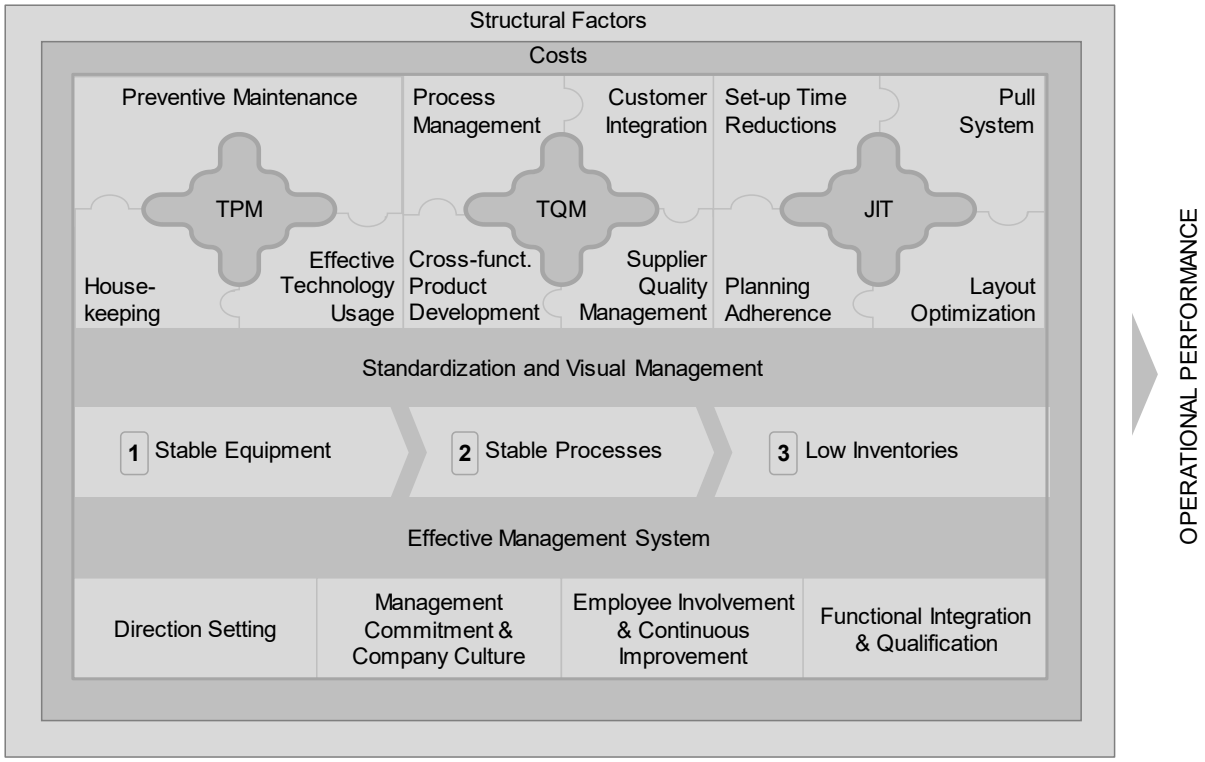

Figure 7: St. Gallen Operational Excellence Model (Friedli & Bellm, 2013)

2.2.4 Requirements of Performance Measures

To measure performance, specific indicators[15] have to be designed which serve as a basis. In the following the OM lens provides an overview about relevant requirements for performance measures in the context of this research.

Performance measures are usually used to monitor, to communicate expectations, and to provide feedback driving desired behavior and motivating the workforce (Van der Stede, Chow, & Lin, 2006). It has to be noted that inadequate measures may drive undesired behavior (Chenhall, 1997; Neely et al., 1997). Historically, the focus was on financial backward looking measures (lagging indicators) (Ghalayini & Noble, 1996; Nudurupati,

[14] In the pharmaceutical industry the technology produced (e.g. drug product solids) is seen as a key structural factor that leads to differing OPEX performance. To determine a suitable reference point for the company's OPEX performance and suitable improvement measures the structural factors have to be considered.

[15] Performance measures are also referred to as indicators, key performance indicators (KPI), or metrics.

Bititci, Kumar, & Chan, 2011). Over time non-financial measures have gained attention and have been discussed as forward looking factors (leading indicators) for the (financial) performance of an organization (Ittner & Larcker, 1998; Nudurupati et al., 2011).

White (1996) classifies internal, external, subjective, and objective measures. The author stresses that objective measures are based on observable facts, whereas subjective measures describe perceptions of the individual (G. P. White, 1996). Taking a process perspective into account, the author also explains that outcome performance measures can be well complemented with input measures referring to enablers (G. P. White, 1996). Nemetz (1990) argues that it is necessary to rely on subjective measures to understand the performance level of an organization. Among others Ward, McCreery, Ritzman, and Sharma (1998) as well as Flynn, Schroeder, and Flynn (1999) support the validity of subjective measures in their empirical studies on competitive priorities in OM. A combination of objective and subjective measures is widely used in OM (Bortolotti et al., 2015; Challis et al., 2005; Flynn et al., 1999; Ward et al., 1998). Moreover, Van der Stede, Chow, and Lin (2006) find evidence that organizations with a comprehensive PMS including objective and subjective non-financial measures in their PMS have a higher performance than those organization that only focus on objective measures.

To achieve effective PM the measures determining performance need to be simple and relevant (Azzone, Masella, & Bertele, 1991; Fortuin, 1988; Globerson, 1985). In this context relevant can be understood as the state of an indicator measuring what it is deployed for. Many authors emphasize that measures need to be linked to the strategy of the organization (Azzone et al., 1991; Globerson, 1985; Kaplan & Norton, 1992; Keegan et al., 1989). Beischel and Smith (1991) underline that measures need to be connected to the competitive priorities of an organization. Azzone, Masella, and Bertele (1991) agree and emphasize that this link between measures and competitive priorities makes effective PM possible. Beischel and Smith (1991) stress that a measure becomes more aggregated including a broader definition the higher these measures are anchored in the organization (Beischel & Smith, 1991). Globerson (1985) and Fortuin (1988) emphasize the fact that measures need to be clearly defined. Furthermore, Globerson (1985) outlines that ratios are preferred over absolute figures, that the measures should reflect operations that can be influenced by the organization and that measures should be selected jointly by its stakeholders (Globerson, 1985).

Based on a comprehensive literature review Neely, Richard, Mills, Platts, and Bourne (1997) identify a list of 22 recommendations how to design performance measures including measure characteristics and measure development process related aspects (cf. appendix 1).

Table 9 depicts an adapted overview of the requirements and explanations for the characteristic of performance measures of Neely et al. (1997) in the context of this research. Requirements that are linked to a PMF and a PMS, the combination of a PMF, its implementation, and application process, within an individual organization are identified.

Table 9: Requirement of performance measures (adapted from Neely et al., 1997)

Dimension	Explanation	PMF	PMS
Title	A measure should have a clear and precise title that explains what it is measuring and it should be easy to understand.	●	●
Purpose	Each measure needs to have a distinct purpose with relevance to the PMF scope to be included.	●	●
Relates to	Measures should always be derived from strategy and be related to the business objective with the focus on improvement.	●	●
Target	A specific goal should be defined for each measure to allow the assessment of the target achievement.		●
Formula	Appropriately defined measures ensure that only aspects are measured that can be influenced. Ratios should be preferred over absolute numbers.	●	●
Frequency	The frequency of measuring should be determined and timely to provide feedback when it is needed.		●
Who measures?	The person who is responsible for data collection and reporting should be identified.		●
Source of data	The source of raw data should be specified. A consistent definition allows comparability. A simple reporting approach should be implemented.		●
Who acts on the data?	The person who acts on the data needs to be identified.		●
What do they do?	It has to be clear what the measures are used for (e.g. visualization, initiating improvement programs).		●

2.2.5 Performance Measurement Implications for Research

Based on the literature review on Performance Measurement, its origin, dimensions, and frameworks as well as requirements of performance measures in OM table 10 depicts the implications for the research.

Table 10: Performance measurement implications for research

No.	Implication
1	PM is a prerequisite for well-structured CI effort enabling sustainable success.
2	PM needs to be aligned with corporate strategy.
3	PM can be used to compare the performance of different organizations.
4	PMFs enable a balanced approach to PM.
5	PM and PMFs include an efficiency and effectiveness dimension.
6	An effective performance measure has to fulfill multiple requirements.
7	Forward looking measures next to backward looking measures help to understand performance.
8	Performance measures can be internal, external, objective, and subjective.
9	Flexibility, quality, delivery, and cost are competitive priorities which address the multidimensional approach of PM.
10	There is no unified understanding of the relation between the competitive priorities.
11	Structural factors play a key role for PM and need to be considered when comparing operational performance.
12	Enablers allow assessing the effort that is invested into improving operational performance.
13	Linking performance measures to competitive priorities of the organization enables effective PM.

2.3 Theoretical Gap

Based on the literature review of Operational Excellence and Performance Measurement the following two-fold theoretical gap can be derived:

The diverse PM literature emphasizes that the approach to operational performance depends on the unit of analysis and cannot be transferred one-to-one from other areas. There is no empirical study from academia that discusses OPEX performance in pharmaceutical QC labs. The relation of enabler, performance, and operating context has not been discussed in the research context yet.

3 Operational Excellence Performance Measurement Model

This chapter depicts the conceptual abstraction of OPEX performance measurement in QC labs. In chapter 3.1 the model development approach is outlined, followed by a general description of the model design process in chapter 3.2. The chapter model design includes a detailed description of the model dimensions. Thereafter, in chapter 3.3 each model dimension is operationalized specifically to the field of research. The chapter closes with propositions and hypotheses to test the credibility and plausibility of the model to meet scientific relevance in chapter 3.4.

3.1 Model Development

This chapter elaborates fundamental principles of the model development. First, the terminology for the purpose of the research is defined, followed by an overview of the model development approach.

3.1.1 Terminology

The conceptual abstraction of performance measurement into a simplified aggregation of relevant dimensions is defined with different terminology in literature (cf. chapter 2.2.2). Authors refer to frameworks (Dahlgaard-Park & Dahlgaard, 2007; Digalwar & Sangwan, 2011; Hanson & Voss, 1995; Lu et al., 2011; Neely et al., 2001, 2007), models (Dahlgaard-Park & Dahlgaard, 2007; Hanson & Voss, 1995; Lu et al., 2011), or systems (Digalwar & Sangwan, 2011; Folan & Browne, 2005). Many authors use the terms framework and model interchangeably (Dahlgaard-Park & Dahlgaard, 2007; Hanson & Voss, 1995; Lu et al., 2011). The combination of a framework, its implementation, and application process is referred to as Performance Measurement System (PMS) (Folan & Browne, 2005).
In the following, the term model is used for the conceptual abstraction. According to Stachowiak (1973), three definite aspects define a model. First, it is a representation of an original entity that can be a model itself (Stachowiak, 1973). Second, a model does not include all attributes of the original entity but only those that are relevant to the model creators and model users for the application purpose (Stachowiak, 1973). Third, the model follows the rules of pragmatism to allow the utilization for a specific purpose of a specific audience at a specific point in time (Stachowiak, 1973).

3.1.2 Approach

Following the exploratory sequential research approach suggested by Creswell (2014) the first phase of the research at hand was dedicated to the qualitative development of the performance measurement model (PMM). The PMM development process was built on data source triangulation to allow a maximum of comprehensiveness by including different points in time, different places, and multiple contributors (Denzin, 1970; Flick, von Kardoff, & Steinke, 2004). To ensure incorporating all relevant dimensions into the PMM the implications from the OPEX and PM literature (cf. chapter 2.1.4 and chapter 2.2.5) were triangulated. The data source triangulation combined the OPEX and PM literature with

findings from joint project results with the co-developing industry partner[16] and workshop results with multiple industry partners. The workshops took place during several meetings of the St. Gallen OPEX Research Group[17] meetings in 2016, 2017, and 2018. Further refinement workshops were held during meetings of the St. Gallen QC Lab Exchange Platform[18] in 2018. In addition, a preliminary version of the model was presented and discussed during numerous industry conferences[19]. The audience during these conferences was a variety of functions from senior executives to lab analysts representing a diverse range of experience of the pharmaceutical industry and more specifically the QC labs.

To conclude, all aspects of data source triangulation highlighted by Denzin (1970) and Flick, von Kardoff, and Steinke (2004) were addressed in the model development phase. Building on existing PMM (cf. chapter 2.2.3) in the context of excellence with iterations throughout the design phase enabled a learning process that led to a better understanding of the relevant PMM dimensions and characteristics.

3.2 Model Design

The fundamental principles of the model design of the PMM for QC labs originate from the commonalities of existing PMMs in literature. The RBV that is used as the theoretical grounding for this research supported the selection of categories that were used to compare the existing PMMs for commonalities. According to RBV, performance is a combination of efficiency and effectiveness built on the appropriate deployment of internal resources to develop capabilities that lead to superior performance (cf. chapter 1.2.2). Hence, the dimensions performance (i.e. effectiveness and efficiency) and internal capabilities (i.e. enablers) represented the criteria to compare existing PMMs. The dimension organizational context complies with the objective of this research to allow an

[16] The co-developing partner is a Swiss multinational pharmaceutical company with more than 100,000 employees worldwide and a revenue of about 50 bn dollars. The organization has launched multiple initiatives at global and local level to improve OPEX in QC labs. These initiatives have shown positive results creating new sponsorship for the continuation of these initiatives.

[17] The St. Gallen OPEX Research Group is an event series organized by the University of St. Gallen with four two-day meetings each year. The group was launched in 2014. From 2016 to 2018 between nine and eleven pharmaceutical companies participated each year to discuss industry- and research-topics of OPEX that they have identified as important to the industry. The participants are senior executives with many years of experience in the field of OPEX in the pharmaceutical industry. An overview of the participating companies is provided in appendix 2.

[18] The St. Gallen QC Lab Exchange Platform is an event series organized by the University of St. Gallen with three two-day meetings in the period of 12 months. The platform was initiated in the first half of 2018. It was launched in parallel to this thesis with the objective to discuss preliminary results with the industry. Sixteen pharmaceutical companies participate in its first edition. The participants are corporate executives and local managers with extensive knowledge related to OPEX in QC labs. An overview of the participating companies is provided in appendix 3.

[19] Lean Lab Conference 2017 (Milan, September 28, 2017), Paperless Lab Academy 2017 (Barcelona, April 4-5, 2017), ISPE Global Pharmaceutical Manufacturing Leaders Forum 2017 (Barcelona, April 2-3, 2017), ISPE Annual Meeting 2017 (San Diego, CA, USA, October 29 to November 1, 2018), ISPE Quality Manufacturing Conference 2018 (Arlington, VA, USA, June 4-6, 2018).

application of the PMM to compare different organizations and was therefore also used for comparison of the existing PMMs.

The effectiveness dimension can be defined as “appropriateness of the outputs of the process” (Barnes & Radnor, 2008, p. 385) relative to the organization’s goal. The efficiency dimension measures the “productivity of a process and the utilization of resources” (Barnes & Radnor, 2008, p. 385) of the organization. The enabler dimension describes internal capabilities that allow the organization to achieve a high performance (cf. chapter 2.2.2). The operating context incorporates aspects that help to gain a better performance understanding related to structural differences or interrelations of the assessed unit of analysis. Table 11 depicts the comparison of existing PMMs in the context of excellence. A detailed description of the extensive models (2), (3), (6), and (7) can be found in chapter 2.2.3.

Table 11: Comparison of existing excellence performance measurement models

Model	Performance		Enablers	Operating Context
	Effectiveness	Efficiency		
Balanced Scorecard (1)	●	●		
European Foundation for Quality Management (EFQM) Excellence Model (2)	●	●	●	
Malcolm Baldrige National Quality Award (MBNQA) Performance Excellence Framework (3)	●	●	●	●
Performance-Measurement-Matrix (4)	●	●		●
Performance Prism Framework (5)			●	
Performance Pyramid (6)	●	●		
St. Gallen Operational Excellence (OPEX) Model (7)	●	●	●	●

(1) Kaplan & Norton (1992), (2) EFQM (2012), (3) MBNQA (2017), (4) Keegan, Eiler, and Jones (1989) (5) Neely, Adams, and Crowe (2001), (6) Cross & Lynch (1988), (7) Kickuth (2005)

The majority of existing performance measurement models in the context of excellence emphasize the two-fold characteristic of performance distinguishing effectiveness and efficiency. More than half of the analyzed models incorporate enablers. The operating context is less frequently included in the performance measurement models. However, the research objective is to build a PMM that can be used for the comparison of QC labs between organizations. This and the argumentation of Gomez, Yasin, and Lisboa (2004) that the operating context impacts performance shows the importance to incorporate it into the PMM. Empirical studies related to this research discuss the operating context as a decisive factor of differing performance results (Ketokivi & Schroeder, 2004; R. E. White et al., 1999). Ketokivi and Schroeder (2004) as well as White, Pearson, and Wilson (1999) emphasize that contingencies[20] may influence the implementation of enablers.

[20] According to Gassmann, Frankenberger, and Sauer (2016), contingencies comprise internal and external factors that have an influence on a given reality. The contingency theory addresses the fact that internal and external factors may impact the transferability of management approaches, rules, and practices (Gassmann et al., 2016).

Therefore, on a high abstraction level the OPEX performance measurement model for QC labs combines the three main dimensions performance, enablers, and operating context. Both OPEX literature and PM literature underline the importance of the linkage of internal capabilities and performance (cf. chapter 2.1.1 and chapter 2.2.2). Including performance and internal capabilities (enablers) into the model addresses the demand of scholars to link these two dimensions for a measurement tool in the context of excellence. In addition, PM literature emphasizes that superior performance may differ for different environments (cf. chapter 2.2.2). Thus, following the objective of this research to build a PMM that allows measurement and comparison of performance with other organizations the operating context of QC labs plays a key role. Consequently, the consideration of performance, enablers, and operating context allows the model to serve as the basis of a meaningful PMM in the context of this research. The following chapter elaborates the three main dimensions performance, enablers, and operating context in detail.

3.2.1 Performance Dimensions

The historical development of PM has shown that today's integrated approaches to PM are balanced including financial and non-financial measures with forward- and backward-looking elements (cf. chapter 2.2.1). The unidimensional, short-term, and efficiency oriented measurement of the past has developed to a multidimensional measurement approach covering a more comprehensive scope of performance (cf. chapter 2.2.1). Scholars and practitioners alike emphasize the high level distinction between the dimensions effectiveness and efficiency for OPEX and PM (cf. chapter 2.1.4 and chapter 2.2.5.).

To enable a more distinct picture of the performance scholars suggest competitive priorities as substitutes for the high level distinction between effectiveness and efficiency (cf. chapter 2.2.2). In literature, the competitive priorities are regarded as a suitable basis to describe the multidimensional approach of PM. Scholars refer most commonly to *flexibility, quality, delivery,* and *cost* as competitive priorities (cf. chapter 2.2.2).

Along the iterative model development practitioners from the pharmaceutical industry confirmed the utilization of the competitive priorities in general to allow a comprehensive picture addressing the multidimensional characteristic of operational performance. In the QC lab context the majority of practitioners value effectiveness over efficiency.

The QC lab target system requires amending the competitive priority flexibility for the unit of analysis of this research. In practice instead of flexibility productivity is measured in QC labs. A closer look at the definition of productivity and flexibility in the QC lab context discloses that QC lab productivity enables QC lab flexibility (Barbarite & Maslaton, 2008). The Performance Pyramid of Cross and Lynch (1988) includes productivity and flexibility. However, productivity better matches the efficiency definition in literature as "productivity of a process and the utilization of resources" (Barnes & Radnor, 2008, p. 385). Productivity also meets the overarching concept of measuring efficiency besides effectiveness in QC labs. In particular, productivity in QC labs addresses the workload handling strategy. Depending on the volatility and volume of tests an optimized workload handling strategy increases throughput and enables flexibility (Reynolds, 2009; Reynolds & Scharton-Kersten, 2013). During a dedicated workshop on performance dimensions in QC labs none

of the practitioners of the QC Lab Exchange Platform suggested flexibility as a performance dimension for QC labs (ITEM-HSG, 2018a). On the contrary, among other performance dimensions the workshop concluded to measure productivity in QC labs (ITEM-HSG, 2018a). Therefore, the dimension productivity meets scientific and practical requirements of measuring performance in QC labs. Considering the link between productivity and the literature based definition of efficiency, the QC lab target system, and the practitioners' expertise productivity is deemed a reasonable efficiency performance dimension for the PMM.

Within pretests of the model with practitioners, two competitive priorities were slightly reworded to allow an easier understanding in the context of the QC lab. The dimension delivery was changed to service keeping the target of timeliness. To have all competitive priorities directional positively phrased cost was reworded to cost efficiency.

All 16 pharmaceutical companies of the St. Gallen QC Lab Exchange Platform use competitive priorities to some extent as part of their day-to-day performance measurement (ITEM-HSG, 2018b). A survey[21] among the participants of the St. Gallen QC Lab Exchange Platform showed that only a minority of participating companies of the St. Gallen QC Lab Exchange Platform use all four dimensions *productivity*, *quality*, *service,* and *cost efficiency* for the OPEX performance measurement in QC labs. Productivity is used by 78 %. 100 % of the participants use quality as a performance dimension. Service is used by 94 % and 33 % use cost efficiency as part of their day-to-day performance measurement. (ITEM-HSG, 2018b)

The survey confirms the fact that effectiveness (quality and service) is valued over efficiency (productivity and cost efficiency). Both effectiveness dimensions are measured by 94 % of the participants (ITEM-HSG, 2018b). Therefore, the dimensions quality and service build the center of the PMM. The practitioners confirmed that historically performance in QC labs was solely measured as effectiveness performance. Today, OPEX performance in QC labs is focused on all four competitive priorities. Figure 8 depicts the performance dimensions of the PMM.

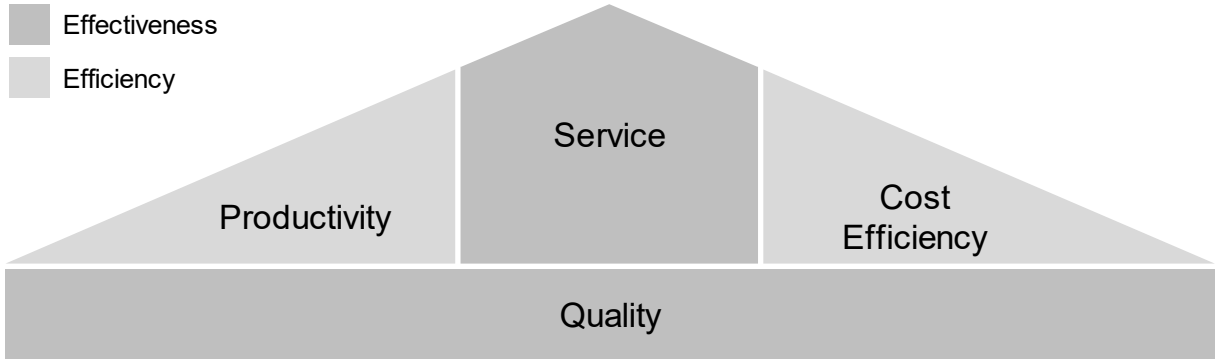

Figure 8: Performance dimensions of the OPEX performance measurement model

[21] The survey was conducted among the 16 participating companies of the St. Gallen QC Lab Exchange Platform as part of the preparation of the kick-off meeting in 2018 (ITEM-HSG, 2018b).

Table 12 exhibits the competitive priorities in literature, key authors, and the wording for this research. As scholars have small but distinct differences in their definition of the competitive priorities, a detailed description of how they are utilized for the QC lab is provided in the paragraphs below.

Table 12: Competitive priorities in literature and wording for research

Dimension	Wording for Research	Authors
Flexibility	Productivity	Adam and Swamidass (1989); Behrouzi and Wong (2011); Boyer and Lewis (2002); Ferdows and De Meyer (1990)[a b]; Flynn and Flynn (2004)[c]; Gößler and Grübner (2006); Kim and Arnold (1996)[c d]; Miller and Roth (1994)[c]; Nand, Singh, and Power (2013); Neely (2007)[b]; Neely, Gregory, and Platts (1995)[a]; Rosenzweig and Easton (2010); Schmenner and Swink (1998);Skinner (1969, 1974); Ward, McCreery, Ritzmann, and Sharma (1998); Wheelwright (1984)[a]; White (1996)[a]
Quality	Quality	
Delivery	Service	
Cost	Cost Efficiency	

[a] Delivery interchangeable with dependability and time or dimensions are not aggregated
[b] Flexibility interchangeable with (reaction) speed or dimensions are not aggregated
[c] Higher granularity for one or more dimensions (e.g. product and volume flexibility)
[d] Cost interchangeable with price

The dimension *productivity* describes how efficiently the lab is operating. The human resource consumption is a key focus of this dimension. The distinction of direct and indirect work effort within this dimension allows a detailed picture of the value-adding productivity level. In addition, the dimension represents the performance outcome of the workload levelling and flow strategy of the lab. The aim of workload levelling and flow strategy in the lab is to achieve a demand-driven smooth work schedule of the testing with a low level of unevenness (Greulich, 2012; Mannion, 2011). Furthermore, insight into utilization and usage of synergy effects are disclosed in the dimension productivity.

The dimension *quality* outlines how effectively the lab is operating. This dimension focuses especially on process robustness. It also captures the traditional quality perception of conformance to specification (cf. chapter 2.2.2) as well as the more recent approach to quality related to satisfying the customer (cf. chapter 2.2.2). Moreover, the lab robustness related to regulatory compliance is addressed within this dimension.

The dimension *service* aims at the lab effectiveness in terms of adherence to the given schedule related targets. Some authors link this competitive priority to speed (cf. chapter 2.2.2). However, in the context of LM too early and too late delivery is seen as waste (cf. chapter 2.2.2). Consequently, in the context of this research, the adherence to the given schedule targets provides a more accurate picture of the service level from a lean perspective. The dimension outlines the reliability of the processes to deliver as planned while handling unplanned tasks that occur regularly in the QC lab (e.g. out-of-specification test results).

The dimension *cost efficiency* addresses the financial resource consumption. The dimension for this research is defined in-line with Neely (2007) who argues that indirect and direct costs should be included in the determination of operational performance (cf. chapter 2.2.2). Apart from the direct QC costs, other costs from the quality organization are covered.

3.2.2 Enabler Dimensions

Today, two thirds of the QC Lab Exchange Platform participants assess capabilities as part of their OPEX performance measurement in QC labs (ITEM-HSG, 2018b). The following provides an overview of OPEX enablers that are associated with operational performance in the manufacturing context. As indicated in chapter 2.1 the QC lab can be seen as a manufacturing unit with timely test results as its products. Therefore, the manufacturing literature is adequate to build a distinct understanding of the multidimensionality of OPEX enablers that should be considered in the PMM.

On a high level of abstraction scholars distinguish technical and social OPEX enablers (cf. chapter 2.2.2). To get a more granular understanding of the multidimensional enablers, the manufacturing literature distinguishes the enabler dimensions Total Productive Maintenance (TPM), Total Quality Management (TQM), Just-In-Time (JIT), Human Resource Management (HRM), and Organization Culture (OC) (cf. chapter 2.2.2). Each of these dimensions combines a number of sub dimensions that provide further details on the individual characteristics of the respective dimension. Table 13 depicts an overview of key literature and the enabler dimensions associated with OPEX in a chronological order from early to most recent work. Due to the differing focus on OPEX in general or its individual aspects, the authors do not always capture all enabler dimensions in their publications. Because the QC lab as an integral part of the value chain often does not focus on customer involvement and supplier management these two dimensions are not included in the overview exhibited in table 13. In the following, the social enablers are referred to as the Management Enabler System (MES). The technical enablers are referred to as the Technical Enabler System (TES).

Table 13: Operational excellence enablers in key literature

Authors	Focus	Enabler Dimensions												
		Technical Enabler System										Management Enabler System		
		Preventive Maintenance	Technology Assessment & Usage	Housekeeping	Process Management	Standardization & Simplification	Set-up Time Reduction	Pull Approach	Layout Optimization	Planning Adherence	Visual Management	Management Commitment & Company Culture	Employee Involvement & Continuous Improvement	Functional Integration & Qualification
Lee and Ebrahimpour (1984)	JIT					●	●	●	●	●		●	●	●
Voss and Robinson (1987)	JIT	●			●	●	●	●	●	●		●	●	●
Flynn et al. (1995)	QM	●		●	●	●			●		●	●	●	●
Flynn et al. (1995)	JIT, TQM			●	●		●	●		●	●	●	●	●
Sakakibara et al. (1997)	JIT	●			●		●	●	●	●	●	●	●	●
Flynn et al.(1999)	WCM, QM, JIT		●		●	●		●			●	●	●	●
White et al. (1999)	JIT	●			●		●	●	●	●		●	●	●
Cua et al. (2001)	TPM, TQM, JIT	●	●		●		●	●	●	●	●	●	●	●
Ahmad et al. (2003)	JIT				●	●	●	●	●	●	●	●	●	●
Shah and Ward (2003)	LM	●	●		●			●	●	●			●	●
Challis et al. (2005)	TPM, TQM, HRM	●	●		●		●			●		●	●	●
Matsui (2007)	JIT, TQM, HRM		●	●	●		●	●	●	●	●	●	●	●
Shah and Ward (2007)	LM	●			●		●	●	●	●	●	●	●	●
Gebauer et al. (2009)	LM	●	●		●		●	●		●		●	●	●
Pettersen (2009)	LM	●		●	●	●	●	●	●	●	●		●	●
Furlan et al.(2011)	JIT, TQM, HRM		●	●	●		●	●	●	●		●	●	●
Chen and Tan (2013)	JIT	●		●			●	●	●	●	●			●
Friedli et al. (2013)	OPEX	●	●	●	●	●	●	●	●	●	●	●	●	●

As highlighted above the authors have different focuses for their analysis of the enabler performance relation. This difference leads to a certain degree of variation as regards the question of how many and which enabler dimensions are incorporated. In addition, the terminology for the same enabler characteristics varies by author. However, all outlined

focuses as well as detailed descriptions of the dimensions covered in table 13 are captured under the OPEX umbrella term (cf. chapter 2.1). Therefore, the outlined dimensions allow building a distinct understanding of the relevant OPEX enablers that need to be incorporated into the PMM.

More than two thirds of the authors stress the importance of *Process Management, Set-up Time Reduction, Pull Approach, Layout Optimization, Planning Adherence, Management Commitment & Company Culture, Employee Involvement & Continuous Improvement*, and *Functional Integration & Qualification*.

In addition, more than half of the authors focus on *Preventive Maintenance* and *Visual Management*. The dimension *Technology Assessment & Usage*, *Housekeeping*, and *Standardization & Simplification* are less often incorporated into the bundle of analyzed enabler dimensions. However, narrowing down the focus to the non-JIT focused authors in table 13 allows an appropriate evaluation of the relevance of the *Technology Assessment & Usage* dimension. Typically, this dimension is only discussed in the context of TPM, LM, and WCM. The majority of the non-JIT authors include the dimension *Technology Assessment & Usage* into the bundle of relevant enablers. Consequently, this dimension is considered in the PMM. In addition, *Housekeeping* and *Standardization & Simplification* can be seen as the fundament forming basic elements that need to be implemented before implementing the remaining enabler dimensions. Early literature emphasizes the fact that these two dimensions reinforce the impact of the other enabler dimensions (Pegels, 1984; Richey, 1996). Chen and Tan (2013) confirm the fundamental characteristic of *Housekeeping*. The authors note that several studies and practice observations prove it to be a prerequisite for implementing JIT (Z. Chen & Tan, 2013). According to Imai (2012), standardization and housekeeping are rooted in the basics of the Japanese approach to CI. Other authors agree and outline the importance of *Standardization & Simplification* as well as *Housekeeping* in the context of CI (Gupta & Jain, 2013). Consequently, next to the often-discussed dimensions *Standardization & Simplification* and *Housekeeping* are incorporated into the PMM as well.

In literature a special role is associated with the above introduced MES. The MES can be defined with three OPEX enabler dimensions: first, *Management Commitment & Company Culture*; second, *Employee Involvement & Continuous Improvement*; third, *Functional Integration & Qualification*. Independent from the authors' focus, all authors examined above include *Function Integration & Qualification* as an enabler for OPEX. Furthermore, all but one publication, listed in table 13, include *Employee Involvement & Continuous Improvement. Management Commitment & Company Culture* is included by 15 out of 18 publications. Practitioners confirm the general understanding of the role of the MES from literature. Along the iterative model development practitioners confirmed the important role of the MES as a basis.

The developed PMM for QC labs reflects the understanding in literature and practice. The MES builds the foundation of the model. The TES builds upon the MES as individual pillars representing the OPEX enabler dimensions. The TES combines two subsystems. It includes the planning- and steering-related dimensions *Set-up Time Reduction*, *Pull Approach*, *Layout Optimization*, *Planning Adherence,* and *Visual Management*. In addition, the maintenance- and quality-related dimensions *Preventive Maintenance*, *Technology*

Assessment & Usage, *Housekeeping*, *Process Management,* and *Standardization & Simplification* are included. Figure 9 depicts how the role of the MES and TES understanding is transferred into the PMM for QC labs.

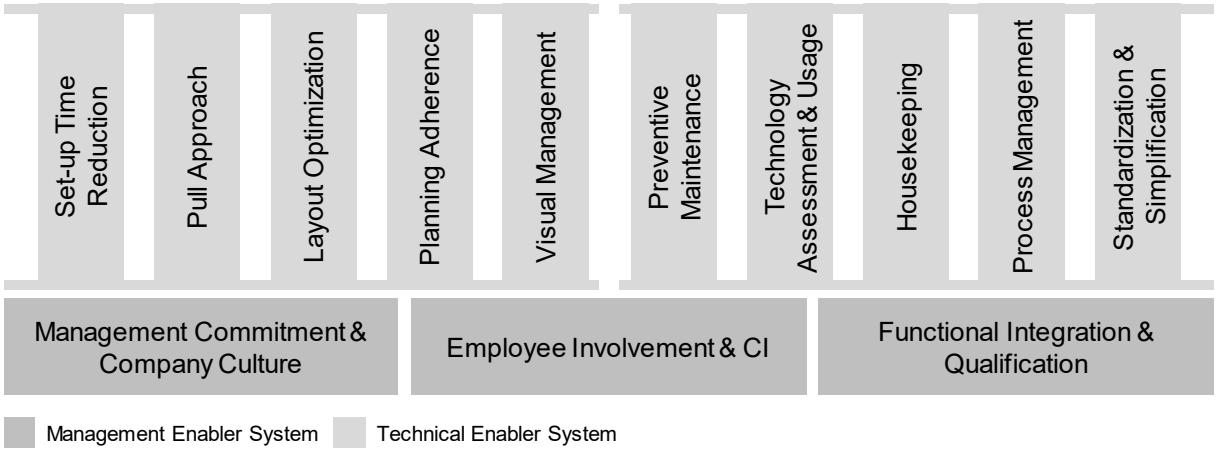

Figure 9: Enabler dimensions of the OPEX performance measurement model

3.2.3 Operating Context

Shah and Ward (2003) highlight that scholars have found mixed evidence of the impact of the implementation of enablers on organizational performance. The authors add that overlooking the operating context in many empirical studies may have caused this mixed evidence (Shah & Ward, 2003). Ahmad, Schroeder, and Sinha (2003) agree and argue with the contingency theory that a factor (e.g. performance) cannot be exceptionally good in all environments and organizational contexts.

The literature of the model development phase to design the performance dimension in chapter 3.3.1 and the enabler dimensions in chapter 3.3.2 build the basis to identify the relevant operating context factors in literature. The focus was on empirical studies in the PM context. Table 14 depicts only those scholars that address the operating context in a chronological order from early to most recent work. The majority of authors do not use specific operating context factors in their empirical investigation. While most authors provide information on the structure of the applied data basis, they do not use context factors to get a more granular result or to explain unexpected results. Therefore, the authors meet the objective to be transparent on their work and aim for generalization but potentially limited knowledge of transferability to specific operating contexts.

Table 14: Operating context factors in literature

Authors	Factors											
	Industry	Geographical Location	Technology (Age or Type)	Organizational Scale (Size)	Age of UoA	Culture	Complexity	Unionization	Capacity Utilization	Production Type	Company Ownership	Other Factors[1]
Performance Literature												
Ferdows and De Meyer (1990)		○		○								
Kim and Arnold (1996)	○	○		○								
Ward et al. (1998)	○	○		○								
Boyer and Lewis (2002)	○		○									
Flynn and Flynn (2004)	●	●				○						
Gößler and Grübner (2006)	○			○								
Behrouzi and Wong (2011)	○											
Nand, Singh, and Power (2013)	○	○		○								
Enabler Literature												
Voss and Robinson (1987)	○	○		○								
Flynn et al. (1995)	○	○		○	○		○					
Flynn et al. (1995)	○	○		○								
Sakakibara et al. (1997)	○	○										
Flynn et al.(1999)	○	○		○								
White et al. (1999)	○	○		●				○				
Cua et al. (2001)	○	○	●	●					●			
Ahmad et al. (2003)	○	○	○	○		○						
Shah and Ward (2003)	●	○		●	●			●				
Challis et al. (2005)		○		○								
Matsui (2007)	○	○										
Shah and Ward (2007)	○			○								
Gebauer et al. (2009)	○	○		●								●
Furlan et al.(2011)	○	○		●	●							
Chen and Tan (2013)	●		○	●[2]						○	○	

[1] Factors are specific to the UoA and not generalizable
[2] Authors use sales revenue per year instead of the number of employees like all other authors
● Empirical study addresses and uses factor to distinguish peers of the overall data basis in the analysis
○ Empirical study addresses factor, but it does not use the factor to distinguish peers of the overall data basis in the analysis

In their empirical study on the relation of competitive capabilities Ferdows and De Meyer (1990) indicate that the dataset is biased toward large and well performing manufacturing companies. However, the authors do not use this as distinguishing factors to test their

findings against another dataset with small and poorly performing manufacturing context. Gößler and Grübner (2006) also highlight a potential bias of their dataset including well performing companies, but the authors do not try to incorporate poorly performing companies to validate their findings.

On the contrary, Flynn and Flynn (2004) introduce environmental contingencies into their analysis of cumulative capabilities. The authors analyze whether the industry and geographical region have an impact on the pattern of cumulative capabilities of an organization. Other authors stress the importance to investigate the (internal) organizational context (Cua et al., 2001; Furlan et al., 2011; Shah & Ward, 2003; R. E. White et al., 1999). These authors argue with the contextual theory that the organizational context may have an impact on performance improvements. Shah and Ward (2003) find evidence that the organizational scale affects the implementation of enablers. This finding is in line with a previous finding by White et al. (1999). However, not all authors find empirical evidence. Cua et al. (2001) conclude that enablers allow better explanation of site performance than the operating context. Furlan et al. (2011) agree as they find no evidence for any impact of age or organizational scale.

Based on the mixed evidence of the relevance of environmental contingencies and organizational context factors for enabler implementation and performance improvements both should be considered in this research to allow robust research results related to the present unit of analysis.

3.2.4 Model Design Conclusion

In the preceding chapters the model design characteristics were described in detail. Chapter 3.2.1 focused on the performance dimensions. It concluded that the efficiency and effectiveness related performance dimensions should be considered in the PMM. Productivity and cost efficiency represent the efficiency related performance dimensions. Quality and service represent the effectiveness related performance dimensions. Chapter 3.2.2 discussed the enabler dimensions.

The enabler dimensions can be summarized in two enabler systems, i.e. the Management Enabler System (MES) and the Technical Enabler System (TES). The MES is located as a foundation to the TES within the PMM. In total, 13 different enabler dimensions are incorporated into the PMM. *Management Commitment & Company Culture*, *Employee Involvement & Continuous Improvement*, and *Functional Integration & Qualification* represent the MES. Ten enabler dimensions are linked to the TES. Half of the TES dimensions is planning- and steering-related (*Set-up Time Reduction*, *Pull Approach*, *Layout Optimization*, *Planning Adherence*, and *Visual Management*). The other half is focused on maintenance and quality (*Preventive Maintenance*, *Technology Assessment & Usage*, *Housekeeping*, *Process Management,* and *Standardization & Simplification*). Chapter 3.2.3 emphasized the relevance of the operating context.

Due to mixed evidence in literature regarding the influence of the operating context for the enabler implementation and performance improvements it is considered as a fundamental element of the PMM. Considering performance, enablers, and operating context allows the model to serve as the basis of a meaningful PMM in the context of this research. Figure 10 depicts the OPEX performance measurement model for QC labs.

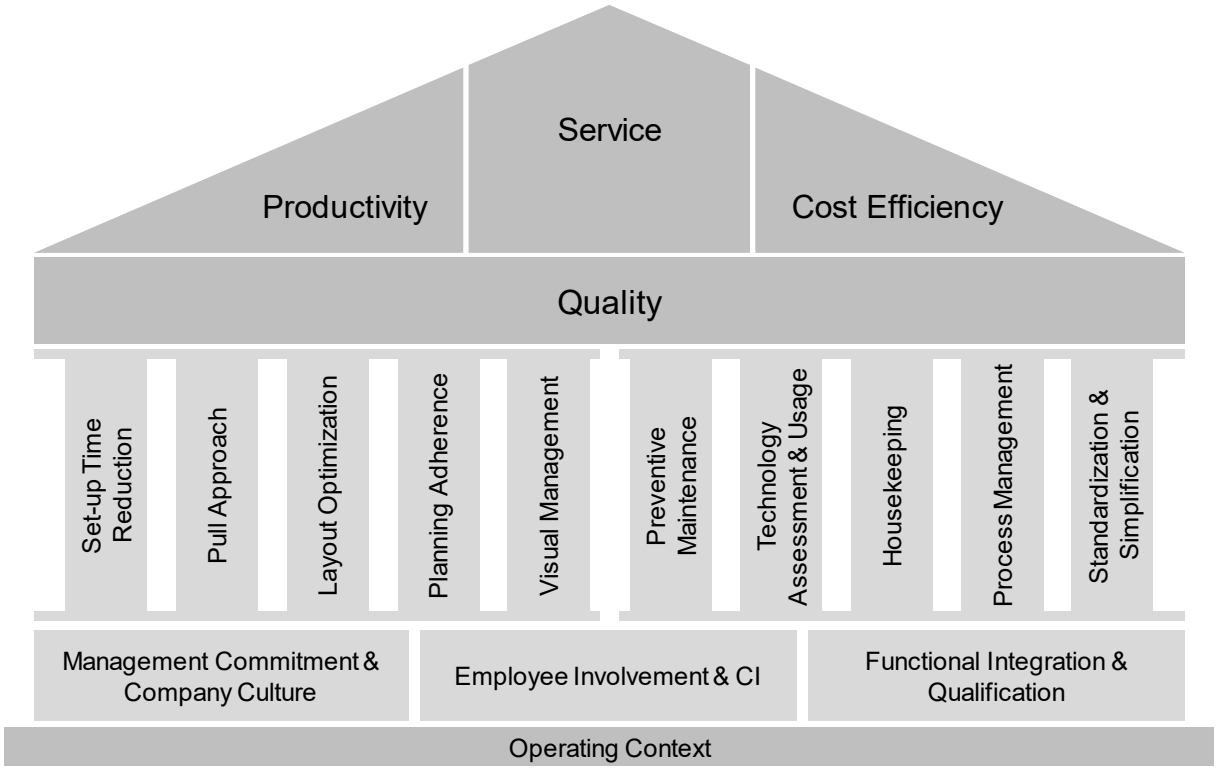

Figure 10: OPEX performance measurement model for QC labs

3.3 Model Operationalization

The following model operationalization specifies the model design (cf. chapter 3.2) to the context of this research. First, the performance operationalization outlines relevant indicators to assess productivity, quality, service, and cost efficiency performance in pharmaceutical QC labs. Second, the enabler operationalization provides details on what activities are related to the introduced enabler dimensions of the model design. Third, the context factors address the contingency-related aspects that are specific for the research context. As specific literature related to the research only covers generic approaches to OPEX in QC labs the researcher relied especially on industry experts to operationalize the performance dimensions and context factors. To ensure reliability and validity the researcher reviewed and refined the operationalization continuously during the pilot phase of the application of the PMM approach. In addition, further refinements during the later research stages helped sharpening the PMM. Triangulating the literature-based understanding of the enabler dimensions with other researchers and practitioners built the basis to operationalize the enablers for this research.

3.3.1 Performance Dimensions

The integrated PMM approach concluded with the performance dimensions productivity, quality, service, and cost efficiency (cf. chapter 3.2.1). Beischel and Smith (1991) as well as Azzone, Masella, and Bertele (1991) stress the importance of measures linked to competitive priorities for effective performance measurement. Consequently, the operationalization in this chapter depicts suitable performance measures of the research context in the four dimensions: productivity, quality, service, and cost efficiency.

Neely et al. (1997) defines several requirements for performance measures. According to the authors, a performance measure should have a clear and precise title that explains what it is measuring and is easy to understand. A performance measure should have a distinct purpose with relevance to the scope of the performance measurement framework (Neely et al., 1997). Additionally, a performance measure should be related to the business objective with the focus on improvement (Neely et al., 1997). Finally, an appropriately defined measure ensures that only aspects are measured that can be influenced. Ratios are preferred over absolute numbers (Neely et al., 1997). In the following, first, the effectiveness-related dimensions quality and service are exhibited. Thereafter, the efficiency-related dimensions productivity and cost efficiency are described.

The quality dimension is especially focused on the lab process robustness to deliver accurate and reliable test results. In total, eight different performance indicators are incorporated into the quality dimension of this research. The metric *Analytical Right First Time* allows understanding how often the QC labs delivers an analytical result right the first time without any analytical error. A high *Analytical Right First Time* contributes to a low rate of reprocessing and re-running of tests. *Customer Complaint Investigation Rate* focuses on how many complaints are handled by the QC lab disturbing the day-to-day routine. The FDA proposed quality metric *Invalidated OOS Rate* enables understanding what proportion of Out-of-Specification (OOS) results were retracted in an investigation because the root cause of the OOS was linked to measurement process of the QC lab (FDA, 2016). In contrast to the FDA proposed normalization by the total number of invalidated and confirmed OOS, the *Invalidated OOS Rate* in this research is normalized by 100,000 tests. The reason for this normalization is that the FDA proposed *Invalidated OOS Rate* is not only linked to lab process robustness, but it rather addresses an overall robustness from a quality system perspective including lab and manufacturing quality. In a dedicated workshop[22] on OPEX performance measurement in QC labs with numerous pharmaceutical companies the participants confirmed the more accurate focus of the normalization per 100,000 test to investigate lab quality for this research. The *Lab Deviation Rate* describes the number of unexplained discrepancies for the routine process. The metric is normalized by 1,000 tests. It summarizes all errors due to technical, human, or environmental factors that caused the discrepancy from the routine process in the lab. *Lab Corrective Action and Preventive Actions (CAPAs) Overdue* indicates how well the QC lab is able to keep track of its actions to adjust its processes and procedures to prevent lab deviations to occur again. The *Lab Investigation Rate* describes a formal procedure to investigate and understand the root cause of OOS results (FDA, 1993). The *Lab Investigation Rate* is normalized by 1,000 tests. *Recurring Lab Deviations* captures the lab's ability to implement measures to avoid deviations with the same root cause to occur again. The metric *Product Re-Tests due to Complaints* allows understanding how much extra-work due to external complaints about product quality exists. The aspect of product quality itself is not directly linked to the QC lab performance but rather a performance

[22] The workshop on OPEX performance measurement in QC labs was conducted at the kick-off meeting of the St. Gallen QC Lab Exchange Platform in September 2018. The workshop agenda can be found in appendix 4.

dimension of the manufacturing function. Thus, metrics related to product quality are not included in the quality dimension of this research. Table 15 provides an overview of all eight quality performance indicators and their definition.

Table 15: Quality indicators of the OPEX performance measurement model

KPI	Unit	Definition
Analytical Right First Time (A)	%	Proportion of tests without any deviation out of the total number of tests (i.e. no test repetition needed due to confirmed OOS/OOT/OOE).
Customer Complaint Investigation Rate	No./100,000 Tests	Number of customer complaints requiring a lab investigation normalized by 100,000 tests.
Invalidated OOS Rate (A)	No./100,000 Tests	Number of occurrences when the assessment of a testing OOS result does not confirm the previous OOS result, but the testing results appear to be accurate normalized by 100,000 tests.
Lab Deviation Rate	No./1,000 Tests	Number of events where an unexplained discrepancy from the routine processes occurs normalized by 1,000 tests. Lab deviations comprise all events where an error occurs due to technical, human factors, or environmental factors that cause differences from the routine processes in the lab.
Lab CAPAs Overdue	%	Proportion of CAPAs on lab deviations that went overdue out of the total number of CAPAs.
Lab Investigation Rate (A)	No./1,000 Tests	Number of lab investigations in the reporting period normalized by 1,000 tests. A lab investigation is undertaken for deviation events to understand the root cause of the OOS test result).
Recurring Lab Deviations	%	Proportion of lab deviations that have already occurred before out of the total number of lab deviations. A deviation is recurring when a second deviation with the same root cause occurs within a one-year rolling period in the same process/system.
Product Re-Tests due to Complaints	%	Proportion of product re-tests (due to complaints by the customer) out of the total number of tests.

(A) Metric is aggregated from different testing types performed in the lab (drug substance, intermediate, in-process-control, raw material, stability, drug product, packaged product, microbial environmental, microbial product, component & packaging material)

According to White (1996), there is a consensus that service performance (i.e. delivery reliability) should be measured with adherence indicators. Consequently, the service dimension is focused on two adherence-related metrics instead of absolute time-span-related speed measures. The metric *Adherence to Lead Time* allows understanding the timeliness of the individual testing batches. The adherence is measured against the individual testing schedule for each batch. *Adherence to Schedule* enables a better understanding if a QC lab achieves the release of all testing batches as planned according to the overall lab schedule. Comparing the performance of both metrics unveils if a QC lab struggles to meet the individual testing lead time but is still able to catch up to meet the overall schedule. In addition, the practitioners argued that metrics that are focused on an absolute time-span (e.g. lead time, cycle time, and release time) are not always comparable between QC labs with a different level of portfolio complexity due to their

operating context. Table 16 provides an overview of the two service performance indicators and their definition.

Table 16: Service indicators of the OPEX performance measurement model

KPI	Unit	Definition
Adherence to Lead Time (A)	%	Proportion of individual testing batches that were tested on-time according to the initial testing schedule.
Adherence to Schedule (A)	%	Proportion of all testing batches that together were finished as planned according to the overall lab testing schedule.

(A) Metric is aggregated from different testing types performed in the lab (drug substance, intermediate, in-process-control, raw material, stability, drug product, packaged product, microbial environmental, microbial product, component & packaging material)

The productivity dimension combines three metrics that allow a better understanding of the resource consumption to meet the target volume that is processed and tested in the QC lab. The number of *Handled Samples per QC FTE* is focused on the resources that are needed to accompany all activities related to sample management (e.g. for shipment or relabeling) in the QC lab. For this metric all samples are counted independent from whether these samples are tested or only processed through the QC lab. The metric *Batches processed per QC FTE* incorporates all batches that are processed and released by the QC lab normalized by the total number of direct and indirect QC FTEs. *Test per Direct QC FTE* addresses the value-adding productivity of the analysts on their task to test sample items as part of the release protocol. Table 17 provides an overview of the three productivity performance indicators and their definition.

Table 17: Productivity indicators of the OPEX performance measurement model

KPI	Unit	Definition
Handled Samples / QC FTE	No./FTE	Total number of samples managed (not necessarily tested but including e.g. sample splitting for shipment) normalized by the total number of direct and indirect QC FTEs.
Batches processed / QC FTE (A)	No./FTE	Total number of batches processed independent from where these batches were produced and if batches are actually tested normalized by the total number of direct and indirect QC FTEs.
Tests / Direct QC FTE (B)	No./FTE	Number of individual sample items (test items) analyzed normalized by the total number of direct QC FTEs.

(A) Metric is aggregated from different type of batches processed in the lab (drug substance, intermediate, raw material, stability, drug product, packaged product, component & packaging material)
(B) Metric is aggregated from different testing types performed in the lab (drug substance, intermediate, in-process-control, raw material, stability, drug product, packaged product, microbial environmental, microbial product, component & packaging material)

The cost efficiency dimension encompasses two metrics that normalize the QC cost in different ways. In the labor-intensive QC lab the metric *QC Cost per QC FTE* helps to understand the labor efficiency. *QC Cost per Test* adds another perspective of efficiency

linking the total of fixed and variable cost with the volume of tests. Table 18 provides an overview of the two cost efficiency indicators and their definition.

Table 18: Cost efficiency indicators of the OPEX performance measurement model

KPI	Unit	Definition
QC Cost / QC FTE	Currency/FTE	Total QC cost normalized by the total number of direct and indirect QC FTEs. Total QC cost includes labor, material, equipment, maintenance, depreciation, service, and other QC related cost.
QC Cost / Test (A)	Currency/Test	Total QC cost normalized by the total number of tests. Total QC cost includes labor, material, equipment, maintenance, depreciation, service, and other QC related cost.

(A) Metric is aggregated from different testing types performed in the lab (drug substance, intermediate, in-process-control, raw material, stability, drug product, packaged product, microbial environmental, microbial product, component & packaging material)

To conclude, the above outlined indicators related to productivity, quality, service and cost efficiency comply with Neely et al. (1997) requirements of performance measures. The indicators have a clear and precise title, a distinct purpose, a link to the business objective and improvement, and an appropriate definition that allows measuring what can be influenced by a QC lab.

3.3.2 Enabler Dimensions

This chapter exhibits the scope of the enabler dimension of the PPM. In the following paragraphs, each enabler dimension outlined in chapter 3.2.2 is described in detail. The operationalization of the enabler dimensions bases on the existing available scales from the St. Gallen OPEX enablers assessment[23]. During the operationalization the applicability of the individual enablers for the research context was analyzed together with the co-developing pharmaceutical company. To meet the requirements of the research context some enablers were reworded. Among others Nemetz (1990), Ward, McCreery, Ritzman, and Sharma (1998) as well as Flynn, Schroeder, and Flynn (1999) emphasize the value of subjective measures for performance measurement. The available scales used for this research represent subjective measures. Appendix 6 depicts the whole data collection template including all enabler-related assessment questions and possible answers.

Independent from their focus on TPM, TQM, JIT, LM, or QM many authors include *Preventive Maintenance* as an enabler dimension (cf. chapter 3.2.2). To avoid equipment breakdowns, White et al. (1999) rely on routine maintenance with actively involved operators. The authors emphasize to establish and to continuously refine a formal maintenance program (R. E. White et al., 1999). Cua et al. (2001) also stress the operator to be crucial in the *Preventive Maintenance* activities. The routine maintenance allows an organization to achieve higher equipment availability and to reduce failure (Z. Chen & Tan,

[23] The St. Gallen OPEX enablers assessment is part of the St. Gallen OPEX Benchmarking focused on the manufacturing function. The benchmarking was initiated in 2004 and updated in 2016. Among other updates the enabler assessment was enhanced by adding detailed implementation descriptions to each enabler scale.

2013; Shah & Ward, 2007). Maintenance optimization techniques help to continuously improve the maturity of the organization's maintenance activities (Shah & Ward, 2003). Additionally, Friedli, Lembke, et al. (2013) highlight the degree to which an organization identifies all bottleneck equipment and supplies it with additional spare parts. The authors also exhibit maintenance as a root to increase quality and planning adherence (Friedli, Lembke, et al., 2013).

Constant effort regarding *Technology Assessment & Usage* allows companies to improve continuously through effective use of existing and new technology (Cua et al., 2001; Flynn et al., 1999). Investing into technology enables an organization to improve maintenance and process capabilities (Flynn et al., 1999). Cua et al. (2001) and Friedli, Lembke, et al. (2013) associate constant screening of the market for leading edge technology as part of this dimension. Apart from the application of new vendor equipment, literature emphasizes the development of proprietary equipment to gain a competitive advantage (Cua et al., 2001; Flynn et al., 1999; Furlan et al., 2011).

The dimension *Housekeeping* follows the Japanese 5S-philosophy[24] (Z. Chen & Tan, 2013). Flynn, Schroeder, et al. (1995) and Matsui (2007) exhibit cleanliness of the workplace as the core principal of *Housekeeping*. Chen and Tan (2013) agree and add orderliness of the shop floor to this dimension. An organization that emphasizes putting all tools and work material into a predefined place follows an orderly approach of *Housekeeping* (Friedli, Lembke, et al., 2013; Furlan et al., 2011).

Process Management activities help to reduce the variation of the processes and consequently to operate at a lower defect rate (Flynn, Schroeder, et al., 1995). Many authors highlight statistical process control as a fundamental aspect of successful *Process Management* (Ahmad et al., 2003; Cua et al., 2001; Friedli, Lembke, et al., 2013; Furlan et al., 2011; Shah & Ward, 2007). Well documented processes represent the basis of *Process Management* (Friedli, Lembke, et al., 2013; Matsui, 2007). Shah and Ward (2007) stress the need to improve process capabilities before introducing a new product. Friedli, Lembke, et al. (2013) suggest monitoring process measures to identify the process performance and to assign dedicated process owners for planning, managing, and improving processes. In addition, the authors emphasize standardized tools for root cause analysis as part of *Process Management* (Friedli, Lembke, et al., 2013).

The dimension *Standardization & Simplification* targets the improvement of three aspects: processes, equipment, and products (Friedli, Lembke, et al., 2013; S. M. Lee & Ebrahimpour, 1984; Voss & Robinson, 1987). Standardized processes can be achieved through documenting operating procedures (Friedli, Lembke, et al., 2013). Standardized equipment and spare parts drive an organization to achieve high equipment uptime and to lower cost (Friedli, Lembke, et al., 2013). Product simplification can be achieved by optimizing the product range and manufacturing techniques (Voss & Robinson, 1987). In

[24] 5S represents the five Japanese words „seiri", „seiton", „seiso", „seiketsu", and „shitsuke". "Seiri" stands for sorting and separating needed and unneeded items. "Seiton" means straightening focused on keeping everything in a defined place for easy access and storage. "Seiso" represents sweeping and targets a clean work environment. "Seiketsu" means standardization of how to keep cleanliness. "Shitsuke" is focused on self-discipline and 5S-activities as part of the everyday work. (Z. Chen & Tan, 2013)

addition, the emphasis on *Standardization & Simplification* allows reducing the numerous functional descriptions for the training of new employees (Friedli, Lembke, et al., 2013).

Set-up Time Reduction is an enabler dimension that many authors associate with JIT (Friedli, Lembke, et al., 2013; S. M. Lee & Ebrahimpour, 1984; Matsui, 2007; Sakakibara et al., 1997). Optimizing and practicing set-ups allow an organization to reduce changeover time (Shah & Ward, 2007), to smoothen their operations (S. M. Lee & Ebrahimpour, 1984), to lower buffer inventories (R. E. White et al., 1999) and to reduce batch size (Voss & Robinson, 1987). Consequently, a reduced set-up time may also lead to more flexibility of the operations (Furlan et al., 2011). Higher equipment uptime can be achieved by appropriate scheduling of the set-ups (Friedli, Lembke, et al., 2013).

The *Pull Approach* originates in a basic JIT principle that aims at achieving demand-oriented material flow (R. E. White et al., 1999). Shah and Ward (2007) stress that the *Pull Approach* allows linking the operations speed to the customer demand. Many authors associate Kanban with the dimension *Pull Approach* (S. M. Lee & Ebrahimpour, 1984; Voss & Robinson, 1987; R. E. White et al., 1999). Kanban is a pull system to trigger material movement and orders on the shop floor (Flynn, Sakakibara, et al., 1995; Voss & Robinson, 1987). It allows companies resolving process bottlenecks and to reduce in-process inventory (S. M. Lee & Ebrahimpour, 1984). The forecast accuracy is fundamental for a *Pull Approach* to work effectively (Friedli, Lembke, et al., 2013).

To smoothen workflow Lee and Ebrahimpour (1984) refer to *Layout Optimization* as a tool to achieve a supportive configuration of the shop floor. Shah and Ward (2007) agree and suggest that grouping of equipment is a suitable approach to improve flow. Cua et al. (2001) add that grouped equipment drives low inventories and a high throughput rate. Grouping of products with similar requirements enables an organization to reduce set-up time and transportation time (Friedli, Lembke, et al., 2013). *Layout Optimization* allows maximizing the level of value-adding time and minimizing the level of non-value-adding time (Voss & Robinson, 1987).

Planning Adherence, also referred to as schedule adherence, addresses the objective to meet the planned production volume for the day (Ahmad et al., 2003; Cua et al., 2001; Matsui, 2007). A stabilized workload supports a smooth workflow matching the production volume with the demand (R. E. White et al., 1999). Friedli, Lembke, et al. (2013) emphasize to improve *Planning Adherence* by eliminating the root cause that leads to variance of the schedule. Additionally, the authors stress that flexible working shift models enable *Planning Adherence* by adjusting available capacity to demand (Friedli, Lembke, et al., 2013).

Visual Management gives feedback on process and performance to employees on the shop floor (Flynn, Sakakibara, et al., 1995). According to Shah and Ward (2007), feedback charts should be posted on the shop floor. Friedli, Lembke, et al. (2013) agree and add that performance objectives as well as current performance should be visualized. Furthermore, the feedback should be provided in a timely manner to derive effective measures (Ahmad et al., 2003; Flynn, Schroeder, et al., 1995).

Management Commitment & Company Culture describes a relatively broad field of individual and organizational behavior toward CI. Management encouragement of their employees embedding a culture of trust and involvement is one of the fundamental aspects

of this dimension (Challis et al., 2005; Cua et al., 2001; Furlan et al., 2011). Aligning corporate and functional strategy enables the organization to carry out their corporate vision throughout the organization (Ahmad et al., 2003; Challis et al., 2005). Transparency in top-down and bottom-up communication supports the acceptance of CI by all employees (Challis et al., 2005; Furlan et al., 2011). Furthermore, working together in teams toward common goals rather than encouraging competition among functions and individuals is valued as a core cultural aspect of CI (Friedli, Lembke, et al., 2013; Furlan et al., 2011). Additionally, long-term thinking and rewarding of CI should replace short-term thinking focusing on short-term gains (Flynn, Schroeder, et al., 1995; S. M. Lee & Ebrahimpour, 1984). Personal involvement of managers in improvement projects and regular visits on the shop floor foster the team effort toward CI (Ahmad et al., 2003; Cua et al., 2001; Friedli, Lembke, et al., 2013).

The dimension *Employee Involvement & Continuous Improvement* combines two key aspects of OPEX capabilities. Voss and Robinson (1987) outline that CI is not a one-time effort but needs constant support from all employees of an organization to be successful. Cua et al. (2001) stress that organizations transfer responsibility to actively involved employees encouraging them to work on their own problem solving. Shah and Ward (2003) agree and emphasize self-directed work teams. Authorizing employees to have certain decision making power by themselves and asking them to make decision recommendations to the management fosters the bond between the different levels of an organization working on the common goal of CI (R. E. White et al., 1999). Employees with improved skills in problem solving, judgement of new situations and work coordination add concrete value to an organization that may lead to economic benefits (Flynn, Sakakibara, et al., 1995). Furthermore, employee suggestion programs drive CI (Friedli, Lembke, et al., 2013; Matsui, 2007).

Functional Integration & Qualification outlines the necessity for an organization that its employees are well equipped with skills their job requires and that departments work together on the common goal of CI. Many authors highlight cross-training as a core element of this dimension (Ahmad et al., 2003; Flynn et al., 1999; Shah & Ward, 2003; Voss & Robinson, 1987). Consequently, an organization needs to develop a suitable employee qualification program that is able to enhance the capabilities of each individual (Flynn et al., 1999; Sakakibara et al., 1997). Job rotation with cross-trained employees allows increasing flexibility of the operations (Shah & Ward, 2003). Regular trainings help to sustain the development toward minimizing the waste of human resources (Furlan et al., 2011).

3.3.3 Environmental Contingencies and Organizational Context

Some studies have found evidence that the operating context of a unit of analysis may impact its performance (Flynn & Flynn, 2004; Shah & Ward, 2003). In addition, some scholars claim that the success of implementing enablers differs depending on the organizational context (Shah & Ward, 2003; R. E. White et al., 1999). This chapter describes the relevant environmental contingencies and (internal) organizational context factors of this research that build the frame to analyze different QC labs using the PMM.

In total, 17 different factors can be used to distinguish the environmental and organizational characteristics of QC labs. These factors represent the peer-group filter characteristics identified during individual benchmarking projects[25] with practitioners who intended to compare their QC lab OPEX performance with others. All altering factors over the 12-month reporting period (calendar year or financial year) were normalized. Table 19 depicts the context factors and their characteristics.

Table 19: Context factors for peer-group building

Category	Context factor	Characteristic
EC	Country	e.g. Switzerland
EC	Region	Africa, Asia, Europe, North America, Oceania, Middle & South America, Middle East
EC	Cost Location	High cost, low cost country
OC	Drug Substance Type	Chemical and/or biological drug substance tested
OC	Drug Product Type	Solids and/or creams, suppositories, sterile liquids, non-sterile liquids, patches, inhalers
OC	No. of final Drug Product Types	Count of final drug product types tested. Different strength and markets of the same product are counted as multiple product types.
OC	Multi-Purpose	Labs that test different drug product types (e.g. solids & sterile liquids) are counted as multi-purpose labs. If a lab does both drug substances chemicals and biologics it is also considered as a multi-purpose lab. In addition, labs are counted as multi-purpose labs if the lab is responsible to assist R&D next to routine release testing. When an external customers is allowed to use capacity of the lab (e.g. in case of peak loads at the customers' labs) the lab should also be considered as a multi-purpose lab.
OC	Centralization	Labs that are responsible to conduct testing for multiple sites of the internal or external network are considered as centralized. If a lab is only conducting test for the site where it is located it is a decentralized lab.
OC	Degree of Centralization	Degree to which a lab does testing for other labs within or outside the organization.
OC	Total Site FTEs	Total number of site FTEs
OC	Total QC FTEs	Total number of direct and indirect (permanent and temporary) QC FTEs
OC	Total No. of Batches	Total number of batches processed in the lab independent from where these batches were produced and if batches were actually tested
OC	Total No. of Tests	Total number of tests performed. The number of tests equals to sample items (test items) analyzed.
OC	Age of Instruments	Proportion of instruments that are less than three years old, between three and five years old, between five and ten years old, and older than ten years
OC	Age of Methods	Proportion of testing methods that are less than three years old, between three and five years old, between five and ten years old, and older than ten years

[25] A detailed description of benchmarking process can be found in chapter 4.1.3.

Category	Context factor	Characteristic
OC	Automation	Proportion of instruments that are manually operated (supervision at any time), operated with IT-support (temporary supervision), and fully automated (without supervision)
EC	Regulatory Approval	Labs that have one or more regulatory approval by health authorities (e.g. FDA) or organizations (e.g. World Health Organization WHO) are counted as regulatory approved. Labs that do not need to meet Good Manufacturing Practice regulations are considered as not regulatory approved.

EC: Environmental contingency factor
OC: Organizational context factor

3.4 Propositions and Hypotheses

This chapter elaborates the propositions and hypotheses for the subsequent analysis of the research. The propositions and hypotheses are derived directly from the developed PMM in chapter 3.2 and its operationalization in chapter 3.3. This chapter concludes with an outline of the research framework. The framework visualizes all propositions and hypotheses for the quantitative analysis of this research.

Following Ferdows' and De Meyer's (1990) cumulative approach to competitive priorities efficiency builds on effectiveness. Thus, effectiveness improvements are a prerequisite for efficiency improvements that can be observed over time (cf. chapter 2.2.2). Based on this understanding, the propositions and hypotheses of this research are linked to QC lab effectiveness performance. It serves as the basis of overall QC lab performance. The available primary data for this research is time-centric data that was collected at a certain point in time (cf. chapter 4.1). Scholars argue that time-centric data does not allow statements on the sequence of two aspects in time but statements on the supportive relation of the two aspects (Gößler & Grübner, 2006). Linking the cumulative approach of Ferdows and De Meyer (1990), the argumentation of Gößler and Grübner (2006) and the primary data of this research QC lab effectiveness is deemed to be a reasonable QC lab performance measure for this research. Gathering the same data again at a future point in time of about three to five years from this research will allow an in-depth analysis of the relation of QC lab effectiveness and efficiency. The focus on QC lab effectiveness performance is supported by feedback from the pharmaceutical industry (ITEM-HSG, 2018b). While 94 % of the QC Lab Exchange Platform participating companies use QC lab effectiveness to measure performance, only 28 % also focus on QC lab efficiency (ITEM-HSG, 2018b).

The following paragraphs depict the research propositions related to the operating context of the QC lab. Chapter 3.2.3 has shown that the operating context of a unit-of-analysis plays an important role for its performance. Many authors agree that the operating context may affect performance and how successful enablers are implemented (cf. chapter 3.3.3). Shah and Ward (2003) stress that the organizational context has been neglected by scholars in the past. Swink and Way (1995) emphasize environmental contingencies for future research. Addressing the demand to better understand the contingencies of the analyzed unit of analysis, this research examines the impact of the operating context of QC labs on their performance. The propositions below summarize the 17 context factors

of QC labs that are described in chapter 3.3.3. All 17 context factors can be summarized in seven distinct categories.
The proposition P1 combines all these seven categories. It addresses the question whether QC labs from a different *Geographical Locations* with a different *Portfolio Complexity*, different *Test Allocation Strategy*, different *Organizational Scale*, different *Economy of Scale*, and different *Technology & Innovation* structure show differing QC lab effectiveness results. In addition, the complexity driven by the *Regulatory Approval* may have an impact on differing QC lab effectiveness.

P1: The operating context of a QC lab has no impact on the QC lab effectiveness.

Each proposition, P2 to P8, incorporates only one aspect of the seven identified categories of the QC lab operating context. Flynn and Flynn (2004) stress countries and regions as potential moderators for the manufacturing site performance. Therefore, the proposition P2 deals with the *Geographical Location* of the QC lab. It combines the three context factors: country, region, and cost location.

P2: The geographical location of the QC lab has no impact on the QC lab effectiveness.

Some practitioners stress the importance to distinguish portfolio complexity for performance measurement in QC labs (Braun & Lehmann, 2018). The proposition P3 analyzes the impact of the QC lab *Portfolio Complexity* on QC lab effectiveness. It examines whether the drug substance type, drug product type, or the number of final drug product types tested lead to differing QC lab effectiveness performance.

P3: The portfolio complexity of the QC lab has no impact on the QC lab effectiveness.

The proposition P4 focuses on the *Test Allocation Strategy*. It discusses the impact of centralization and the degree of centralization on QC lab effectiveness.

P4: The test allocation strategy of the QC lab has no impact on the QC lab effectiveness.

Shah and Ward (2003) propose that large manufacturers have implemented operational excellence enablers more often. Therefore, the authors indirectly link the organizational scale of the manufacturer with performance. Other authors anticipate the same relation and reason excluding datasets linked to small manufacturers in their empirical studies (Flynn, Sakakibara, et al., 1995; Flynn, Schroeder, et al., 1995; J. S. Kim & Arnold, 1996). This research replicates *Organizational Scale* as a potentially decisive operating context factor in a new unit of analysis. The proposition P5 studies the relation between QC lab effectiveness and the *Organizational Scale* of the QC lab and of the site where is located. For this proposition *Organizational Scale* refers to the number of FTEs.

P5: The organizational scale of the QC lab and site has no impact on the QC lab effectiveness.

In proposition P6 the *Economy of Scale* and its impact on QC lab effectiveness is analyzed. It examines the volume of batches processed through the QC lab independent from whether these batches are tested or other activities are performed. In addition, this proposition investigates whether there is an impact of the number of tests performed in the QC lab on QC lab effectiveness.

P6: The economy of scale of the QC lab has no impact on the QC lab effectiveness.

Some scholars have discussed the relation of technology and performance (Ahmad et al., 2003; Z. Chen & Tan, 2013; Cua et al., 2001). Cua et al. (2001) investigate the impact of age of technology on the link between enablers and manufacturing performance. The proposition P7 studies the relation of technology and QC lab effectiveness. The category technology combines the age of instruments and the level of automation as well as the age of methods that specify the testing procedure.

P7: The technology and innovation of the QC lab has no impact on the QC lab effectiveness.

Practitioners often mention the burden that health authorities put on their business (Friedli, Köhler, Buess, Basu, & Calnan, 2017). Consequently, the proposition P8 deals with the *Regulatory Approval* by health authorities or organizations and its impact on QC lab effectiveness.

P8: The regulatory approval of the QC lab has no impact on the QC lab effectiveness.

Figure 11 depicts an overview of the unknown relation between the operating context and QC lab effectiveness that is addressed with the propositions of this research.

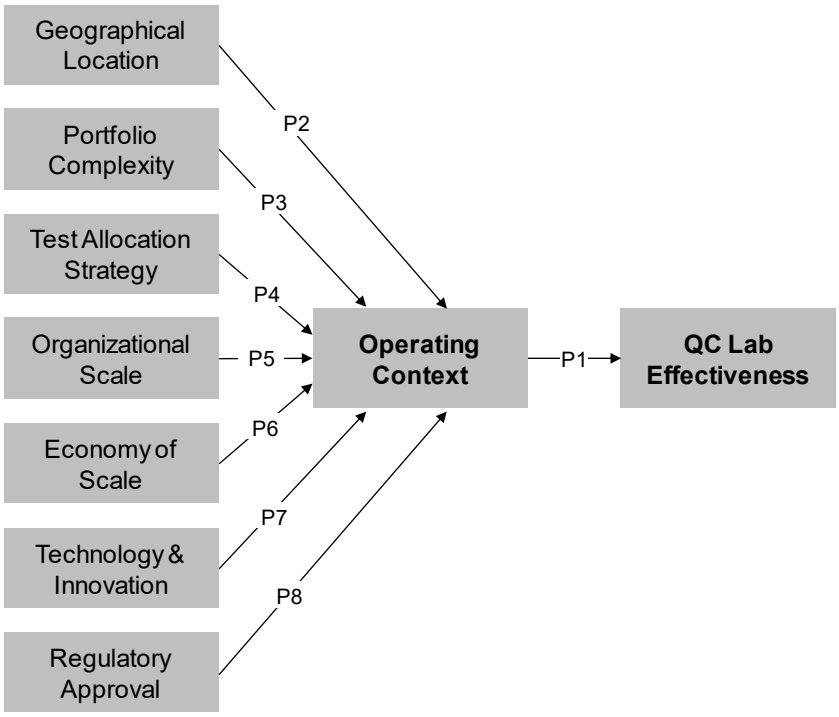

Figure 11: Research framework part I – propositions

The following paragraphs discuss the hypotheses of this research. The hypotheses are linked to QC lab effectiveness and the implementation of the enabler systems. QC Lab Effectiveness High Performers (QCHPs) are defined as a group of top performing QC labs. The group includes all labs that belong to QC labs with an above median QC lab effectiveness performance[26]. The below median performing QC labs constitute the QC Lab Effectiveness Low Performers (QCLPs). Hypothesis H1 aims at identifying whether QC lab effectiveness performance allows a meaningful distinction of QCHPs and QCLPs. The objective of hypotheses H1a and H1b is to understand the differences between QCHPs and QCLPs regarding the composition of QC lab effectiveness performance. H1a investigates if QCHPs have a significantly better quality performance. H1b analyzes if QCHPs have a significantly better service performance. Hereinafter, QC lab effectiveness performance is referred to QC lab effectiveness.

H1: QC lab effectiveness high performers do not have a significantly higher QC lab effectiveness compared to QC lab effectiveness low performers.

H1a: QC lab effectiveness high performers do not have a significantly higher quality performance compared to QC lab effectiveness low performers.

H1b: QC lab effectiveness high performers do not have a significantly higher service performance compared to QC lab effectiveness low performers.

[26] The QC lab effectiveness performance is a combination of the effectiveness performance dimensions quality and service of the PMM. The definition of QC lab effectiveness and its calculation are elaborated in chapter 4.1.5.

Flynn et al. (1995) argue that top-management support builds the basis of all other operational excellence enabler dimensions. The authors stress that a long-term oriented encouraging management drives the workforce and is an integral part of the overall system (Flynn, Schroeder, et al., 1995). Hypothesis H2a relates to the impact of the Management Enabler System (MES). It analyzes whether the MES positively correlates with the Technical Enabler System (TES). Hypothesis H2b aims at identifying whether one dimension of the MES contributes more than another dimension. It is focused on the three dimensions: *Management Commitment & Company Culture* (1), *Employee Involvement & Continuous Improvement* (2), and *Function Integration & Qualification* (3).

> *H2a: The implementation of the management enabler system does not have a positive impact on the implementation of the technical enabler system.*

> *H2b: The implementation of all three individual dimensions of the management enabler system does not have a positive impact on the implementation of the technical enabler system.*

Hypothesis H3 addresses the TES as an essential aspect to achieve QC lab effectiveness. More than two thirds of the analyzed authors in chapter 3.2.2 include eight of the ten dimensions of the TES. Cua et al. (2001) include all commonly used technical enabler systems TPM, TQM, and JIT into their analysis between technical enablers and operational performance. Samson and Terziovski (1999) highlight technical enablers specifically focused on quality, planning, and steering to drive effectiveness (quality performance). All authors mentioned above agree on having a strong focus on the TES as a basis of performance.

> *H3: The implementation of the technical enabler system does not have a positive impact on the QC lab effectiveness.*

In literature and practice the MES is often seen as the foundation for operational performance (cf. chapter 3.2.2). The MES builds the fundament of the PMM for QC labs (cf. chapter 3.2.2). Hypothesis H4 reflects the special role of the MES. The aim of this hypothesis is to identify whether the MES is positively related to the QC lab effectiveness.

> *H4: The implementation of the management enabler system does not have a positive impact on the QC lab effectiveness.*

The socio-technical system theory argues that the joint optimization of social and technical enablers drives performance (Cua et al., 2001). According to Cua et al. (2006), technical and social enablers should always be implemented systematically as part of an overall program. Hypothesis H5 combines hypothesis H2 and hypothesis H4 following the socio-technical system theory.

H5: The implementation of the management enabler system and the technical enabler system does not have a positive impact on the QC lab effectiveness.

Hypotheses H6a and H6b follow Meyer's, Tsui's, and Hinings' (1993) configurational approach to organizations. The authors define configurations as "any multidimensional constellation of conceptually distinct characteristics that commonly occur together" (Meyer et al., 1993, p. 1175). In the context of this research the enablers represent these distinct characteristics. Shah and Ward (2007) as well as Ahmad et al. (2003) link the configurational approach to operational excellence enablers. The authors stress that operational excellence enablers represent configurations that are closely tied together. The aim of this hypothesis is to identify whether the average implementation of all enabler dimensions for QCHPs is significantly higher compared to QCLPs (H6a). In addition, the objective is to determine if an integrated bundling effect of enabler dimensions can be observed for QCHPs (H6b). The integrated bundling effect matches the configurations definition of the configurational theory outlined above.

H6a: The QC lab effectiveness high performers do not have a significantly higher average implementation of all system enabler dimensions compared to QC lab effectiveness low performers.

H6b: The QC lab effectiveness high performers do not have a significantly higher integrated implementation of all system enabler dimensions compared to QC lab effectiveness low performers.

Figure 12 depicts an overview of the unknown relations among the performance dimensions and with the enabler systems that are addressed with the hypotheses of this research.

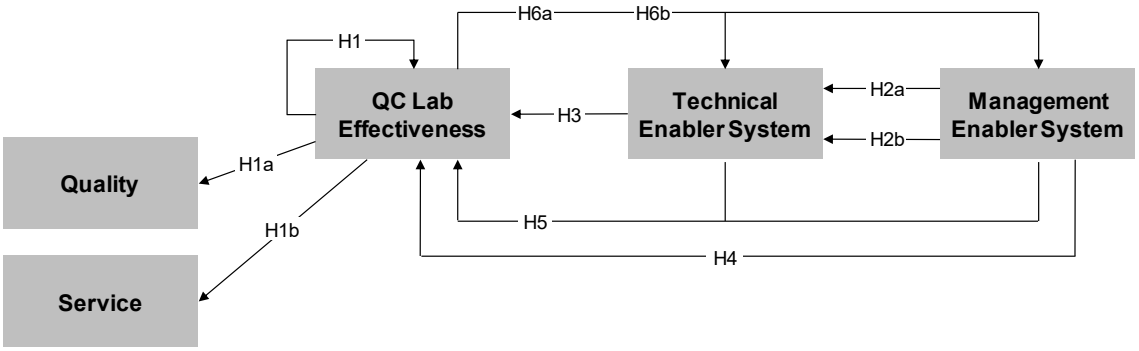

Figure 12: Research framework part II – hypotheses

Figure 13 combines all propositions and hypotheses of this research in one overall research framework. It shows an overview of the unknown relations among performance, enabler, and operating context that are addressed with the propositions and hypotheses of this research. The framework serves as the basis of the quantitative analysis that follows in the subsequent chapter.

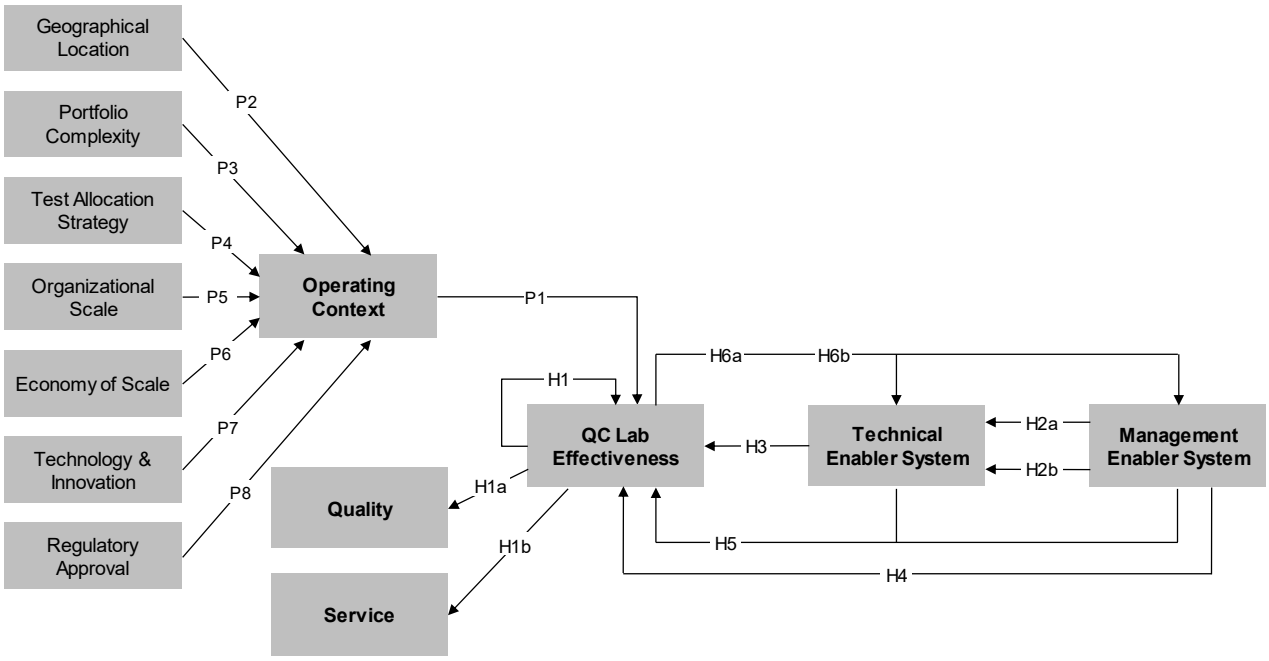

Figure 13: Research framework

4 Relation of Performance Measurement Model Dimensions

This chapter is focused on the quantitative analysis related to the propositions and hypotheses of the previous chapter 3.4. First, in chapter 4.1 an overview of the data basis, the gathering process, and definitions is provided. Thereafter, chapter 4.2 and chapter 4.3 focus on the quantitative analysis of the operating context, enabler system implementation, and QC lab effectiveness. The chapter closes with a summary of the findings in chapter 4.4.

4.1 Methods

This chapter depicts the primary data basis of this research. First, the development of the data collection template is elaborated. Second, the data collection template is described, followed by the data collection process. Among other aspects, both chapters focus on how high data quality was ensured for this research. Third, an overview of the environmental contingencies and the organizational context of the QC labs of this research is provided. Thereafter, QC Lab Effectiveness High Performers (QCHPs) that are used in the subsequent analysis are introduced.

4.1.1 Instrument Development Process

At the beginning of 2016 and in preparation for the quarterly meetings of the St. Gallen OPEX Research Group[27] the University of St. Gallen conducted a survey to gather input from the group's participants. The survey intended to gather feedback on the exchange topics with the highest individual priority for all senior executive participants of the ten participating companies in 2016. The objective was to identify the OPEX exchange topics that have the highest common priority among the senior executives.

The topic OPEX in QC labs was determined as one of these highly prioritized topics (ITEM-HSG, 2016a). During the kick-off meeting in March 2016 seven out of eight present companies contributed with their relevant experience regarding OPEX in QC labs and elaborated on past initiatives in this area. Table 20 provides an overview of all contributing companies. The companies raised open questions to the other OPEX Research Group participants in the area of OPEX in QC labs. PharmaCo I stressed their current challenge to compare QC labs at different sites to each other. The company struggled with the differing operating context. In addition, the company defined a set of performance indicators but did not have transparency between their sites. The company did not see any improvements based on the selected indicators. PharmaCo J was specifically interested in performance indicators and the design of the other company's performance measurement approach. PharmaCo G questioned the unidimensional QC lab performance

[27] The St. Gallen OPEX Research Group is an event series organized by the University of St. Gallen with four two-day meetings each year. The group was launched in 2014. From 2016 to 2018 between nine and eleven pharmaceutical companies participated each year to discuss industry- and research-topics of OPEX that they have identified as important to the industry. The participants are senior executives with many years of experience in the field of OPEX in the pharmaceutical industry. An overview of the participating companies is provided in appendix 2.

measurement focused on compliance[28]. The company stressed the industry's narrow compliance-focused performance definition for QC labs that should move to a compliance- and business-focused QC lab performance. PharmaCo E and PharmaCo D were especially interested to design a performance measurement tool and to learn which enablers drive success. PharmaCo H established a company-wide tool to collect data and compare their QC labs. However, the company specifically asked for a tool to do an industry-wide comparison as they saw the same problems in different labs but different solutions. The above outlined company focus areas for OPEX in QC were consolidated and taken as input for the second OPEX Research Group meeting in June 2016.
Table 20 depicts details on the pharmaceutical companies that contributed to the instrument development. The column main focus outlines the origin of the business value creation. Some of the companies in table 20 categorized as pharmaceutical companies also have business units focusing on biopharmaceuticals or biosimilar.

Table 20: Pharmaceutical companies that contributed to the instrument development

Company	Origin	Main Focus	Employees (,000)[1]	Revenue [USD][1]
PharmaCo A	US	Biopharmaceuticals	10 to 20	20 to 30 bn
PharmaCo B	DE	Pharmaceuticals	90 to 100	30 to 40 bn
PharmaCo C	IT	Machine Supplier	5 to 10	1 to 5 bn
PharmaCo D	CH	Pharmaceuticals	120 to130	40 to 50 bn
PharmaCo E	FI	Pharmaceuticals	Below 5	Below 5 bn
PharmaCo F	US	Biopharmaceuticals	90 to 100	50 to 60 bn
PharmaCo G	CH	Biopharmaceuticals	90 to 100	50 to 60 bn
PharmaCo H	FR	Pharmaceuticals	100 to 110	40 to 50 bn
PharmaCo I	CH	Pharmaceuticals	Below 5	Below 1 bn
PharmaCo J	US	Biopharmaceuticals	20 to 30	10 to 20 bn

[1] Information retrieved from annual report 2017 of the respective company

The meeting in June 2016 was specifically focused on OPEX in QC labs (ITEM-HSG, 2016b). On the first meeting-day, some companies shared their approach to OPEX in QC labs and successful practices. On the second meeting-day, a workshop allowed to draft a preliminary across-industry understanding to performance measurement in QC. A more detailed overview of the QC lab workshop tasks in June 2016 can be found in appendix 5. The first phase of the actual development of the data collection template used for this research started after the meeting in June 2016. Based on the workshop outcome of the meeting a preliminary data collection template was built. The data collection template development was a joint effort between the University of St. Gallen and the co-developing

[28] A pure compliance-focused performance measurement approach in the pharmaceutical industry often coincides with a strategy to meet minimum requirements that are enforced by regulators to produce safe and effective products of good quality and to pass inspections by regulatory authorities.

industry partner[29]. The joint development enabled a scientifically reliable development process of an industry applicable data collection template.
In the second development phase the preliminary data collection template was tested with three QC labs of the co-developer. This test allowed identifying issues of the preliminary template. The rewording of some questions ensured a better understanding for the future application of the template. The restructuring of the performance dimensions improved the holistic performance measurement approach described in chapter 3. The dimensions process, productivity, and cost were replaced with the dimensions quality, service, productivity, and cost (Köhler, 2016, 2018). Furthermore, the test of the preliminary data collection template revealed that one of the three performance measurement dimensions in the context of excellence was missing. While the preliminary template only included performance and operating context, the enabler dimension was added in the revised template (Köhler, 2016, 2018).
During the third phase of the development additional practitioners reviewed the revised data collection template. For the final template additional questions and increasing reporting effort were balanced. The final data collection template that was used for this research is described in the subsequent chapter. Figure 14 exhibits an overview of the three phases of the instrument development.

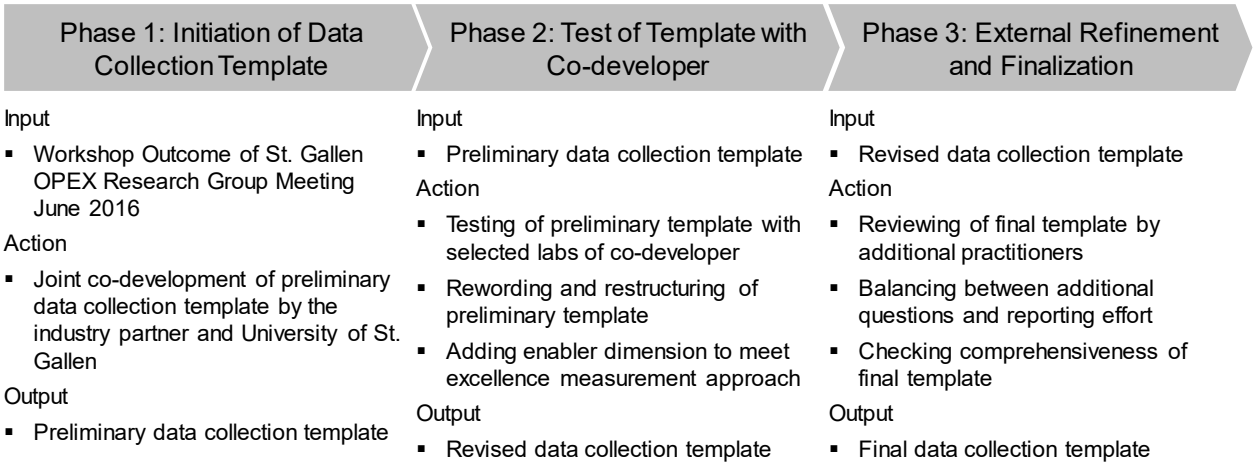

Figure 14: Data collection template development phases

4.1.2 Data Collection Template

The data collection template for this research was a Microsoft Excel-based questionnaire. The template comprised 352 different data points, thereof 134 performance-related, 68 enabler-related, and 122 context-related data points (Köhler, 2018). Table 21 provides a detailed overview of the count of metrics and data points of each template section. A definition was added to all data points in the template to increase the comparability of responses.

[29] The co-developing partner is a Swiss multinational pharmaceutical company with more than 100,000 employees worldwide and a revenue of about 50 bn dollars. The organization has launched multiple initiatives at global and local level to improve OPEX in QC labs. These initiatives have shown positive results creating new sponsorship for the continuation of these initiatives.

Table 21: Count of metrics in each section of the data collection template

Template Section	PMM Section	Count of Metrics	Count of Individual Data Points
General Information[1]	Operating Context	11 (3)	11 (3)
Lab Overview	Operating Context	23	60
Organizational Structure	Operating Context	15	51
Enabler	Enabler Dimensions	68	68
Productivity	Productivity	8	28
Quality	Quality	17	57
Service	Service	8	55
Cost	Cost Efficiency	5	22

[1] Not all data points of the general information section are included in the PMM. 8 of 11 data points identify the company name and contact details of the person that was responsible for the data collection. 3 out of 11 data points of this section are included in the PMM.

The majority of data points in the template asked for numerical values (e.g. number of tests performed). Additionally, the template included dichotomous questions (in which the respondent must choose between two alternatives), multiple choice questions (where more than one alternative can apply) and closed-ended rating questions. At the end of each template section the respondent was able to provide comments.

To ensure high data quality the data collection template incorporated an automated validation functionality for all numerical values at the point of data collection. In case the sum of multiple numerical data points required 100 % and the data input did not meet this requirement, an error message was displayed. The respondent was then able to change the data input accordingly. To allow comparability between QC labs, aggregated data points (e.g. total quality control cost) were only calculated if a minimum threshold of individual data points that built the aggregation was met. To avoid tool miscalculations caused by incorrectly entered zero values, this data input was not allowed for numerical data points that cannot be zero (e.g. number of tests performed). If a numerical data point was not applicable to a QC lab and the respondent tried to enter zero (e.g. no tests performed) an error message was displayed. It informed the respondent to enter N/A (not applicable).

The final data collection template can be found in appendix 6. The data collection template was initiated, developed, and used for data collection as part of this research. It will continue to be used for data collection in the future to carry out individual industry assessments and to conduct further research.

4.1.3 Data Collection Process

The data collection process for this research was directly linked to individual projects with the pharmaceutical industry. To motivate pharmaceutical companies to collect data in their QC labs the researcher developed a comprehensive benchmarking and reporting tool. Each participating QC lab received a personalized report with 40 pages of detailed benchmarking analyses. To allow seamless flow of data from the data collection template to the assessment tool and into the report additional tools were developed. These tools are not described in this research but reference should be made to the author. The close

link of the primary data basis of this research to the industry demand of a QC lab OPEX benchmarking ensured an appropriate sample size (cf. chapter 4.1.4). In total, 17 companies contributed with data from one or multiple QC labs. The companies range from R&D-driven and generic manufacturing organizations to contract manufacturing organizations. Table 22 shows an overview of the anonymized companies that participated in the data collection process. Some of the companies in table 22 categorized as pharmaceutical companies also have business units focusing on biopharmaceuticals or biosimilar.

Table 22: Participating companies in data collection for this research

Company	Origin	Main Focus	Employees (,000)[1]	Revenue [USD][1]
PharmaCo 1[2]	DE	Pharmaceuticals	Below 5	Below 1 bn
PharmaCo 2	UK	Biopharmaceuticals	60 to 70	20 to 30 bn
PharmaCo 3	IN	Pharmaceuticals	20 to 30	1 to 5 bn
PharmaCo 4	US	Pharmaceuticals	40 to 50	20 to 30 bn
PharmaCo 5	CH	Biopharmaceutical	5 to 10	1 to 5 bn
PharmaCo 6	DE	Pharmaceuticals	30 to 40	5 to 10 bn
PharmaCo 7	FR	Pharmaceuticals	Below 5	Below 1 bn
PharmaCo8	BE	Biopharmaceuticals	130 to 140	70 to 80 bn
PharmaCo 9	ES	Pharmaceuticals	Below 5	Below 1bn
PharmaCo10	DE	Biopharmaceuticals	50 to 60	10 to 15 bn
PharmaCo 11	CH	Pharmaceuticals	120 to130	40 to 50 bn
PharmaCo 12	FI	Pharmaceuticals	Below 5	1 to 5 bn
PharmaCo 13	US	Biopharmaceuticals	90 to 100	50 to 60 bn
PharmaCo 14	SE	Pharmaceuticals	5 to 10	Below 1 bn
PharmaCo 15	BE	Biopharmaceutical	5 to 10	5 to 10 bn
PharmaCo 16[2]	DE	Pharmaceuticals	Below 5	Below 1 bn
PharmaCo 17	CH	Pharmaceuticals	Below 5	1 to 5 bn

[1] Information retrieved from annual report 2017 of the respective company
[2] Information retrieved from other sources (e.g. bloomberg.org or company material) if annual report was not public

The overall project period ranged from one month to more than 12 months depending on how much effort each company was able to invest into the data collection. To reach the appropriate sample size in the limited timeframe of this research the researcher conducted multiple projects in parallel. The following paragraph describes the ten phases of data collection of the 17 individual industry projects linked to this research.

In the first phase the researcher invited the company project sponsor to an introductory telephone conference to provide details on the project scope, assessment approach, and data collection process. In addition, to manage expectations the project outcome was outlined. After the project confirmation, the second phase encompassed an administrative step. To ensure data protection both parties signed a non-disclosure agreement (NDA). The third phase started with a kick-off telephone conference. The researcher invited the company project team to provide an introduction to the project scope, assessment approach, and data collection process. In addition, the researcher presented the data

collection template and elaborated on the data collection process. During the kick-off the project timeline and deadlines were agreed upon. As a follow-up activity, the company project team received the kick-off meeting presentation, the data collection template, and a FAQ-document with frequently asked questions (FAQ) of previous benchmarking participants. In the fourth phase the company project team familiarized themselves with the provided material with a special focus on the data collection template and the data point definitions. The fifth phase was a telephone conference to clarify all open questions of the company project team. After this phase a common understanding of the project scope, assessment approach, data collection process, and template was ensured. The sixth phase represented the actual data collection. It was the phase with the longest duration of the project. The reporting period was always the last calendar year or financial year. The collected data was self-reported. Due to the limited resources of the researcher, the company project team needed to ensure the collection of appropriate data. However, the self-reporting nature of the data collection did not impact the data quality. The overall project design guaranteed a high data quality with different mechanisms throughout all phases (cf. table 23). In the seventh phase the project team submitted the filled in data collection template to the researcher. The eighth phase was focused on data validation. In this phase the researcher analyzed the submitted data. Depending on the quality of the submitted data this phase had multiple iterations until all open questions were clarified and a high data quality was achieved. The validation phase allowed finding outliers as well as inconsistencies within the datasets. In addition, it ensured that the company provided at least the minimum threshold of indicators to calculate productivity, quality, service, and cost efficiency performance. The average actual completeness rate of all datasets provided to the researcher totals at 76 %[30]. This can be seen as a very high rate because not all data points of the data collection template apply to all QC labs[31]. In the ninth phase the validated dataset was incorporated into the overall benchmarking database. In addition, selected operating context factors (cf. chapter 3.3.3) were applied as filters. The resulting peer-group allowed benchmarking the new data set to a selected number of QC labs that had a similar operating context. In the tenth phase the researcher presented the benchmarking results to the company. The result presentation was focused on the management summary of the benchmarking report and improvement areas identified by the researcher. It was primarily held as a 1 to 1.5 hours telephone conference. Some companies decided to extend the project to include a one-day result workshop at their manufacturing site. The workshop allowed the researcher to derive improvement measures for the QC labs together with the company. The data collection phases with the respective data quality mechanisms and phase leader are summarized in table 23.

[30] The actual completeness rate for each dataset is calculated from the proportion of filled in data points to the overall number of data points in the data collection template.

[31] Because not all data points apply to each QC lab the theoretical completeness rate is higher than the actual completeness rate. However, the theoretical completeness rate cannot be measured from the primary data used for this research. All not-filled-in-data-points show the same label. This label does not allow distinguishing if these data points were not available in the QC lab or not applicable to the QC lab.

Table 23: Data collection phases with respective data quality mechanisms and leader

No.	Phase	Data Quality Mechanism	Leader
1	Project Introduction	N/A	Researcher
2	Administrative Tasks	N/A	Researcher
3	Project Kick-Off	Live data collection template walk-through, Q&A session	Researcher
4	Review Project Material	Kick-off documentation, FAQ-document	Company project team
5	Q&A Session	Q&A session	Researcher
6	Data Collection	Automated template validation, Q&A sessions, ad hoc support	Company project team
7	Data Submission	N/A	Company project team
8	Data Validation	Tool-based outlier and inconsistency detection, Iterations	Researcher
9	Data Analysis and Report Creation	N/A	Researcher
10	Report Presentation	N/A	Researcher

4.1.4 Data Characteristics

The available 53 QC labs of this research have a differing operating context that is described in the following paragraphs. Table 24 to table 30 depict an overview of the data basis of the quantitative analyses. Each table represents one of the seven identified categories following the proposition P2 to P8 in chapter 3.4. A detailed description can be found in chapter 3.3.3. P1 summarizes all factors to operating context.

The category *Geographical Location* includes the following three dimensions: country, regional distribution, and cost location. In total, the QC labs are from 21 different countries. 72 % of the QC labs are located in Europe. Therefore, the data basis has a strong representation of European QC labs. The three most represented countries are Switzerland (15 %), USA (13%), and Ireland (11%). The proportion of QC labs in North America totals at 15 %. Middle and South America as well as Asia are represented with below 10 %. Consequently, a considerable proportion of QC labs is from high cost locations. 81 % of the QC labs are located in high cost countries. 19 % of the QC labs are located in low cost countries. Table 24 depicts the geographical distribution of the available QC labs.

Table 24: Geographical location of QC labs data basis

Category	Dimension	Characteristic	Proportion of Sample	Number of Labs
Geographical Location	Country	Belgium	4 %	2
		Brazil	4 %	2
		France	6 %	3
		Germany	9 %	5
		India	4 %	2
		Ireland	11 %	6
		Italy	8 %	4
		Spain	6%	3
		Switzerland	15 %	8
		USA	13 %	7
		Other Countries[1]	21 %	11
	Regional Distribution	Europe	72 %	38
		North America	15 %	8
		Middle and South America	8 %	4
		Asia	6 %	3
	Cost Location	High Cost Countries[2]	81 %	43
		Low Cost Countries[3]	19 %	10

[1] All other countries are represented with one QC lab: Austria, Canada, China, Finland, Mexico, Netherlands, Poland, Portugal, Puerto Rico, Slovenia, Sweden
[2] High Cost Countries: Austria, Belgium, Canada, Finland, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, Switzerland, USA
[3] Low Cost Countries: Brazil, China, India, Mexico, Poland, Portugal, Puerto Rico, Slovenia

The category *Portfolio Complexity* distinguishes three dimensions: drug substance type, drug product type, and number of final drug product types tested. More than 90 % of all QC labs of the data basis conduct drug substance tests. The largest proportion accounts chemical drug substance testing QC labs (45%). These labs exclusively test chemical drug substance. 28 % of the QC labs of the data basis conduct both chemical and biological drug substance tests. A minority of 17 % of QC labs only test biological drug substance. Drug product testing is conducted by 85 % of the QC labs. More than 50% of these labs test multiple drug products. 21% of the QC labs focus only on sterile liquids tests. Below 10 % of the QC labs do testing for solids or non-sterile liquids only. The number of final drug product types tested ranges from below 50 to above 100. More than 50 % of the data basis tests less than 50 final drug product types. However, no tendency toward a low number of tested product types can be observed. 34 % of the QC labs test more than 100 different drug product types. The rest of QC labs (11 %) tests between 51 and 100 different drug product types. Table 25 exhibits the *Portfolio Complexity* in detail.

Table 25: Portfolio complexity of QC lab data basis

Category	Dimension	Characteristic	Proportion of Sample	Number of Labs
Portfolio Complexity	Drug Substance Type	Chemicals	45 %	24
		Biologics	17 %	9
		Mixed[1]	28 %	15
		No Drug Substance	9 %	5
	Drug Product Type	Solids	9 %	5
		Sterile Liquids	21 %	11
		Non-sterile Liquids	4 %	2
		Mixed[2]	51 %	27
		No Drug Product	15 %	8
	No. of final Drug Product Types tested	Up to 50	55 %	29
		51 to 100	11 %	6
		Above 100	34 %	18

[1] Mixed drug substance type refers to the testing of both drug substances (i.e. chemicals and biologics)
[2] Mixed drug product type refers to the testing of different drug products (i.e. a combination of solids, creams, suppositories, sterile liquids, non-sterile liquids, patches, and inhalers)

The category *Test Allocation Strategy* addresses two dimensions: centralization and the degree of centralization. The data basis is almost evenly split in centralized and decentralized QC labs. 45 % of the QC labs are decentralized and only conduct tests for their own manufacturing site. 55 % of the QC labs are centralized conducting tests for their own but also other manufacturing sites. However, the degree of centralization varies. A large majority (69 %) is less than 25 % centralized. Two thirds of their tests are conducted for the company's own manufacturing site. 17 % of the data basis has a degree of centralization between 26 and 50 %. The remaining 14 % of the data basis are more than 50 % centralized. Table 26 depicts an overview of the *Test Allocation Strategy*.

Table 26: Test allocation strategy of QC labs data basis

Category	Dimension	Characteristic	Proportion of Sample	Number of Labs
Test Allocation Strategy	Centralization	Centralized	55 %	29
		Decentralized	45 %	24
	Degree of Centralization	Up to 25 %	69 %	20
		26 to 50 %	17 %	5
		Above 50 %	14 %	4

The category *Organizational Scale* is focused on the two dimensions: QC Full-Time Equivalents (FTEs) and site FTEs. Regarding QC FTEs, the data basis is almost evenly distributed from below 30 FTEs to above 90 FTEs. 26 % of the data basis has less than 30 QC FTEs. The same proportion applies to the QC labs that have 31 to 60 FTEs. 23 %

of the data basis operates with 61 to 90 QC FTEs. 25 % of the data basis has 90 QC FTEs. On the site level both the below 200 FTEs and the 201 to 400 FTEs ranges, are represented by 20 % of the QC labs. 25 % of the QC labs are located at sites with 401 to 600 FTEs. 35 % of the data basis represents sites with above 600 FTEs. Table 27 provides an overview of the organization scale.

Table 27: Organizational scale of QC labs and of the sites data basis

Category	Dimension	Characteristic	Proportion of Sample	Number of Labs
Organizational Scale	QC FTEs	Up to 30	26 %	14
		31 to 60	26 %	14
		61 to 90	23 %	12
		Above 90	25 %	13
	Site FTEs[1]	Up to 200	20 %	10
		201 to 400	20 %	10
		401 to 600	25 %	13
		Above 600	35 %	18

[1] Number of labs does not add up to 53 due to missing data points

The category *Economy of Scale* distinguishes two dimensions: first, the number of batches processed by the QC lab; second, the number of tests conducted. Both measures are normalized by the reporting period of one year. The largest proportion (34 %) processes below 4,000 batches per year. 25 % process 4,001 to a maximum of 8,000 batches each year. Each year 8,001 to 12,000 batches are processed by 19 % of the data basis. 23 % process above 12,000 batches each year. The testing volume of the data basis varies from below 100,000 tests to above 400,000 tests per year. More than two thirds of the QC labs conduct up to 200,000 tests per year. Almost half of the data basis (45 %) conducts less than 100,000 tests. Approximately a quartile conducts above 200,000 tests. Table 28 highlights all details on the *Economy of Scale* of the QC lab data basis.

Table 28: Economy of scale of QC lab data basis

Category	Dimension	Characteristic	Proportion of Sample	Number of Labs
Economy of Scale	No. of Batches processed	Up to 4,000	34 %	18
		4,001 to 8,000	25 %	13
		8,001 to 12,000	19 %	10
		Above 12,000	23 %	12
	No. of Tests	Up to 100,000	45 %	24
		100,001 to 200,000	30 %	16
		200,001 to 300,000	11 %	6
		300,001 to 400,000	4 %	2
		Above 400,000	9 %	5

The category *Technology & Innovation* includes the following three dimensions: age of instruments, age of methods, and automation. The large majority (81%) of the QC labs use old instruments. 50 % or more of the instruments are older than five years. Only 19 % of the QC labs have more than 50 % of instruments that are less than five years old. The age of methods shows a similar distribution. However, the propensity toward old is even stronger. 91 % of the QC labs use old testing methods that were introduced five or more years ago. Only 9 % of the QC labs have more than 50 % of their methods introduced in the past five years. The level of automation is almost equally distributed between the QC labs of the data basis. 42 % of the QC labs have more than half of their instruments partially or fully automated. 58 % of the data basis has a low automation level with more than half of their instruments manually operated. Table 29 depicts the category *Technology & Innovation* of the QC lab data basis.

Table 29: Technology and innovation of QC lab data basis

Category	Dimension	Characteristic	Proportion of Sample	Number of Labs
Technology & Innovation	Age of Instruments	New[1]	19 %	10
		Old[2]	81 %	43
	Age of Methods	New[1]	9 %	5
		Old[2]	91 %	48
	Automation	High[3]	42 %	22
		Low[4]	58 %	31

[1] New is defined as more than 50 % of the instruments or methods less than five years old
[2] Old is defined as more than 50 % of the instruments or methods more than five years old
[3] High is defined as more than 50 % of instruments (partially or fully) automated
[4] Low is defined as more than 50 % of instruments manually operated

The category *Regulatory Approval* distinguishes four dimensions. Each dimension is linked to a regulatory agency. 74 % of the QC labs are US Food and Drug Administration (FDA) approved and release drugs that are sold on the US market. 85 % of the QC labs are European Medicines Agency (EMA) approved for the European market. 49 % of the QC labs are China Food and Drug Administration (CFDA) approved for the Chinese market. With an approval of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) 60 % of the QC labs release drugs to the Japanese market. Table 30 outlines the type of *Regulatory Approval* of the QC labs that build the basis of this research.

Table 30: Regulatory approval of QC lab data basis

Category	Dimension	Characteristic	Proportion of Sample	Number of Labs
Regulatory Approval	US Approval	FDA	74 %	39
		No FDA	26 %	14
	European Union Approval	EMA	85 %	45
		No EMA	15 %	8
	China Approval	CFDA	49 %	26
		No CFDA	51 %	27
	Japan Approval	PMDA	60 %	32
		No PMDA	40 %	21

FDA: US Food and Drug Administration, CFDA: China Food and Drug Administration, EMA: European Medicines Agency, PMDA: Pharmaceuticals and Medical Devices Agency

As outlined above the data basis represents a wide variety of different QC labs across the pharmaceutical industry. Some characteristics occur more often than others. The data basis tends to have a strong representation of European high cost locations. In addition, more than two thirds of the data basis conducts less than 200,000 tests. However, overall the data basis does not have a strong tendency toward additional characteristics.

4.1.5 QC Lab Effectiveness Calculation

The QC lab effectiveness is an aggregation of the PMM performance dimensions quality and service. For the context of this research both PMM dimensions are operationalized (cf. chapter 3.3.1). The performance indicators outlined below concur with the operationalization in chapter 3.3.1.

To calculate the QC lab effectiveness each indicator is normalized on a scale from 0 to 1 using the quantile rank. This allows aggregating indicators with different scales to an average value between 0 and 1. The normalized values of the indicators are directly aggregated to one overall QC lab effectiveness value for each QC lab. The aggregated QC lab effectiveness is only calculated in case the indicator minimum threshold of 70 % is met. For the QC lab effectiveness the service performance contributes with fewer indicators (2 out of 10) compared to the quality performance (8 out of 10). The direct aggregation of indicators without calculating dimensional service and quality performance values avoids an unwanted higher weighting of the individual service indicator belonging to the performance dimension with fewer indicators.

Table 31 shows the QC lab effectiveness indicators and how these indicators are normalized to one QC lab effectiveness performance value. The definitions of the indicators in table 31 can be found in chapter 3.3.1.

Table 31: QC lab effectiveness definition

Performance Dimension	Indicator	Unit	Directional Positive	Normalized Value	QC Lab Effectiveness Value
Service	Adherence to Lead Time	%	Up	0 to 1	
Service	Adherence to Schedule	%	Up	0 to 1	
Quality	Analytical Right First Time (A)	%	Up	0 to 1	
Quality	Customer Complaint Investigation Rate	No./100,000 Tests	Down	0 to 1	
Quality	Invalidated OOS Rate (A)	No./100,000 Tests	Down	0 to 1	
Quality	Lab CAPAs Overdue	%	Down	0 to 1	0 to 1
Quality	Lab Deviation Rate	No./1,000 Tests	Down	0 to 1	
Quality	Lab Investigation Rate (A)	No./1,000 Tests	Down	0 to 1	
Quality	Product Re-Tests due to Complaints	%	Down	0 to 1	
Quality	Recurring Lab Deviations	%	Down	0 to 1	

(A) Metric is aggregated from different testing types performed in the lab (drug substance, intermediate, in-process-control, raw material, stability, drug product, packaged product, microbial environmental, microbial product, component & packaging material

The following paragraphs describe the internal construct validity for the QC lab effectiveness. This analysis builds the basis to use a reliable QC lab effectiveness operationalization for all subsequent quantitative analyses of this research. First, a Spearman correlation analysis reveals the individual indicator relations with other indicators of QC lab effectiveness. Second, Cronbach's Alpha, a measure for internal validity, is measured.

The non-parametric Spearman correlation ranks the indicators on its original scale before the correlation is calculated (Weinberg & Abramowitz, 2008). Unlike the Pearson correlation, the Spearman correlation allows correlating two variables with a non-linear but monotonical relation (Weinberg & Abramowitz, 2008). Table 32 depicts the correlation between the ten indicators that build the QC lab effectiveness performance. Unlike aggregating individual indicators to one overall QC lab effectiveness performance, the Spearman correlation does not require directional positive normalized values to be correlated. In fact, this normalization would make the interpretation more difficult. The indicators in table 32 are not directionally adjusted. A high *Lab Investigation Rate* means a high number of lab investigations per 1,000 tests. Datasets that showed an irregular relation between number of investigations and number of deviations were excluded.

Table 32: Correlation of QC lab effectiveness indicators

Indicator	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Adherence to Lead Time (1)		.620	.106	.481	.248	.168	.167	.040	.351	.750
Adherence to Schedule (2)	.109		.436	.710	.213	.545	.156	.149	.478	.035
Analytical Right First Time (3)	.324	.143		.008	.505	.369	.238	.134	.370	.391
Customer Complaint Invest. Rate (4)	-.145	.070	**-.446**		.465	.921	.753	.027	.001	.657
Invalidated OOS Rate (5)	-.226	-.219	-.110	.126		.542	.018	.000	.621	.105
Lab CAPAs Overdue (6)	-.273	-.111	.152	-.018	.101		.077	.338	.118	.401
Lab Deviation Rate (7)	.274	-.253	-.196	-.055	**.373**	-.290		.009	.063	.078
Lab Investigation Rate (8)	**-.391**	-.253	-.244	**.369**	**.660**	.158	**.408**		.464	.077
Prod. Re-Tests due to Complaints (9)	-.195	.132	-.156	**.549**	.084	.269	-.314	.124		.974
Recurring Lab Deviations (10)	.070	**-.399**	-.152	-.083	.279	.151	.306	.303	-.006	

The upper half of the table shows the significance level. The lower half of the table shows the correlation coefficient. The bold coefficients are significant at p = 0.05 or p = 0.01.

Many authors argue that a construct has internal validity in case the Cronbach's Alpha value exceeds a threshold of 0.5 (Bagozzi & Yi, 1988; J. S. Kim & Arnold, 1996), 0.6 (R. G. Schroeder et al., 2011), or 0.7 (Shah & Ward, 2003). To assess the convergent construct validity of QC lab effectiveness Cronbach's Alpha is calculated. The Cronbach's Alpha value of 0.742 for QC lab effectiveness is high and exceeds the most rigor threshold mentioned by the authors above. Consequently, this analysis indicates high convergent construct validity for QC lab effectiveness.

Not all correlations within the QC lab effectiveness indicators are significant. Nevertheless, the correlation analysis allows understanding the interaction between the indicators better. The combination of the Spearman correlation results and a high Cronbach's Alpha value of 0.742 allow using the ten different indicators as reasonable measures of QC lab effectiveness for this research.

4.1.6 Enabler Implementation Calculation

The enabler system is a fundamental element of the PMM (cf. chapter 3.2). In total, 68 individual enablers are summarized into 13 enabler dimensions (cf. chapter 3.3.2). Each individual enabler is a specific question. A complete list of all individual enabler questions and corresponding answers can be found in appendix 6. During the pilot phase with the first three QC labs of data collection the enablers were not yet part of the data collection template. Consequently, all enabler-related analyses are conducted with the remaining 50 QC labs.

While the QC lab effectiveness calculation is based on actual performance data of the QC lab, the enabler data is based on a self-assessment of the company that provided the data. The individual enablers are rated on a 5-point Likert scale. Each Likert scale item has a description to increase comparability of the answers (cf. appendix 6). For this research the Likert scale values between 1 and 5 are transformed to a value between 0 and 1. This allowed better interpretation in correspondence with the QC lab effectiveness value between 0 and 1. The implementation of each enabler dimensions is an average value of all individual enablers of the respective dimension. For the TES and MES implementation

its enabler dimensions are aggregated to an overall average. The aggregated implementation scores are only calculated in case the indicator minimum threshold of 50 % is met.

The following paragraphs describe the internal construct validity for the 13 enabler dimensions. The analysis aims at testing the reliability of the enabler operationalization. It builds the basis of all subsequent enabler-related quantitative analyses of this research. First, a Pearson correlation analysis reveals the relations with other enabler dimensions. Second, Cronbach's Alpha, a measure for internal validity, is measured.

The Pearson correlation analysis is conducted due to the linear nature of the enablers. Table 33 exhibits the Pearson correlation between the enabler dimensions. The analysis reveals many significant correlations. With few exceptions the MES enabler dimensions (11, 12, and 13) seem to be significantly correlated with all TES enabler dimensions. In addition, the analysis determines two correlation blocks within the TES (cf. table 33). The maintenance- and quality-related enabler dimensions (1, 2, 3, 4, and 5) show a strong link. The average correlation of these dimensions totals at 0.458. In addition, the planning- and steering-related enabler dimensions (6, 7, 8, 9, and 10) show a relatively strong relation. The average correlation of these dimensions totals at 0.344. However, the average correlation is not as high as it is within the maintenance- and quality-related block. At the point in time of this research with a data basis of 53 QC labs no factor analysis is applied to reduce the 68 individual enablers to fewer dimensions. For a meaningful factor analysis more datasets are needed.

Table 33: Correlation of enabler dimensions

Dimension	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
Preventive Maintenance (1)		.001	.003	.005	.000	.002	.025	.196	.009	.063	.007	.004	.000
Techn. Assess. & Usage (2)	**.439**		.004	.001	.005	.070	.053	.273	.073	.191	.014	.000	.001
Housekeeping (3)	**.412**	**.402**		.001	.000	.001	.199	.003	.106	.331	.019	.009	.004
Process Management (4)	**.393**	**.474**	**.449**		.006	.003	.093	.007	.230	.180	.051	.001	.009
Standardization & Simplif. (5)	**.635**	**.388**	**.605**	**.383**		.000	.003	.011	.000	.077	.000	.000	.000
Set-up Time Reduction (6)	**.433**	.259	**.439**	.406	**.520**		.002	.008	.001	.057	.000	.000	.000
Pull Approach (7)	**.316**	.275	.185	.240	**.416**	**.431**		.006	.003	.305	.059	.002	.002
Layout Optimization (8)	.186	.158	**.409**	**.376**	**.358**	**.369**	**.384**		.004	.180	.133	.028	.017
Planning Adherence (9)	**.365**	.256	.232	.173	**.482**	**.438**	**.408**	**.399**		.004	.008	.000	.001
Visual Management (10)	.264	.188	.140	.193	.253	.271	.148	.193	**.396**		.162	.000	.089
Mgmt. Com. & Co. Cult. (11)	**.375**	**.347**	**.331**	.278	**.552**	**.575**	.269	**.215**	**.369**	**.201**		.000	.000
Empl. Involvement & CI (12)	**.404**	**.523**	**.366**	**.450**	**.584**	**.511**	**.437**	**.311**	**.481**	**.483**	**.504**		.000
Funct. Integr. & Qualif. (13)	**.554**	**.470**	**.403**	**.368**	**.631**	**.610**	**.426**	**.335**	**.464**	.243	**.564**	**.570**	

The upper half of the table shows the significance level. The lower half of the table shows the correlation coefficient. The bold coefficients are significant at p = 0.05 or p = 0.01.
n = 50

In contrast to the construct validity analysis for QC lab effectiveness the enabler construct validity analysis for the enabler dimension can be enhanced by comparing the Cronbach's Alpha value of each dimension with different interscale correlations. This approach allows

increasing the reliability of the construct validity analysis whenever more than one dimension is analyzed. For the enablers 13 different dimensions are analyzed. Therefore, the approach of comparing Cronbach's Alpha values with interscale correlations is applicable. Following Flynn et al. (1999) in this research the Cronbach's Alpha value is compared to different interscale correlations. To increase the granularity of the results three different interscale correlations are described in the following.
Table 34 depicts the Cronbach's Alpha value for each dimension and the three different interscale correlations. First, the average correlation within the focus (e.g. Maintenance & Quality) is outlined. Second, the average correlation "outside the focus but within the system" (TES or MES) is shown. Third, the average correlation "outside the focus and outside the system" is exhibited.

Table 34: Convergent and divergent validity of enabler dimensions

Focus	Dimension (no. of items within dimension)	Cronbach's Alpha	Average Interscale Correlation (dimensions within focus)	Average Interscale Correlation (dimensions outside focus within system)	Average Interscale Correlation (dimensions outside focus outside system)
Maintenance & Quality	**Technical Enabler System (10)**	.808	N/A	N/A	N/A
	Preventive Maintenance (4)	.585	.470	.313	.444
	Technology Assessment & Usage (6)	.548	.426	.227	.446
	Housekeeping (4)	.797	.467	.281	.367
	Process Management (5)	.619	.425	.278	.365
	Standardization & Simplification (6)	.672	.503	.406	.589
Planning & Steering	Set-up Time Reduction (4)	.613	.378	.412	.565
	Pull Approach (3)	.335	.343	.286	.377
	Layout Optimization (6)	.688	.336	.297	.287
	Planning Adherence (5)	.662	.410	.301	.438
	Visual Management (2)	.937	.252	.208	.309
Mgmt.	**Management Enabler System (3)**	.776	N/A	N/A	N/A
	Mgmt. Com. & Company Culture (7)	.700	.534	N/A	.351
	Employee Involvement & CI (8)	.575	.537	N/A	.455
	Funct. Integration & Qualification (4)	.687	.567	N/A	.450

n = 50

With one exception the Cronbach's Alpha value for almost all dimensions is fairly high with a value above 0.5. This indicates a high convergent construct validity. The dimension *Pull Approach* is the only dimension with a low Cronbach's Alpha value (0.335). The divergent construct validity is supported by the fact that the average interscale correlation is lower than the Cronbach's Alpha value. This can be confirmed for the "within focus" and "outside focus but within system" comparison for all dimensions except *Pull Approach*. The

Cronbach's Alpha value for the dimension *Pull Approach* does not fulfil this requirement for both interscale correlations. However, the Cronbach's Alpha of *Pull Approach* does exceed the "outside focus but within system" interscale correlation. Consequently, one of the two requirements is fulfilled and *Pull Approach* is not excluded from this research. The dimension *Set-up Time Reduction* shows a higher "outside focus but within system" interscale correlation compared to the "within focus" correlation. However, taking into account content validity it rather belongs to the planning and steering focus than the maintenance and quality focus.
The three MES enabler dimensions show a strong correlation to all enabler dimensions of the TES. The Pearson correlation already indicated this result. At this point, the high average "outside focus and outside system" interscale correlations that on average (average of the last column in table 34) exceeds all "outside focus but within system" correlations (average of second last column in table 34) are notable. It gives some indication for the research objective of hypotheses H2a and H2b. It is discussed at a later stage of the research process in chapter 4.3.3.

4.2 Operating Context and QC Lab Effectiveness Relation

Authors found mixed evidence of the impact of the operating context for the enabler implementation and performance improvements (cf. chapter 3.2.3). Considering the operating context allows robust research results related to the present unit of analysis. Consequently, this chapter discusses the operating context of QC labs and its relation to QC lab effectiveness.
In the following, the analysis approach is described. Then, the relation of the organizational context is elaborated. This analysis relates to internal organizational factors of the operating context (cf. chapter 3.3.3) and QC lab effectiveness. In addition, the focus is maintained on the relation of the external environmental contingencies (cf. chapter 3.3.3). This chapter concludes with a summary of the relation between the operating context and QC lab effectiveness.

4.2.1 Analysis Approach

Chapter 3.4 outlined propositions related to the operating context and QC lab effectiveness. Table 35 shows a summary of the propositions and related details. Each proposition addresses two or more related dimensions of the analyzed operating context category. The following analysis is focused on each proposition and related dimension whether it shows a striking relation with QC lab effectiveness. The 53 QC labs described in chapter 4.1.4 build the basis of the subsequent analyses.

Table 35: Propositions related to the operating context and QC lab effectiveness

No.	Proposition	Dimensions	Focus
P1	The operating context of a QC lab has no impact on the QC lab effectiveness.	Summary of P2 to P8	EC, OC
P2	The geographical location of the QC lab has no impact on the QC lab effectiveness.	Country, Regional Distribution, Cost Location	EC
P3	The portfolio complexity of the QC lab has no impact on the QC lab effectiveness.	Drug Substance Type, Drug Product Type, No. of final Drug Product Types Tested	OC
P4	The test allocation strategy of the QC lab has no impact on the QC lab effectiveness.	Centralization, Degree of Centralization	OC
P5	The organizational scale of the QC lab and site has no impact on the QC lab effectiveness.	QC FTEs, Site FTEs	OC
P6	The economy of scale of the QC lab has no impact on the QC lab effectiveness.	No. of Batches processed, No. of Tests	OC
P7	The technology and innovation of the QC lab has no impact on the QC lab effectiveness.	Age of Instruments, Age of Methods, Automation	OC
P8	The regulatory approval of the QC lab has no impact on the QC lab effectiveness.	US Approval, EU Approval, China Approval, Japan Approval	EC

EC: Environmental contingency factor
OC: Organizational context factor

The relatively small number of QC labs regarding most characteristics of the context factors (cf. chapter 4.1.4) did not allow employing most statistical methods.[32] However, a descriptive statistic separating above median performing QC labs from below median performing QC labs allows finding indication how the operating context impacts the QC lab effectiveness.

The aggregated QC lab effectiveness, defined in chapter 4.1.5, builds the basis to distinguish above from below performing QC labs. In this context, reference should be made to the discussion between scholars on the value of variable dichotomization (transforming continuous variables into categorical variables). Cohen (1983) and DeCoster, Gallucci, and Iselin (2011) emphasize that the statistical effect size may be reduced or screwed when continuous variables are transformed to artificial categorical variables (dichotomous variables).

The present statistic approach is limited to a descriptive comparison of the operating context between above and below performing QC labs. Due to the nature of the descriptive statistic no effect size is measured. Consequently, separating above from below performing QC labs is seen as reasonable. The group of above median performing QC labs represents the QC Lab Effectiveness High Performers (QCHPs). The group of QC Lab Effectiveness Low Performers (QCLPs) includes all below median performing QC labs. The overall number of 53 QC labs can be distinguished into 26 QCHPs and 27

[32] In the future, an increased number of QC labs will allow conducting an Analysis of Variance (ANOVA) to distinguish QC labs with different operating context characteristics. The ANOVA enables an identification of significant differences between two or more independent groups. In the context of this research the ANOVA can be used to analyze whether QC labs with different operating context have a significantly different QC lab effectiveness performance.

QCLPs. The comparison is focused on analyzing whether there are striking context factors for QCHPs and QCLPs. The conclusions are based on comparing the characteristics of QCHPs and QCLPs as well as comparing the characteristics within both groups. The decision to reject a proposition is primarily based on the between groups comparison. The within group comparison allows understanding the relation better. For characteristics with equal or less than five QC labs assigned no conclusion was derived. In the following, the analysis of the organizational context is followed by an analysis of the environmental contingencies. In this chapter the focus is maintained on describing the results of the quantitative analysis. The results of the descriptive analysis are deepened in chapter 5.

4.2.2 Organizational Context

In this chapter the organizational context related propositions P3 to P7 are discussed. The organizational context comprises the five categories: *Portfolio Complexity*, *Test Allocation Strategy*, *Organizational Scale*, *Economy of Scale*, and *Technology & Innovation*. The following paragraphs discuss these categories regarding QCHPs and QCLPs.

The category *Portfolio Complexity* distinguishes the three dimensions: drug substance type, drug product type, and number of final drug product types tested. While drug product type refers to different dosage forms, the number of final drug product types refers to a multitude of those drug product types counting different strength and markets. The proposition P3 related to the *Portfolio Complexity* is outlined below.

> *P3: The portfolio complexity of the QC lab has no impact on the QC lab effectiveness.*

Comparing QCHPs and QCLPs on their *Portfolio Complexity* differences occur in all three dimensions of this category. Regarding the drug substance type, two major differences can be noted. A majority (78%) of the biological drug substance testing QC labs belong to the QCHPs. On the contrary, 67 % of the QC labs testing chemical drug substance belong to the QCLPs. For mixed QC labs testing both biological and chemical drug substance no difference can be observed. Of 15 QC labs testing both drug substances 53 % are QCHPs and 57 % are QCLPs. QCHPs and QCLPs also show differences related to their drug product type structure. 64 % of the QC labs testing sterile liquids are QCHPs. On the contrary, the mixed drug product type QC labs testing multiple drug product types show a majority of QCLPs. 63 % of the mixed drug product type QC labs are QCLPs. A notable proportion of 75 % QC labs testing no drug products are QCHPs. Taking into account the within group comparison for the QCLPs it is striking that 63 % of all QCLPs are mixed drug product type testing QC labs. While QCHPs show a lower number of final drug product types, the same relation cannot be observed for QCLPs. 65 % of the QCHPs test up to 50 different final drug product types. 19 % of QCHPs test above 100 different final drug product types. The same relation does not exist for QCLPs. Only 44 % of QCLPs test up to 50 different final drug product types. 48 % of QCLPs test more than 100 different final drug product types. Comparing QCHPs with QCLPs it can be noted that the majority of QC labs testing up to 50 drug product types are QCHPs (59 %). A majority of the QC labs testing above 100 different final drug product types belong to the QCLPs (72 %).

Based on the discussed differences between QCHPs and QCLPs related to their *Portfolio Complexity* proposition P3 can be rejected. The analysis indicates that QCHPs and QCLPs have a different *Portfolio Complexity*. A majority of QC labs testing biological drug substance, sterile liquids, and a low number of final drug product types belong to the QCHPs. A majority of QC labs testing chemical drug substance, multiple drug products, and a high number of final drug product types belong to the QCLPs. Table 36 depicts the *Portfolio Complexity* of the QCHPs and QCLPs. The characteristics that do not meet the minimum threshold of five QC labs are not included. All aspects outlined above are highlighted in bold.

Table 36: Portfolio complexity of above and below median performing QC labs

Category	Dimension	Characteristic	n (QCHP)	n (QCLP)	Between Groups		Within Group	
					QCHP	QCLP	QCHP	QCLP
Portfolio Complexity	Drug Substance Type	Chemicals	8	16	33 %	**67 %**	31 %	59 %
		Biologics	7	2	**78 %**	22 %	27 %	7 %
		Mixed	8	7	**53 %**	**57 %**	31 %	26 %
	Drug Product Type	Sterile Liquids	7	4	**64 %**	36 %	27 %	15 %
		Mixed	10	17	37 %	**63 %**	38 %	**63 %**
		No DP	6	2	**75 %**	25 %	23 %	7 %
	No. of final Drug Product Types tested	Up to 50	17	12	**59 %**	41 %	**65 %**	**44 %**
		51 to 100	4	2	67 %	33 %	15 %	7 %
		Above 100	5	13	28 %	**72 %**	**19 %**	**48 %**

The *Test Allocation Strategy* combines two dimensions: centralization and the degree of centralization. A QC lab is classified centralized in case it conducts test for other manufacturing sites next to the tests for the company's own manufacturing site. A QC lab with up to 25 % centralization conducts at least 75 % of test for the company's own manufacturing site. The proposition P4 related to the *Test Allocation Strategy* is outlined below.

> *P4: The test allocation strategy of the QC lab has no impact on the QC lab effectiveness.*

QCHPs and QCLPs show an almost equal distribution across centralized and decentralized QC labs. 58 % of all QCHPs are centralized. 52 % of the QCLPs are centralized. Closely linked to the equal distribution within the groups the characteristics centralized and decentralized QC labs show a similar pattern. Both characteristics depict almost the same number of QCHPs and QCLPs. 52 % of the centralized QC labs are QCHPs. 54 % of the decentralized QC labs are QCLPs. Regarding the degree of centralization, the within group comparison depicts a large difference for QCHPs compared to QCLPs. 86 % of QCLPs have a degree of centralization up to 25 %. Only 53

% of QCHPs are centralized up to 25 %. Comparing QCHPs with QCLPs it is striking that 78 % of the above 25 % centralized QC labs are QCHPs.
Based on the discussed commonalities and differences between QCHPs and QCLPs related to their *Test Allocation Strategy* proposition P4 can be rejected. The analysis indicates that the *Test Allocation Strategy* does drive QC effectiveness. Especially the degree of centralization shows a striking relation. However, the decision on centralization and decentralization does not seem to influence QC effectiveness directly. Table 37 depicts the *Test Allocation Strategy* of the QCHPs and QCLPs. The individual characteristics that did not meet the minimum threshold of five QC labs were aggregated. All aspects outlined above are highlighted in bold.

Table 37: Test allocation strategy of above and below median performing QC labs

Category	Dimension	Characteristic	n (QCHP)	n (QCLP)	Between Groups		Within Group	
					QCHP	QCLP	QCHP	QCLP
Test Allocation Strategy	Centralization	Centralized	15	14	**52 %**	48 %	**58 %**	**52 %**
		Decentralized	11	13	46 %	**54 %**	**42 %**	**48 %**
	Degree of Centralization	Up to 25 %	8	12	40 %	60 %	**53 %**	**86 %**
		Above 25 %	7	2	**78 %**	22 %	47 %	14 %

The *Organizational Scale* comprises two dimensions: QC FTEs and site FTEs. The proposition P5 related to the *Organizational Scale* is outlined below.

> *P5: The organizational scale of the QC lab and site has no impact on the QC lab effectiveness.*

Comparing QCHPs and QCLPs on the number of QC FTEs and site FTEs there seems to be a different relation within both dimensions. The between group and within group comparison of QCHPs and QCLPs for the top and bottom end of the scale shows a differing pattern for QC FTEs. The QCLPs represent a majority (71 %) of the QC labs with up to 30 FTEs. In addition, the within group comparison of QCLPs depicts 37 % of QCLPs having up to 30 QC FTEs. None of the other FTE categories has the same or a higher proportion of QCLPs. Above 90 QC FTEs the QCHPs represent a majority of 62 % of the QC labs. Between 31 and 90 QC FTEs the distribution between QCHPs and QCLPs is almost even. Regarding site FTEs, it is notable that QCHPs show a high proportion (40 %) of sites with above 600 FTEs. Comparing QCHPs with QCLPs for each site FTE category a mostly equal distribution can be observed. The largest gap exists for up to 200 site FTEs. 60 % of this category are QCLPs.
The discussed differences and commonalities between QCHPs and QCLPs related to the *Organizational Scale* suggest rejecting proposition P5. The analysis indicates that QCHPs and QCLPs have a different *Organizational Scale*. Both dimensions, QC FTEs and site FTEs, show a larger proportion of QCLPs at the bottom end of the scale. However, there

is further investigation needed. Table 38 depicts the *Organizational Scale* of the QCHPs and QCLPs. All aspects outlined above are highlighted in bold.

Table 38: Organizational scale of above and below median performing QC labs

Category	Dimension	Characteristic	n (QCHP)	n (QCLP)	Between Groups		Within Group	
					QCHP	QCLP	QCHP	QCLP
Organizational Scale	QC FTEs	Up to 30	4	10	29 %	**71 %**	15 %	**37 %**
		31 to 60	8	6	57 %	43 %	31 %	22 %
		61 to 90	6	6	50 %	50 %	23 %	22 %
		Above 90	8	5	**62 %**	38 %	31 %	19 %
	Site FTEs	Up to 200	4	6	40 %	**60 %**	15 %	23 %
		201 to 400	5	5	50 %	50 %	20 %	19 %
		401 to 600	6	7	46 %	54 %	24 %	27 %
		Above 600	10	8	56 %	44 %	**40 %**	31 %

The *Economy of Scale* combines the two dimensions: number of batches processed and number of tests conducted. The proposition P6 related to the *Economy of Scale* is outlined below.

> *P6: The economy of scale of the QC lab has no impact on the QC lab effectiveness.*

Comparing the number of batches processed for QCHPs and QCLPs there is no major difference between the proportions of QCHPs for up to and above 8,000 batches. It ranges between 41 % (above 8,000) and 55 % (up to 8,000). However, the within group comparison reveals that the majority of QCHPs (65 %) process less than 8,000 batches. The same relation does not apply to QCLPs. The distribution of QCLPs is almost equal. Regarding the number of tests, the comparison of QCHPs and QCLPs for up to 200,000 and above 200,000 depicts an equal respectively almost equal distribution. Both groups show a majority (77 % QCHPs, 74 % QCLPs) of QC labs with up to 200,000 batches compared to above 200,000. However, as it does not distinguish QCHPs from QCLPs it only represents the data characteristic of all QC labs of the data basis.
Based on the discussed commonalities between QCHPs and QCLPs related to the *Economy of Scale* proposition P6 cannot be rejected. The between groups and the within group comparison does not lead to a striking pattern for QCHPs and QCLPs. The analysis indicates that the *Economy of Scale* does not drive QC lab effectiveness. Table 39 depicts the *Economy of Scale* of the QCHPs and QCLPs. All aspects outlined above are highlighted in bold.

Table 39: Economy of scale of above and below median performing QC labs

Category	Dimension	Characteristic	n (QCHP)	n (QCLP)	Between Groups		Within Group	
					QCHP	QCLP	QCHP	QCLP
Economy of Scale	No. of Batches processed	Up to 8,000	17	14	55 %	45 %	**65 %**	52 %
		Above 8,000	9	13	41 %	59 %	35 %	48 %
	No of Tests	Up to 200,000	20	20	50 %	50 %	**77 %**	**74 %**
		Above 200,000	6	7	46 %	54 %	23 %	26 %

The category *Technology & Innovation* includes three dimensions: age of instruments, age of methods, and automation. The proposition P7 related to the innovation structure is outlined below.

> *P7: The technology and innovation of the QC lab has no impact on the QC lab effectiveness.*

Comparing QCHPs and QCLPs regarding the age of instruments, both groups do not show substantial differences. 84 % of the QCHPs and 78 % of the QCLPs work with old equipment. The distribution of QCHPs and QCLPs for new and old equipment is closely linked to the aspect outlined above. The distribution of QCHPs and QCLPs for new equipment is almost equal. For old equipment the distribution is equal. The same relation applies to the age of methods, too. 92 % of QCHPs and 89 % of QCLPs use old methods. The distribution of new and old methods is the same depicted for age of instruments. New methods are almost equally distributed across QCHPs and QCLPs. Old methods are equally distributed across QCHPs and QCLPs. However, the dimension automation shows differences between QCHPs and QCLPs. While QCHPs are equally distributed across a high and low level of automation, 67 % of the QCLPs have a low level of automation. Consequently, for the high automation category the QCHPs show a higher proportion of QC labs (59 %). The proportion of QCLPs for the low automation category is 58 %.
The discussed differences and commonalities between QCHPs and QCLPs related to the *Technology & Innovation* structure suggest rejecting proposition P7. However, this is solely driven by the level of automation. QCHPs have a higher level of automation compared to QCLPs. For age of instruments and age of methods no major difference is present. Table 40 depicts the *Technology & Innovation* structure of the QCHPs and QCLPs. All aspects outlined above are highlighted in bold.

Table 40: Technology and innovation of above and below median performing QC labs

Category	Dimension	Characteristic	n (QCHP)	n (QCLP)	Between Groups		Within Group	
					QCHP	QCLP	QCHP	QCLP
Technology & Innovation	Age of Instruments[1]	New[2]	4	6	40 %	60 %	16 %	22 %
		Old[3]	21	21	50 %	50 %	**84 %**	**78 %**
	Age of Methods	New[2, 4]	2	3	40 %	60 %	8 %	11 %
		Old[3]	24	24	50 %	50 %	**92 %**	**89 %**
	Automation	High[5]	13	9	**59 %**	41 %	50 %	33 %
		Low[6]	13	18	42 %	**58 %**	50 %	**67 %**

[1] Number of labs does not add up to total number of QCHPs (26) due to missing data points
[2] New is defined as more than 50 % of the instruments or methods less than five years old
[3] Old is defined as more than 50 % of the instruments or methods more than five years old
[4] Characteristic included for completeness of this dimension although required number of labs not greater than 5
[5] High is defined as more than 50 % of instruments (partially or fully) automated
[6] Low is defined as more than 50 % of instruments manually operated

4.2.3 Environmental Contingencies

The analysis of the environmental contingencies addresses propositions P2 and P8.The environmental contingencies include two categories: *Geographical Location* and *Regulatory Approval*. The following paragraphs discuss both categories regarding QCHPs and QCLPs.

The *Geographical Location* comprises three dimensions: country, regional distribution, and cost location. The proposition P2 related to the *Geographical Location* is outlined below.

> *P2: The geographical location of the QC lab has no impact on the QC lab effectiveness.*

The comparison of QCHPs and QCLPs regarding their regional distribution reveals that both groups are equally represented in the analyzed regions. In Europe and North America about half of the QC labs are QCHPs and half of the QC labs represent QCLPs. In Europe 54 % of the QC labs are QCLPs. 57 % of the North American QC labs are QCHPs. The within group comparison illustrates the high proportion of QC labs from Europe in the overall data basis. The distribution of QCHPs and QCLPs regarding high versus low cost location also shows an equal representation of QCHPs and QCLPs in both categories. 51 % of the high cost QC labs belong to the group of QCLPs. In low cost category 50 % of the QC labs represent QCHPs and 50 % QCLPs. No dimension of the category *Geographical Location* shows striking differences between QCHPs and QCLPs.

Based on the discussed commonalities between QCHPs and QCLPs related to their *Geographical Location* proposition P2 cannot be rejected. There is no indication that QC lab effectiveness is driven by the *Geographical Location*. Table 41 depicts the *Geographical Location* of the QCHPs and QCLPs. The characteristics that do not meet the

minimum threshold of five QC labs are not included. Consequently, no conclusions can be made for individual countries. All aspects outlined above are highlighted in bold.

Table 41: Geographical location of above and below median performing QC labs

Category	Dimension	Characteristic	n (QCHP)	n (QCLP)	Between Groups		Within Group	
					QCHP	QCLP	QCHP	QCLP
Geographical Location	Regional Distribution	Europe	18	21	46 %	**54 %**	69 %	78 %
		North America	4	3	**57 %**	43 %	15 %	11 %
	Cost Location	High Cost[1]	21	22	49 %	**51 %**	81 %	81 %
		Low Cost[2]	5	5	**50 %**	**50 %**	19 %	19 %

[1] High Cost Countries: Austria, Belgium, Canada, Finland, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, Switzerland, USA
[2] Low Cost Countries: Brazil, China, India, Mexico, Poland, Portugal, Puerto Rico, Slovenia

The category *Regulatory Approval* includes four dimensions: US, EU, China, and Japan. The proposition P8 related to the *Regulatory Approval* is outlined below.

> *P8: The regulatory approval of the QC lab has no impact on the QC lab effectiveness.*

Comparing QCHPs and QCLPs and their regulatory approvals across the world, no major differences can be noted. All four analyzed regulatory approvals show an almost equal distribution of QCHPs and QCLPs. The proportion of QCHPs for all four regulatory approval ranges from 49 % to 58 %. The within group comparison reveals that QCHPs and QCLPs both have a strong focus on the European and US market.
The discussed commonalities between QCHPs and QCLPs related to the *Regulatory Approval* suggest not rejecting proposition P8. Table 42 exhibits the *Regulatory Approval* of the QCHPs and QCLPs. All aspects outlined above are highlighted in bold.

Table 42: Regulatory approval of above and below median performing QC labs

Category	Dimension	Characteristic	n (QCHP)	n (QCLP)	Between Groups		Within Group	
					QCHP	QCLP	QCHP	QCLP
Regulatory Approval	US	FDA Approved	20	19	51 %	49 %	77 %	70 %
	EU	EMA Approved	22	23	**49 %**	51 %	85 %	85 %
	China	CFDA Approved	15	11	**58 %**	42 %	58 %	41 %
	Japan	PMDA Approved	18	14	56 %	44 %	69 %	52 %

FDA: US Food and Drug Administration, CFDA: China Food and Drug Administration, EMA: European Medicines Agency, PMDA: Pharmaceuticals and Medical Devices Agency

4.2.4 Operating Context Conclusion

The analyses in chapter 4.2.2 and 4.2.3 allowed a better understanding of the operating context of QC labs and its impact on QC effectiveness. In total, the propositions addressed 17 different context factors of QC labs that were summarized in seven distinct categories. For each of these seven categories a proposition was determined (P2 to P8). Each of these categories was then analyzed separately and it was concluded whether the proposition can or cannot be rejected.

The proposition P1 combines all seven categories (P2 to P8). It addresses whether QC labs from different a *Geographical Location* with a different *Portfolio Complexity*, different *Test Allocation Strategy*, different *Organizational Scale*, different *Economy of Scale*, and different *Technology & Innovation* structure show differing QC lab effectiveness results. In addition, it includes the impact driven by the *Regulatory Approval*. The proposition P1 related to the operating context is outlined below.

P1: The operating context of a QC lab has no impact on the QC lab effectiveness.

The results in chapter 4.2.2 and 4.2.3 suggest rejecting the proposition P1. The operating context of a QC lab seems to have an impact on the QC lab effectiveness. The results of the descriptive analysis are expanded in chapter 5 within the qualitative case study research. Table 43 exhibits an overview of all propositions discussed before, their dimensions, and the decisions whether to reject the propositions or not.

Table 43: Summary of propositions and conclusion

No.	Proposition	Dimensions	P_0
P1	The operating context of a QC lab has no impact on the QC lab effectiveness.	Summary of P2 to P8	Rejected
P2	The geographical location of the QC lab has no impact on the QC lab effectiveness.	Country, Regional Distribution, Cost Location	Not rejected
P3	The portfolio complexity of the QC lab has no impact on the QC lab effectiveness.	Drug Substance Type, Drug Product Type, No. of final Drug Product Types Tested	Rejected
P4	The test allocation strategy of the QC lab has no impact on the QC lab effectiveness.	Centralization, Degree of Centralization	Rejected
P5	The organizational scale of the QC lab and site has no impact on the QC lab effectiveness.	QC FTEs, Site FTEs	Rejected
P6	The economy of scale of the QC lab has no impact on the QC lab effectiveness.	No. of Batches processed, No. of Tests	Not rejected
P7	The technology and innovation of the QC lab has no impact on the QC lab effectiveness.	Age of Instruments, Age of Methods, Automation	Rejected
P8	The regulatory approval of the QC lab has no impact on the QC lab effectiveness.	US Approval, EU Approval, China Approval, Japan Approval	Not rejected

4.3 QC Lab Effectiveness and Enabler System Relation

This chapter examines the QC lab effectiveness, enabler system, and their relation. First, the analysis approach is described. Second, a detailed analysis of QC lab effectiveness and its sub-categories is provided. Third, the inter-dependencies of the enabler system are elaborated. Fourth, the relation between the QC lab effectiveness and the enabler system is analyzed. Fifth, the enabler system configuration of QC Lab Effectiveness High Performers (QCHPs) is compared to the configuration of QC Lab Effectiveness Low Performers (QCLPs).

4.3.1 Analysis Approach

Chapter 3.4 outlined hypotheses related to the PMM dimensions. To understand the QC lab effectiveness, the enabler system, and their relation better, in the following multiple quantitative analyses are conducted. The 53 QC labs described in chapter 4.1.4 build the basis of the quantitative analyses. At the point of analysis the data basis of 53 QC labs limit the ability to distinguish different operating contexts for the subsequent analyses. To allow generalization of the findings to a broad set of pharmaceutical QC labs the results of chapter 4.2 are not used to separate the overall sample into different groups. Consequently, the analyses in this chapter are conducted with the overall sample of 53 QC labs if no other indication is given. Table 44 shows all hypotheses and the applied statistical methods.

Table 44: Hypotheses and corresponding statistical method

No.	Hypothesis	Method
H1	QC lab effectiveness high performers do not have a significantly higher QC lab effectiveness compared to QC lab effectiveness low performers.	T-test
H1a	QC lab effectiveness high performers do not have a significantly higher quality performance compared to QC lab effectiveness low performers.	T-test
H1b	QC lab effectiveness high performers do not have a significantly higher service performance compared to QC lab effectiveness low performers.	T-test
H2a	The implementation of the management enabler system does not have a positive impact on the implementation of the technical enabler system.	Linear Regression
H2b	The implementation of all three individual dimensions of the management enabler system does not have a positive impact on the implementation of the technical enabler system.	Linear Regression, Multiple Linear Regression
H3	The implementation of the technical enabler system does not have a positive impact on the QC lab effectiveness.	Linear Regression
H4	The implementation of the management enabler system does not have a positive impact on the QC lab effectiveness.	Linear Regression
H5	The implementation of the management enabler system and the technical enabler system do not have a positive impact on the QC lab effectiveness.	Multiple Linear Regression
H6a	The QC lab effectiveness high performers do not have a significantly higher average implementation of all system enabler dimensions compared to QC lab effectiveness low performers.	T-test
H6b	The QC lab effectiveness high performers do not have a significantly higher integrated implementation of all system enabler dimensions compared to QC lab effectiveness low performers.	Pearson Correlation Analysis, T-test

The author of this research acknowledges the discussion between scholars on the value of dichotomization of variables. Cohen (1983) and DeCoster, Gallucci, and Iselin (2011) emphasize that the statistical effect size may be reduced or screwed when continuous variables are changed to artificial categorical variables (dichotomous variables). However, the statistical methods applied in this research are only mentioned in the context of reduced effect size.

In Operations Management (OM) many scholars use the dichotomization approach for their data analyses (Bortolotti et al., 2015; Ferdows & De Meyer, 1990; Power, Sohal, Amrik, & Rahman, 2001; R. E. White et al., 1999). Bortolotti, Boscari, and Denese (2015) distinguish companies with above and below median implementation of enablers as well as above and below median performance. Power, Amrik, and Rahman (2001) use the mean to separate agile from less agile companies. Ferdows and De Meyer (1990) sharpen their results by comparing above average improving companies with not improving companies. White, Pearson, and Wilson (1999) follow this approach and elaborate more distinct results by comparing the bottom and top end of the organizational scale (i.e. large vs. small manufacturers).

Unless the dichotomization does not meet the normal distribution of the original continuous variable dichotomization is seen as a reasonable approach. It allows a better understanding of the analyzed data by comparing distinct groups to each other. In addition, conclusions can be easily transferred to practice. Specifically when differentiating high from low performance the split into two groups can be seen as reasonable. The reduced effect size mentioned above is coherent with a more conservative analysis approach of distinguishing above and below median groups (DeCoster et al., 2011). In addition, the impact of outliers has a much greater impact on the continuous variables than on dichotomous variables (Kutner, Nachtsheim, Neter, & Li, 2005). Due to the limited number of datasets for this research, the impact of outliers would have a greater impact on the results than dichotomization. Consequently, QC Lab Effectiveness High Performers (QCHPs) are defined as a group of above median performing QC labs regarding the aggregated QC lab effectiveness performance defined in chapter 4.1.5. The below median performing QC labs constitute the QC Lab Effectiveness Low Performers (QCLPs). The categorization allows analyzing hypotheses H1, H1a, H1b, H6a, and H6b. For all analyses that do not require separating high performing from low performing QC labs the dichotomous variable is omitted. For hypotheses H2a, H2b, H3, H4, and H5 QC the original continuous variable QC lab effectiveness is used.

To test hypotheses H1, H1a, H1b, H6a, and H6b an independent samples T-test is performed. The T-test allows examining whether two independent groups have a significant mean difference of a continuous variable. The normal distribution of the continuous variable for both groups and equal variance of the continuous variable for the two groups are prerequisite for the credibility of the test results (Weinberg & Abramowitz, 2008). A combination of the Shapiro-Wilk test ($p > 0.05$) and the graphical interpretation of a histogram and a Q-Q Plot allow judging the normal distribution of the continuous variable for the two groups. The assumption of equal variances of the continuous variable is judged with the Levene's test ($p > 0.05$).

To test hypotheses H2a, parts of H2b, H3, and H4 linear regressions are performed. A linear regression allows determining how much variation of the dependent variable (DV) can be explained by the independent variables (IVs) (Huizingh, 2008). The prerequisites of a normally distributed DV and IV, a linear relation between the IV and DV, little or no autocorrelation, and homoscedasticity need to be met to allow credibility of the results (Brosius, 2013; Weinberg & Abramowitz, 2008). A combination of the Shapiro-Wilk test ($p > 0.05$) and the graphical interpretation of a histogram and a Q-Q Plot allow judging the normal distribution of the variables. The linear relation between the IV and DV is confirmed using a scatter plot. The Durbin-Watson test allows identifying autocorrelation. A Durbin-Watson value of 2 means no autocorrelation; a value between 1.5 and 2.5 supports the assumption of little autocorrelation (Brosius, 2013). Little autocorrelation allows proceeding with the analysis. A residual plot that shows no heteroscedastic pattern confirms homoscedasticity.
To test parts of the outlined hypothesis H2b and hypothesis H5 a multiple linear regression is performed. Next to the prerequisites of a linear regression a multiple linear regression has one additional prerequisite. The IVs need to be analyzed for multi-collinearity. It has no impact on the credibility of the degree of determination (R^2) of the model, but the beta coefficients may be distorted if multi-collinearity exists (Brosius, 2013). Therefore, multi-collinearity needs to be considered for the interpretation of the multiple linear regression results. The Variance Inflation Factor (VIF) in combination with a correlation analysis between the IVs allows identifying existing multi-collinearity. A VIF below 10 indicates no multi-collinearity exists (Brosius, 2013).

4.3.2 Understanding QC Lab Effectiveness

This chapter is focused on understanding QC lab effectiveness and its variation between QCHPs and QCLPs better. In the following hypotheses H1, H1a, and H1b are examined.

> *H1: QC lab effectiveness high performers do not have a significantly higher QC lab effectiveness compared to QC lab effectiveness low performers.*
>
> *H1a: QC lab effectiveness high performers do not have a significantly higher quality performance compared to QC lab effectiveness low performers.*
>
> *H1b: QC lab effectiveness high performers do not have a significantly higher service performance compared to QC lab effectiveness low performers.*

Due to the calculation of QCHPs as the above median QC lab effectiveness performers, it is self-evident that the mean QC lab effectiveness of QCHPs is higher than the mean of the QCLPs (below median performers). In addition, caused by the calculation of QC lab effectiveness as an aggregation of quality and service performance, it seems coherent that the mean for both performance dimensions shows a higher value for QCHPs compared to QCLPs. However, the latter is likely but most not occur. A detailed overview of the calculation approach of QC lab effectiveness can be found in chapter 4.1.5.

In the following paragraphs, the focus of the analysis is on the question whether the mean difference of QC lab effectiveness, quality performance, and service performance is significant for QCHPs compared to QCLPs. The calculation of the quality performance and service performance follows the same approach as described for QC lab effectiveness in chapter 4.1.5. The minimum indicator threshold to calculate the quality and service performance was set to 50 %. The minimum indicator threshold for QC lab effectiveness remained at 70%. The lower threshold for the quality and service performance was mainly caused by the low number of indicators in the service performance dimension. For the service performance only two indicators are aggregated to a normalized overall service performance (cf. chapter 4.1.5). For the quality performance eight indicators are aggregated to a normalized overall quality performance (cf. chapter 4.1.5). For consistency between the two performance dimensions of the aggregated QC lab effectiveness, the quality performance followed the minimum indicator threshold of the service performance. First, the assumption of normal distribution of the QC lab effectiveness, quality performance, and service performance were analyzed. For the quality and service performance the normal distribution was met for both groups, QCHPs and QCLPs. In all Shapiro-Wilk tests the analysis determined a p-value > 0.05. For QC lab effectiveness this assumption was not met for both groups. A square root and logarithmic transformation did not improve the non-linear distribution significantly. However, a quantile rank transformation of the QC lab effectiveness resolved this issue. Some scholars argue that a quantile-ranked transformation into a uniform distribution allows proceeding with the analysis (Zimmerman & Zumbo, 2005). Among others, Boyer and Lewis (2002) stress that a transformation into a uniform distribution forces correlations occur. Because uniform distribution is not equal to the initial T-test assumption of normal distribution and the near normal distribution of QC lab effectiveness for QCHPs and QCLPs the transformation effort was terminated. Instead, the near normal distribution of QC lab effectiveness was seen as sufficient. Weinberg and Abramowitz (2008) stress that non-normal distributions do not impact the test results in case the parent population counts 30 or more. In this research the parent population totals at 53 QC labs. Consequently, for this analysis the researcher followed the widely accepted minor violation of the normal distribution assumption and used the non-transformed QC lab effectiveness. Second, the Levene's test for equality of variances was performed for QC lab effectiveness, quality performance, and service performance. All three tests showed a p-value > 0.05. Therefore, equal variances for QCHPs and QCLPs can be assumed. With the exception of the normal distribution of QC lab effectiveness all assumptions for the T-test were met.

The T-test result reveals that QCHPs have a significantly higher QC lab effectiveness compared to the QCLPs. Due to the normalization the QC lab effectiveness can only result in a value between 0 and 1 (cf. chapter 4.1.5). The mean QC lab effectiveness of QCHPs totals at 0.64, whereas the QCLPs mean is 0.39. The difference between QCHPs and QCLPs is 0.25 and significant at p = 0.01. Figure 15 visualizes the distribution of QC lab effectiveness separated by above and below median performing QC labs.

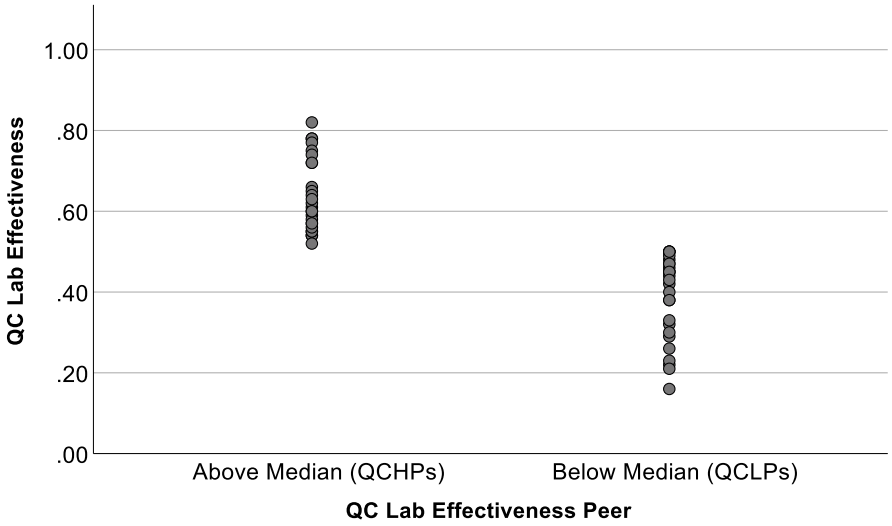

Figure 15: QC lab effectiveness for above and below median performer

The T-test results show that the QCHPs also have a significantly higher quality and service performance compared to QCLPs. The mean quality performance of QCHPs is 0.65, the mean quality performance of QCLPs is 0.39. The mean service performance of QCHPs totals at 0.61. QCLPs achieve a mean service performance of 0.45. Comparing the two performance dimensions it can be noted that the mean difference for the quality performance exceeds the difference for the service performance. Both T-test results are significant at p = 0.01.

Due to the differing calculation of QC lab effectiveness (aggregating all individual indicators together) and an aggregated quality and service performance in figure 16 some QCLPs have a higher quality or service performance compared to QCHPs. Separately aggregating the quality and service indicators is not part of the overall QC lab effectiveness calculation to avoid unwanted higher weighting of the dimension service with substantially fewer indicators (cf. chapter 4.1.5). However, in the present analysis the aggregation into a quality and service performance allows a more practical performance understanding than comparing each individual indicator separately. In addition, unwanted weighting is not caused since the quality and service performance dimensions are not further aggregated.

The present analysis reveals a significantly higher standard deviation for the service performance (cf. figure 16 and table 45) compared to the quality performance. Both QCHPs and QCLPs show this pattern. The distribution of the quality and service performance for QCHPs and QCLPs is exhibited in figure 16.

The reduced number of QCHPs and QCLPs for the service performance is notable. The service indicators *Adherence to Lead Time (ATL)* and *Adherence to Schedule (ATS)* were reported less frequently than most of the other performance indicators. Only 15 out of 26 QCHPs provided a service indicator. 17 out of 27 QCLPs provided one service indicator.

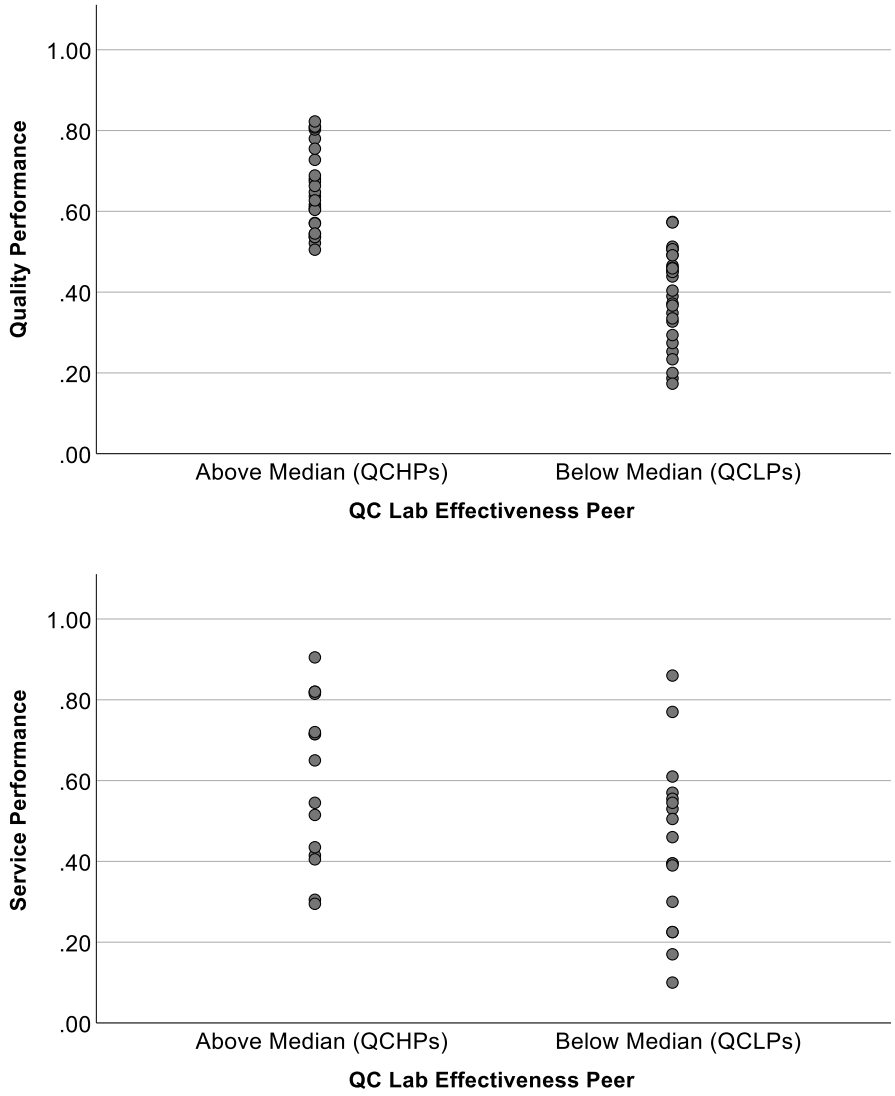

Figure 16 Quality and service performance for above and below median performer

Table 45 depicts the results of the T-test for hypotheses H1, H1a, and H1b. The significant results at p = 0.01 are highlighted in bold. Hypotheses H1, H1a, and H1b can all be rejected. QCHPs have a significantly higher QC lab effectiveness (H1), a significantly higher quality performance (H1a), and a significantly higher service performance (H1b).

Table 45: Hypotheses H1, H1a, and H1b results

Hypo-thesis	Dependent Variable	n QCHP	Average QCHP	Std. Deviation QCHP	n QCLP	Average QCLP	Std. Deviation QCLP	t-value	Sig. (2-tailed)
H1	QC Lab Effectiveness	26	.64	.09	27	.39	.10	9.415	**.000**
H1a	Quality Performance	26	.65	.10	27	.39	.12	8.690	**.000**
H1b	Service Performance	15	.61	.20	17	.45	.21	2.186	**.000**

4.3.3 Management and Technical Enabler System Relation

This chapter is focused on understanding the inter- and intra-dependencies of the MES and TES. First, hypothesis H2a is discussed. The analysis determines whether the QC lab data basis supports the common understanding of the management system as the foundation of the PMM. Hypothesis H2b addresses the intra-dependencies of the MES enabler dimensions. It is focused on the question whether one dimension of the management enabler system plays an exceptional role.

> *H2a: The implementation of the management enabler system does not have a positive impact on the implementation of the technical enabler system.*
>
> *H2b: The implementation of the individual dimension of the management enabler system does not have a positive impact on the implementation of the technical enabler system.*

The objective of building five regression models is to determine in detail how much variation of the TES can be explained by the MES and its three dimensions: *Management Commitment & Company Culture* (1), *Employee Involvement & Continuous Improvement* (2), and *Functional Integration & Qualification* (3) (cf. chapter 3.2.2). First, the analysis addresses hypothesis H2a to determine how much variation of the TES can be explained by the MES (model 1). Second, addressing hypothesis H2b models 2, 3, and 4 analyze the three dimensions of the MES separately. The objective is to provide more details than in model 1. The analysis is also focused on identifying whether there is consistency between the results of models 1, 2, 3, and 4. Third, model 5 addresses hypothesis H2b by analyzing all three dimensions of the MES in parallel. Therefore, model 5 focuses on the intra-dependencies of the dimensions within the MES as predictor for the TES. The aim is to determine whether the interaction between the three dimensions influences the degree how much variation can be explained by each of them. Table 46 depicts an overview of the five regression models that are elaborated in the following paragraphs. First, all variables used to test H2a and H2b are analyzed to investigated whether they meet the prerequisites to conduct a regression analysis. Then, the results of the regression models are elaborated.

Table 46: Regression models to test hypotheses H2a and H2b

Model	Hypo-thesis	Method	Independent Variable(s)	Dependent Variable
1	H2a	LR	Management Enabler System	Technical Enabler System
2	H2b	LR	Management Commitment & Company Culture	
3		LR	Employee Involvement & Continuous Improvement	
4		LR	Functional Integration & Qualification	
5		MLR	Management Commitment & Company Culture Employee Involvement & Continuous Improvement Functional Integration & Qualification	

LR: Linear Regression, MLR: Multiple Linear Regression

A combination of the Shapiro-Wilk test ($p > 0.05$) and the graphical interpretation of a histogram and a Q-Q Plot allowed judging the normal distribution of the IVs and DV of the different regression models outlined in table 46. With the exception of the *Employee Involvement & Continuous Improvement* all variables were normally distributed. The IV *Employee Involvement & Continuous Improvement* showed a slightly positive skew. However, due to the near normal distribution of this IV it was not transformed.
The linear relation between the IVs and DV for the different regression models was confirmed using a scatter plot. The Durbin-Watson test allowed identifying autocorrelation. All Durbin-Watson values for the different regression models ranged between 1.765 and 2.365. Following Brosius (2013) this result supports the assumption of only little autocorrelation. Residual plots that showed no heteroscedastic patterns confirmed homoscedasticity for all regression models. For the multiple linear regression in model 5 the Variance Inflation Factor (VIF) in combination with a correlation analysis allowed investigating the IVs on multi-collinearity. Significant correlations between the IVs of model 5 exist. However, all VIF showed a value below 1.747. Following Brosius (2013) no multi-collinearity exists as all three VIF are significantly below 10. With one exception all assumptions of the linear and multiple linear regression were met. Although the IV *Employee Involvement & Continuous Improvement* only shows a near normal distribution the researcher followed the widely accepted minor violation of the normal distribution assumption and used the non-transformed variable.
Model 1 shows that the MES explains 60.0 % of the variation of the TES at a significance level $p = 0.01$. Figure 17 visualizes the relation between the MES and TES. A QC lab with a high implementation of the MES tends to have also a high implementation of the TES. A low implementation of MES is accompanied with a low implementation of the TES.

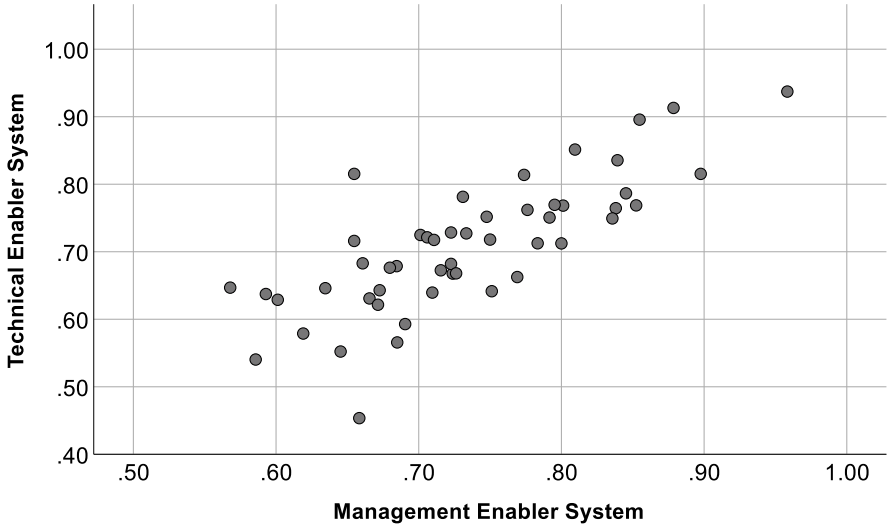

Figure 17: Relation between the management and the technical enabler system

The models 2, 3, and 4 focus on the individual relation between the TES and the three MES enabler dimensions: Management *Commitment & Company Culture (1)*, *Employee Involvement & Continuous Improvement (2),* and *Functional Integration & Qualification (3).* All three models show a significant relation at $p = 0.01$ between the enabler dimension and

the TES. However, the degree of explanation of the models differs. Comparing model 2, 3, and 4 it can be noted that model 3 has the highest degree of explanation. *Employee Involvement & Continuous Improvement* explains 50.7 % of the variation of the TES. Model 4 shows that *Functional Integration & Qualification* explains 45.6 % of the variation of the TES. *Management Commitment & Company Culture* explains only 27.5 % of the variation of the TES (model 2). To deepen the understanding of the relation between the MES enabler dimensions and the TES model 5 focused on the interaction between the three MES enabler dimensions and the effect of it on their relation with the TES. For the multiple linear regression the enter method of the IVs was applied in model 5. Model 5 determines that the three MES enabler dimensions explain 61 % of the variance of the TES. The model 5 is significant at p = 0.01. The MES dimensions *Employee Involvement & Continuous Improvement* and *Functional Integration & Qualification* are significant at p = 0.01. The MES *dimensions Management Commitment & Company Culture* does not show a significant relation with the TES in model 5. It cannot be concluded that one MES dimension plays an exceptional role. However, model 5 shows that the relation of model 1 is mainly driven by the two MES dimensions *Employee Involvement & Continuous Improvement* and *Functional Integration & Qualification*.

The high correlations of the MES dimensions with the TES dimensions during the construct validity analysis were a first indication of the MES importance (cf. chapter 4.1.6). The regression analysis confirms this presumption. Table 47 depicts the results of the five regression models to test hypotheses H2a and H2b. The significant results at p = 0.01 are highlighted in bold. Both hypotheses (H2a and H2b) can be rejected. The implementation of the MES has a positive impact on the implementation of the TES (H2a). All three MES dimensions have a partly significant impact on the implementation of the TES (H2b).

Table 47: Hypotheses H2a and H2b results

Model	Independent Variable(s)	Model Summary (n=50)				Coefficient		
		R Square	Adjusted R Square	Sig.	F-value	Stand. Coef. Beta	t-value	Sig.
1	Management Enabler System	.608	.600	.000	74.528	.780	8.633	**.000**
2	Management Commitment & Company Culture	.289	.275	.000	19.553	.538	4.422	**.000**
3	Employee Involvement & Continuous Improvement	.517	.507	.000	51.354	.719	7.166	**.000**
4	Functional Integration & Qualification	.467	.456	.000	42.127	.684	6.491	**.000**
5	Management Commitment & Company Culture	.634	.610	.000	26.598	.100	.895	.376
	Employee Involvement & Continuous Improvement					.461	4.087	**.000**
	Functional Integration & Qualification					.365	3.094	**.003**

DV: Technical Enabler System

4.3.4 Enabler System Relation with QC Lab Effectiveness

Reflecting the widely discussed scholars' understanding to associate a high enabler implementation with high performance, this chapter analyzes the relation between the enabler system and the QC lab effectiveness. Hypotheses H3, H4, and H5 are outlined below.

H3: The implementation of the technical enabler system does not have a positive impact on the QC lab effectiveness.

H4: The implementation of the management enabler system does not have a positive impact on the QC lab effectiveness.

H5: The implementation of the management enabler system and the technical enabler system do not have a positive impact on the QC lab effectiveness.

In preparation of analyzing the enabler system relation with QC lab effectiveness a scatter plot for the two variables was built. It indicated that not all 53 QC labs of this research showed the widely acknowledged understanding of the enabler performance relation in the Operations Management (OM) literature (cf. figure 18). Many scholars argue that the enabler system builds the basis of performance (cf. chapter 2.2.2). To understand the enabler performance relation of the data basis better a two-step cluster analysis was conducted. The exploratory technique allows forming distinct groups according to their similarity. The similarity within each cluster is maximized and the difference is maximized between the clusters. The objective of this analysis was to divide the total number of 53 QC labs into groups of QC labs that support or do not support the OM literature. Specifically, the goal of the cluster analysis was to divide the overall number of QC labs into a number of sub-groups (clusters) in case these groups with maximum similarity and difference between each other existed.

The two-step cluster analysis employed the default log-likelihood method. Both variables, QC lab effectiveness and the enabler implementation, were used to build the cluster. The overall enabler implementation represents the average of the MES and TES implementation. To conduct a two-step cluster analysis the continuous variables need to be independent and have a normal distribution (Norusis, 2007). The variables enabler implementation and QC lab effectiveness are independent from each other. The assumption of normal distribution was confirmed for QC lab effectiveness and the overall enabler implementation using the Shapiro-Wilk test ($p > 0.05$) and the graphical interpretation of a histogram and a Q-Q Plot.

The cluster analysis reveals three distinct clusters of which two support the scholars' understanding outlined above. The low QC lab effectiveness, low enabler implementation cluster includes 26 QC labs (cluster 1). The low QC lab effectiveness but high enabler implementation cluster includes 15 QC labs (cluster 2). The remaining nine QC labs are within the high QC lab effectiveness, high enabler implementation cluster (cluster 3). The two-step cluster analysis determines a good cluster quality with a cluster size ratio between

the largest and smallest cluster of 2.89. Figure 18 depicts the three identified clusters regarding enabler implementation and QC lab effectiveness.

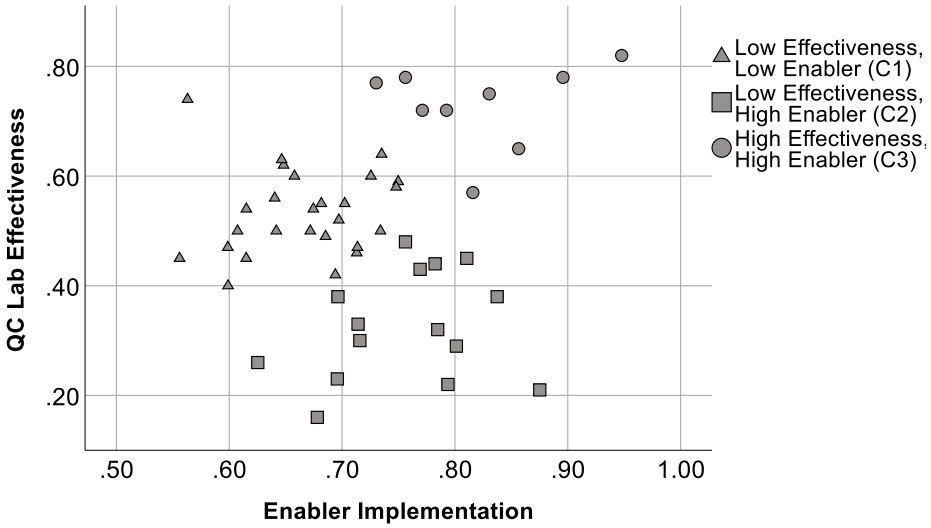

Figure 18: Scatter plot of enabler relation with QC lab effectiveness for three clusters

The subsequent quantitative analysis only includes those QC labs (clusters 1 and 2) supporting the Operations Management (OM) understanding of enablers driving performance. Consequently, 35 QC labs constitute the basis to test hypotheses H3, H4, and H5. The second cluster with high enabler implementation and low QC lab effectiveness is discussed in detail in chapter 5. The qualitative case study approach in chapter 5 aims at a better understanding of cluster 2 with a high enabler implementation but low QC lab effectiveness better. The objective is to determine why the QC labs of this cluster have a high enabler implementation but not a high QC lab effectiveness. It should be noted that no fourth cluster was identified that shows a low enabler implementation and a high QC lab effectiveness. Figure 19 depicts the remaining cluster 1 and cluster 3 that are used in the subsequent analysis.

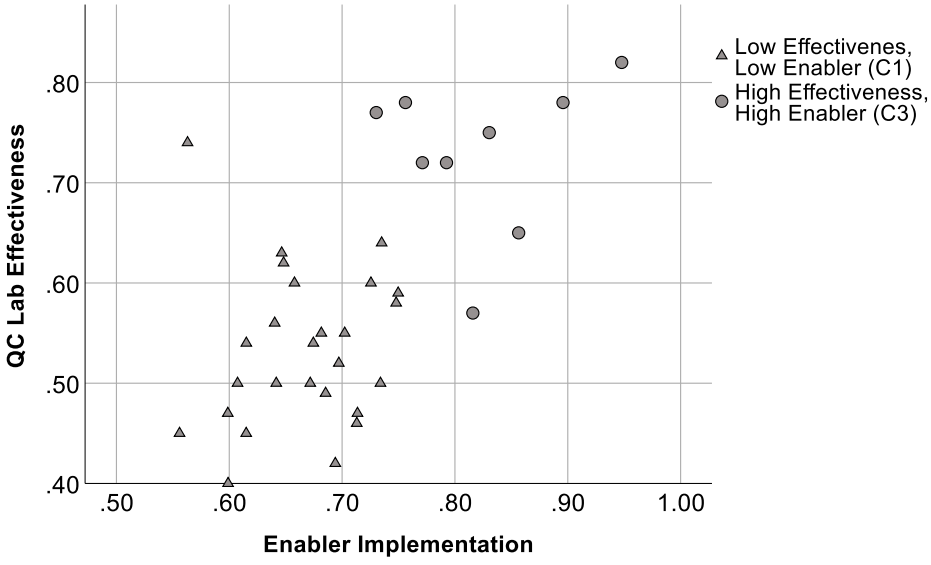

Figure 19: Scatter plot of enabler relation with QC lab effectiveness for two clusters

Table 48 depicts an overview of the three regression models that are elaborated in the following paragraphs. The objective to build three regression models was to determine how much variation of the QC lab effectiveness can be explained by the TES and MES. The analysis approach concurs with the regression models of the preceding analysis. First, the subsequent analysis addresses hypothesis H3 to determine how much variation of QC lab effectiveness can be explained by the TES (model 1). Second, addressing hypothesis H4 model 2 analyzes how much variation can be explained by the MES. Third, model 3 analyzes both TES and MES in parallel. For the multiple linear regression in model 3 the enter method was applied. Combining the TES and MES in one model allows analyzing the inter-dependencies of the two enabler systems and the effect of it on their relation with QC lab effectiveness. The aim is to determine whether the interaction between the two enabler systems influences their relation with QC lab effectiveness and how much variation can be explained by each of them. In the following the prerequisites for the regression models are discussed. Then, the results of the regression models are elaborated.

Table 48: Regression models to test hypotheses H3, H4, and H5

Model	Hypo-thesis	Method	Independent Variable(s)	Dependent Variable
1	H3	LR	Technical Enabler System	QC Lab Effectiveness
2	H4	LR	Management Enabler System	
3	H5	MLR	Management Enabler System Technical Enabler System	

LR: Linear Regression, MLR: Multiple Linear Regression

The Shapiro-Wilk test ($p > 0.05$), the graphical interpretation of a histogram and a Q-Q Plot confirmed the normal distribution of the IVs and DV of the different regression models outlined in table 48. A scatter plot confirmed the linear relation between the IVs and DV for the different regression models. The Durbin-Watson test allowed identifying autocorrelation. The Durbin-Watson values for the different regression models ranged between 1.733 and 1.894. Following Brosius (2013) this result supports the assumption of only little autocorrelation. Residual plots that showed no heteroscedastic patterns confirmed homoscedasticity for all regression models. To identify existing multi-collinearity of the IVs in model 3 the Variance Inflation Factor (VIF) was calculated. In addition, a correlation analysis between the IVs of model 3 was conducted. Coherent with the previous findings of this research the correlation analysis confirmed the strong link between the TES and MES (cf. chapter 4.3.3). However, both VIFs showed a value of 2.559. Following Brosius (2013) no multi-collinearity exists because both VIF are significantly below 10. All assumptions of the linear and multiple linear regression were met.

Model 1 shows that the TES explains 35.4 % of the variation of the QC lab effectiveness at a significance level of $p = 0.01$. A QC lab with a high implementation of the TES tends to have also a high QC lab effectiveness. A low implementation of the TES is accompanied with a low QC lab effectiveness. Figure 20 visualizes the relation analyzed in the regression model 1.

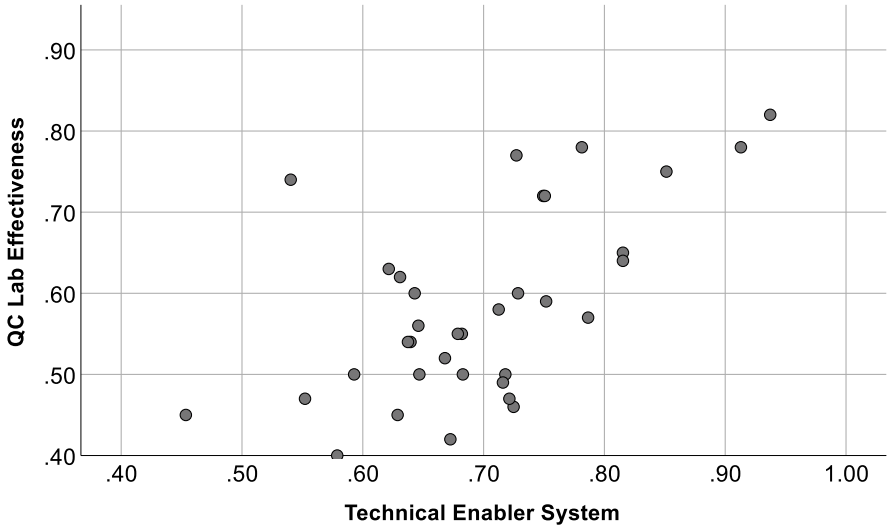

Figure 20: Relation between QC lab effectiveness and the technical enablers

The same relation disclosed for the TES and QC lab effectiveness exists between the MES and QC lab effectiveness. Model 2 determines that the MES explains 29.6 % of the variation of the QC lab effectiveness at a significance level of p = 0.01. Figure 21 visualizes the relation analyzed in the regression model 2.

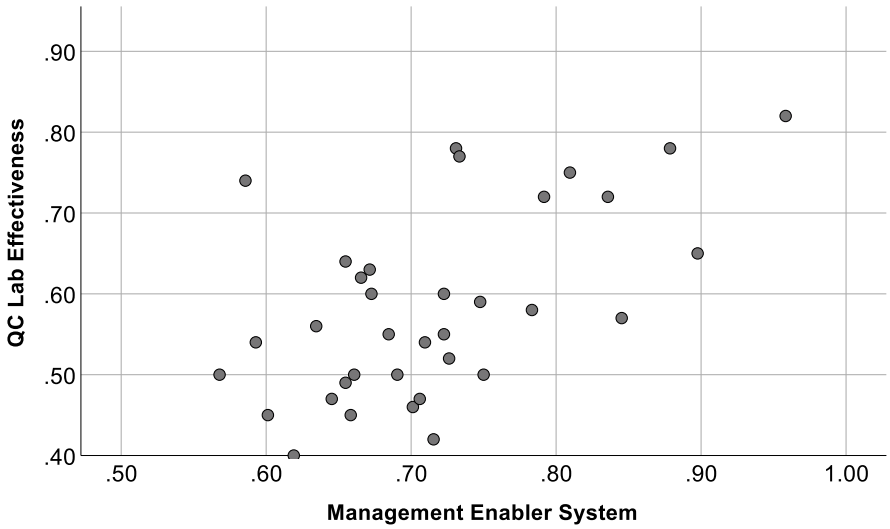

Figure 21: Relation between QC lab effectiveness and the management enablers

In model 3 both variables are entered into the regression providing additional context to the findings of models 1 and 2. The multiple linear regression reveals that a high degree of interaction exists between both systems. This confirms the previous findings on the relation between the MES and TES (cf. chapter 4.3.3). Model 3 is significant at p = 0.01. However, in model 3 the IVs TES and MES are not significant predictors at p = 0.05. Table 49 depicts the results of the three regression models to test hypotheses H3, H4, and H5. The significant results at p = 0.01 are highlighted in bold. Hypotheses H3 and H4 can be rejected. The implementation of the TES (H3) and the MES (H4) have a positive impact on QC lab effectiveness. Hypothesis H5 can also be rejected. However, a closer look at the results shows that only the model to test H5 is significant at p = 0.01. Both variables,

the MES and TES, are not significant at p = 0.01 in model 3. If a lower p-level of 0.1 is considered the TES has a significant impact on QC lab effectiveness. Following Gößler and Grübner (2006) argumentation model 3 may indicate the sequence regarding a supportive relation of the MES, the TES, and QC lab effectiveness. However, this assumption needs to be further analyzed as the time-centric data of this research cannot be used to conclude on a time-sequence between enablers.

Table 49: Hypotheses H3, H4, and H5 results

Model	Independent Variable(s)	Model Summary (n=35)				Coefficient		
		R Square	Adjusted R Square	Sig.	F-value	Stand. Coef. Beta	t-value	Sig.
1	Technical Enabler System	.373	.354	.000	19.614	.611	4.429	**.000**
2	Management Enabler System	.317	.296	.000	15.319	.563	3.914	**.000**
3	Management Enabler System	.392	.354	.000	10.313	.221	1.004	.323
	Technical Enabler System					.438	1.985	.056

DV: QC Lab Effectiveness

4.3.5 Enabler System Configuration of QC Lab Effectiveness High Performers

In this chapter the focus of the analysis shifts back to the QC Lab Effectiveness High Performers (QCHPs). The analysis examines whether QCHPs show a different configuration of the enabler system compared to QC Lab Effectiveness Low Performers (QCLPs). In this context, configuration can be interpreted as enabler dimensions that commonly occur together (cf. chapter 3.4). Hypotheses H6a and H6b are outlined below.

> *H6a: The QC lab effectiveness high performers do not have a significantly higher average implementation of all system enabler dimensions compared to QC lab effectiveness low performers.*

> *H6b: The QC lab effectiveness high performers do not have a significantly higher integrated implementation of all system enabler dimensions compared to QC lab effectiveness low performers.*

Based on the cluster analysis results in chapter 4.3.4 the subset of 35 QC labs was used in the subsequent analyses. Regarding hypothesis H6a, in the following a detailed analysis of the overall enabler implementation, the TES, and MES implementation as well as the implementation of the enabler dimensions of each system is provided. First, the T-Test prerequisites are discussed. Then the results are presented.

The normal distribution of the MES, the TES, and the overall enabler implementation for the subset of 35 QC labs was already confirmed in chapter 4.3.4. However, the T-test assumption of normal distribution refers to the two groups that are compared to each other. Consequently, the MES, the TES, the overall enabler implementation, and the enabler dimensions (e.g. preventive maintenance) were analyzed for QCHPs and QCLPs

separately. For the MES and the overall enabler implementation the normal distribution was met for both groups, QCHPs and QCLPs. In all Shapiro-Wilk tests the analysis determined a p-value > 0.05. For the TES the normal distribution was only met for the QCHPs. For QCHPs four enabler dimensions were not normally distributed. *Housekeeping*, *Process Management*, *Planning Adherence*, and *Visual Management* violated the assumption for QCHPs. For QCLPs two enabler dimensions were not normality distributed. *Visual Management* and *Functional Integration & Qualification* violated the assumption for QCLPs. However, the near normal distribution of the TES for QCLPs and the above-outlined enabler dimensions was seen as sufficient. Weinberg and Abramowitz (2008) stress that non-normal distributions do not impact the test results in case the parent population counts 30 or more. After the cluster analysis the parent population totals at 35 QC labs. Consequently, for this analysis the researcher followed the widely accepted minor violation of the normal distribution assumption and used the non-transformed variables. Second, the Levene's test for equality of variances was performed. The result of the Levene's test is depicted in the footnote of table 50 and table 51. 3 out of 16 variables do not meet the assumption of equal variances. However, if both groups have equal or almost equal size the violation does not impact the test result (Glass, Peckham, & Sanders, 1972; Weinberg & Abramowitz, 2008). In this analysis both groups are of almost equal size (17 QCHPs and 18 QCLPs). Consequently, the assumption of equal variance can be violated.

The T-test result reveals that the QCHPs have a significantly higher average implementation of all enablers. The same applies to the TES. Both results are significant at p = 0.01. For the MES the QCHPs also have a higher implementation. However, this result is only significant at p = 0.05. The normalized enabler implementation is a value between 0 and 1. The overall average enabler implementation of QCHPs totals at 0.75. QCLPs achieve a lower average implementation level of 0.66. The two T-tests focused on the MES and TES show that there is no difference in the implementation level for QCHPs. In both system, the MES and TES, the QCHPs have an average implementation of 0.75. The QCLPs have a slightly higher implementation of the MES (0.68) compared to the TES (0.65). Table 50 summarizes the results as described above. All significant results at p = 0.01 are highlighted in bold.

Table 50: Hypothesis H6a results part I

Dependent Variable	n QCHP	Average QCHP	Std. Deviation QCHP	n QCLP	Average QCLP	Std. Deviation QCLP	t-value	Sig. (2-tailed)
All Enablers[1]	17	.75	.10	18	.66	.05	3.090	**.005**
Technical Enabler System	17	.75	.11	18	.65	.07	3.123	**.004**
Management Enabler System[1]	17	.75	.11	18	.68	.05	2.653	.015

[1] Equal variances not assumed

Next to the average implementation of all enablers, the TES, and MES for QCHPs and QCLPs the enabler dimensions were also tested individually. This allows a better

understanding of the differences within the TES and MES. Generally, QCHPs have a higher average implementation level compared to the QCLPs in all dimensions. However, not all results are significant. In *Visual Management* the QCLPs do not show a significantly lower implementation compared to the QCHPs. In addition, the standard deviation for both peer-groups is very high. This can be explained by the nature of how *Visual Management* was measured for this research. It is a combination of two individual enablers focusing on visualizing current performance and performance objectives. In reality QCHPs might do additional activities in this context.

In 7 out of 10 enabler dimensions of the TES the QCHPs have a significantly higher implementation compared to QCLPs at p = 0.05. QCHPs outperform QCLPs in *Technology Assessment & Usage*, *Housekeeping*, *Process Management*, *Standardization & Simplification*, *Pull Approach*, *Layout Optimization*, and *Planning Adherence*. Within the MES the QCHPs have a significantly higher implementation in 2 out of 3 dimensions. The significantly higher implementation of QCHPs applies to *Employee Involvement & Continuous Improvement* and *Functional Integration & Qualification* at p = 0.05. Table 51 summarizes the results. All significant results at p = 0.05 are highlighted in bold.

Table 51: Hypothesis H6a results part II

	Dependent Variable	n QCHP	Average QCHP	Std. Deviation QCHP	n QCLP	Average QCLP	Std. Deviation QCLP	t-value	Sig. (2-tailed)
TES	Prev. Maintenance	17	.72	.15	18	.69	.12	.626	.536
	Tech. Assess. & Usage[1]	17	.64	.12	18	.56	.06	2.372	**.027**
	Housekeeping	17	.86	.13	18	.73	.19	2.315	**.027**
	Process Management	17	.79	.12	18	.69	.12	2.420	**.021**
	Standardization & Simplif.	17	.83	.13	18	.73	.11	2.399	**.022**
	Set-up Time Reduction	17	.66	.19	18	.55	.16	1.830	.076
	Pull Approach	17	.74	.19	18	.60	.17	2.353	**.025**
	Layout Optimization	17	.75	.14	18	.64	.11	2.436	**.020**
	Planning Adherence	17	.78	.14	18	.67	.13	2.542	**.016**
	Visual Management	17	.69	.30	18	.64	.26	.528	.601
MES	Mgmt. Com. & Co. Cult.[1]	17	.79	.11	18	.75	.06	1.073	.294
	Empl. Involvement & CI[1]	17	.69	.10	18	.60	.06	3.098	**.005**
	Funct. Integr. & Qualif.	17	.79	.14	18	.68	.11	2.528	**.016**

[1] Equal variances not assumed

To conclude, hypothesis H6a cannot be rejected. However, the QCHPs have a significantly higher implementation for the aggregation of all enablers as well as for both enabler systems. QCHPs have a significantly higher implementation in 9 out of 13 enabler dimensions.

To test hypothesis H6b a T-test and Pearson correlation analysis were employed. The T-test allows answering hypothesis H6b, i.e. whether QCHPs have a significantly higher integrated system enabler dimension implementation compared to QCLPs. The Pearson correlation analysis enables a deeper understanding of the integrated enabler

implementation comparing QCHPs and QCLPs. The configurational lens of this analysis allows concluding which characteristics (i.e. enabler dimensions) occur commonly together for QCHPs and QCLPs. First, the perquisites for the T-test are presented. Then the results of the T-Test and Pearson correlation analysis are elaborated.

The T-test allows examining whether QCHPs and QCLPs have a significant mean difference of the average enabler dimension correlation. The average enabler dimension correlation represents the average of all correlation values between the 13 enabler dimensions. A combination of the Shapiro-Wilk test ($p > 0.05$) and the graphical interpretation of a histogram and a Q-Q Plot confirmed the normal distribution of the average enablers' correlation for QCHPs and QCLPs. The assumption of equal variances of the average enablers' correlation was confirmed with the Levene's test ($p > 0.05$).

The T-test reveals that QCHPs have a significantly higher average enabler dimension correlation compared to QCLPs. While QCLPs reach an average of 0.12, the QCHPs achieve an average of 0.46. In the context of this research and the given sample size the QCHPs average can be seen as a moderate to high correlation. The average of QCLPs can be seen as a low correlation. The mean difference between QCHPs and QCLPs is significant at $p = 0.01$. Following the configurational approach, a high correlation between the enabler dimensions represents an integrated implementation of the system enabler dimensions. A low correlation shows a relatively scattered implementation of individual enabler dimensions. To conclude, hypothesis H6b can be rejected. The QCHPs have a significantly higher integrated system enabler implementation compared to QCLPs. Table 52 summarizes the described results. The significant result at $p = 0.01$ is highlighted in bold.

Table 52: Hypothesis H6b results

Dependent Variable	n QCHP	Average QCHP	Std. Deviation QCHP	n QCLP	Average QCLP	Std. Deviation QCLP	t-value	Sig. (2-tailed)
Average Enabler Dimension Correlation	13	.46	.11	13	.12	.09	8.352	**.000**

Increasing the degree of detail regarding the integrated enabler dimension implementation, the Pearson correlation analysis result depicts very different enabler configurations for QCHPs and QCLPs (cf. figure 22 and figure 23). QCHPs show 10 out of 13 enabler dimensions with a high average enabler dimension correlation above 0.400. QCLPs do not have any high correlations above 0.400. The highest average enabler dimension correlation of QCLPs is a medium high correlation level above 0.200 but below 0.400 in 2 out of 13 enabler dimensions.

For QCHPs the average correlation of all 13 enabler dimensions ranges between 0.182 for *Visual Management* and 0.583 for *Functional Integration & Qualification*. Only one negative correlation exists between two individual enabler dimensions. However, the negative correlation is low and not significant. Consequently, the QCHPs do not see the enabler dimensions as trade-offs. The enabler dimensions with the highest integration are *Standardization & Simplification* and *Function Integration & Qualification*. Both dimensions

show seven very high correlations above 0.600. *Management Commitment & Company Culture* has six very high correlations. *Set-up Time Reduction* and *Pull Approach* still have five very high correlations with other enabler dimensions. Combining the very high correlations above 0.600 with the high correlations above 0.400 allows deepening the understanding of the enabler configuration of QCHPs. Of 13 possible high and very high correlations *Preventive Maintenance*, *Pull Approach*, and F*unctional Integration & Qualification* show equal to or above ten high and very high correlations above 0.400. *Technology Assessment & Usage*, *Standardization & Simplification*, *Set-up Time Reduction*, and *Employee Involvement & Continuous Improvement* show nine high and very high correlations above 0.400. *Planning Adherence* and *Management Commitment & Company Culture* still show 8 out of 13 correlations above 0.400.

Separating the MES from all enabler dimensions highlights the importance of an integrated MES. The three MES dimensions *Management Commitment & Company Culture*, *Employee Involvement & Continuous Improvement*, and *Functional Integration & Qualification* show a very high integration with all other enabler dimensions. All MES dimensions have equal to or more than eight high (above 0.400) and very high (above 0.600) correlations with other dimensions. Figure 22 depicts the enabler configuration for QCHPs.

	Preventive Maintenance	Technology Assessment & Usage	Housekeeping	Process Management	Standardization & Simplification	Set-up Time Reduction	Pull Approach	Layout Optimization	Planning Adherence	Visual Management	Management Commitment & Company Culture	Employee Involvement & Continuous Improvement	Functional Integration & Qualification	Average Enabler Dimension Correlation
Preventive Maintenance		.636	.467	.437	.706	.572	.696	.412	.497	.096	.522	.504	.714	.522
Technology Assessment & Usage	.636		.459	.550	.509	.475	.512	.293	.297	.096	.486	.427	.458	.433
Housekeeping	.467	.459		.342	.455	.688	.489	.366	.296	.228	.357	.369	.402	.410
Process Management	.437	.550	.342		.154	.345	.463	.389	.246	.118	.239	.374	.339	.333
Standardization & Simplification	.706	.509	.455	.154		.609	.613	.374	.782	.262	.830	.685	.855	.570
Set-up Time Reduction	.572	.475	.688	.345	.609		.705	.209	.514	-.045	.658	.501	.742	.498
Pull Approach	.696	.512	.489	.463	.613	.705		.416	.420	.002	.623	.468	.699	.509
Layout Optimization	.412	.293	.366	.389	.374	.209	.416		.566	.341	.295	.376	.430	.372
Planning Adherence	.497	.297	.296	.246	.782	.514	.420	.566		.250	.683	.568	.807	.494
Visual Management	.096	.096	.228	.118	.262	-.045	.002	.341	.250		.168	.536	.136	.182
Management Commitment & Company Culture	.522	.486	.357	.239	.830	.658	.623	.295	.683	.168		.775	.768	.534
Employee Involvement & Continuous Improvement	.504	.427	.369	.374	.685	.501	.468	.376	.568	.536	.775		.649	.519
Functional Integration & Qualification	.714	.458	.402	.339	.855	.742	.699	.430	.807	.136	.768	.649		.583

Key	.200	.400	.600

Figure 22: Enabler configuration for QC lab effectiveness high performers

For QCLPs the average correlation of all 13 enabler dimensions ranges between -0.095 for *Technology Assessment & Usage* and 0.259 for *Preventive Maintenance*. A closer look at the individual enabler dimensions shows negative correlations for several dimensions. It seems that the enabler dimensions are seen as trade-offs. In contrast to the QCHPs the QCLPs do not follow an integrated approach for the enabler implementation but follow an approach of implementing single enabler dimensions. One exception of the single enabler implementation approach of QCLPs exists. The enabler dimension with the highest integration for QCLPs is *Standardization & Simplification*. The enabler dimension shows two very high correlations above 0.600. Both *Preventive Maintenance* and *Housekeeping* show one very high correlation. A closer look at these three enabler dimensions reveals an integrated approach of QCLPs for these three dimensions. Although QCLPs do not have a strong overall integrated approach to the enabler implementation it seems that they still focus on the triangle of three fundamental enabler dimensions: *Standardization & Simplification*, *Preventive Maintenance*, and *Housekeeping*. Combining the very high correlations of above 0.600 with the high correlations above 0.400 *Preventive Maintenance* stands out from the rest. The dimension shows three high correlations and one very high correlation resulting in the highest average enabler dimension correlation for QCLPs. On the lower end, the QCLPs show very limited integration for *Technology Assessment & Usage*, *Process Management*, *Pull Approach*, *Planning Adherence*; *Management Commitment & Company Culture*, and *Employee Involvement & Continuous Improvement*. All these enabler dimensions show at least eight or more low correlations below 0.200. The low integration of *Technology Assessment & Usage* can be linked to the low automation level of QCLPs (cf. chapter 4.2.2). 67 % of QCLPs use more than 50 % manually operated instruments (cf. chapter 4.2.2). Figure 23 depicts the enabler configuration for QCLPs.

	Preventive Maintenance	Technology Assessment & Usage	Housekeeping	Process Management	Standardization & Simplification	Set-up Time Reduction	Pull Approach	Layout Optimization	Planning Adherence	Visual Management	Management Commitment & Company Culture	Employee Involvement & Continuous Improvement	Functional Integration & Qualification	Average Enabler Dimension Correlation
Preventive Maintenance		.173	.424	.331	.678	.268	-.026	-.126	.082	.324	.032	.476	.473	.259
Technology Assessment & Usage	.173		-.041	-.146	-.125	-.499	-.366	-.290	.018	-.177	-.215	.325	.205	-.095
Housekeeping	.424	-.041		.242	.646	.153	-.221	.307	.005	-.134	.300	-.121	.249	.151
Process Management	.331	-.146	.242		.349	.142	-.031	.193	-.248	-.015	-.163	.197	.039	.074
Standardization & Simplification	.678	-.125	.646	.349		.234	-.048	.035	-.051	-.015	.360	.012	.417	.208
Set-up Time Reduction	.268	-.499	.153	.142	.234		.094	.322	.200	.449	.318	.260	.417	.196
Pull Approach	-.026	-.366	-.221	-.031	-.048	.094		.339	.427	.327	.011	.142	-.187	.038
Layout Optimization	-.126	-.290	.307	.193	.035	.322	.339		.312	.245	.030	.163	.029	.130
Planning Adherence	.082	.018	.005	-.248	-.051	.200	.427	.312		.550	-.236	.199	-.024	.103
Visual Management	.324	-.177	-.134	-.015	-.015	.449	.327	.245	.550		-.200	.237	.246	.153
Management Commitment & Company Culture	.032	-.215	.300	-.163	.360	.318	.011	.030	-.236	-.200		-.282	.229	.015
Employee Involvement & Continuous Improvement	.476	.325	-.121	.197	.012	.260	.142	.163	.199	.237	-.282		.134	.145
Functional Integration & Qualification	.473	.205	.249	.039	.417	.417	-.187	.029	-.024	.246	.229	.134		.186

Key	.200	.400	.600

Figure 23: Enabler configuration for QC lab effectiveness low performers

4.3.6 QC Lab Effectiveness and Enabler System Conclusion

The quantitative analysis allowed a better understanding of the QC lab effectiveness, enabler system, and their relation.

Chapter 4.3.2 focused on identifying whether the QCHPs have a significantly higher QC lab effectiveness as well as quality and service performance. The analysis showed that QCHPs perform better in all three dimensions. Both QCHPs and QCLPs had limited ability to report service performance indicators.

In chapter 4.3.3 the relation of the Management Enabler System (MES) and the Technical Enabler System (TES) was discussed. Overall, a high implementation of the MES is accompanied with a high implementation of the TES. QC labs with a low implementation of the MES tend to also have a low implementation of the TES. All three dimensions of the MES have a significant impact on the TES. *Management Commitment & Company Culture*, *Employee Involvement & Continuous Improvement*, and *Functional Integration & Qualification* have a significant impact on the TES. However, the last two dimensions showed a higher impact on the TES.

Chapter 4.3.4 examined the relation of the enabler systems with QC lab effectiveness. The analysis determined that a positive relation exists between the enablers and QC lab effectiveness for the majority of the data basis. A positive link between the MES and QC lab effectiveness was identified. In addition, a positive link between the TES and QC lab effectiveness was disclosed. A stronger link between the TES and QC lab effectiveness

compared to the MES and QC lab effectiveness was identified. The analysis also disclosed that not all QC labs show the positive relation between enabler and QC lab effectiveness. Three different patterns could be identified. A number of QC labs achieve a high enabler implementation and a high QC lab effectiveness. Other QC labs show a low enabler implementation and a low QC lab effectiveness. The analysis also revealed that there is a group of QC labs with high enabler implementation but low QC lab effectiveness. This last cluster contradicts the widely acknowledged understanding of enablers supporting performance in OM literature (cf. chapter 2.2.2). This fact is deepened in chapter 5.
In chapter 4.3.5 the enabler system configuration for QCHPs and QCLPs was compared. The analysis concludes a significantly higher implementation of the enablers for QCHPs. QCHPs have a significantly higher implementation of the MES and TES. In detail, QCHPs have a significantly higher implementation in 9 out of 13 enabler dimensions: *Technology Assessment & Usage, Housekeeping, Process Management, Standardization & Simplification, Pull Approach, Layout Optimization*, *Planning Adherence, Employee Involvement & Continuous Improvement*, and *Functional Integration & Qualification*. In addition, QCHPs show a much higher integration of the enabler dimensions compared to QCLPs. The most integrated enabler dimensions for QCHPs are *Standardization & Simplification* and *Functional Integration & Qualification.* On the contrary, QCLPs have a scattered enabler dimension implementation. QCLPs focus on implementing single enabler dimensions. Consequently, the degree of integration between enabler dimensions is much lower than the integration of QCHPs.

Table 53: Summary of hypotheses and conclusion

No.	Hypothesis	H_0
H1	QC lab effectiveness high performers do not have a significantly higher QC lab effectiveness compared to QC lab effectiveness low performers.	Rejected
H1a	QC lab effectiveness high performers do not have a significantly higher quality performance compared to QC lab effectiveness low performers.	Rejected
H1b	QC lab effectiveness high performers do not have a significantly higher service performance compared to QC lab effectiveness low performers.	Rejected
H2a	The implementation of the management enabler system does not have a positive impact on the implementation of the technical enabler system.	Rejected
H2b	The implementation of all three individual dimensions of the management enabler system does not have a positive impact on the implementation of the technical enabler system.	Rejected
H3	The implementation of the technical enabler system does not have a positive impact on the QC lab effectiveness.	Rejected
H4	The implementation of the management enabler system does not have a positive impact on the QC lab effectiveness.	Rejected
H5	The implementation of the management enabler system and the technical enabler system do not have a positive impact on the QC lab effectiveness.	Rejected
H6a	The QC lab effectiveness high performers do not have a significantly higher average implementation of all system enabler dimensions compared to QC lab effectiveness low performers.	Not rejected[1]
H6b	The QC lab effectiveness high performers do not have a significantly higher integrated implementation of all system enabler dimensions compared to QC lab effectiveness low performers	Rejected

[1] H6a can only be rejected for 9 out of 13 enabler dimensions

4.4 Summary of Findings

Chapter 4 was focused on understanding the relation of the performance measurement model dimensions better. The focus was to use quantitative data of 53 available QC labs to analyze the relation between the operating context, the enabler system implementation, and QC lab effectiveness. The following paragraphs summarize the result of the quantitative analysis. First, the conclusions related to the operating context and QC lab effectiveness relation is given. Second, conclusions regarding the QC lab effectiveness and enabler system relation are elaborated. Reference should be made to chapter 4.2 for details on the propositions. Chapter 4.3 depicts the detailed analysis regarding the hypotheses.

The analysis of the operating context concludes that it has an impact on the effectiveness of QC labs. QCHPs and QCLPs show a different *Portfolio Complexity*, *Test Allocation Strategy*, *Organizational Scale*, and *Technology & Innovation* structure.

A large proportion of biological drug substance testing QC labs belongs to the QCHPs. In addition, regarding the drug products tested there are notably more QCHPs that conduct sterile liquids testing or no drug product testing compared to QCLPs. Moreover, QCHPs show a low number of final drug product types tested. More than two thirds of the centralized QC labs with a degree of centralization above 25 % are QCHPs. QCLPs are especially those organizations with a lower number of employees, whereas the QCHPs include a larger proportion of large scale organizations. In addition, a high level of automation can be linked to the group of QCHPs.

No evidence was found for any difference between QCHPs and QCLPs regarding *Geographical Location*, *Economy of Scale*, and *Regulatory Approval*. Table 54 exhibits an overview of the conclusions of each research proposition.

Table 54: Conclusions regarding research propositions

No.	Conclusion
P1	The operating context has an impact on QC lab effectiveness.
P2	The geographical location does not have an impact on QC lab effectiveness.
P3	The portfolio complexity has an impact on QC lab effectiveness.
P4	The test allocation strategy has an impact on QC lab effectiveness.
P5	The organizational scale has an impact on QC lab effectiveness.
P6	The economy of scale does not have an impact on QC lab effectiveness.
P7	The technology and innovation has an impact on QC lab effectiveness.
P8	The regulatory approval does not have an impact on QC lab effectiveness.

The analysis of QC lab effectiveness and its relation to the enabler system concludes that QCHPs have a significantly higher QC lab effectiveness, quality, and service performance. The Management Enabler System (MES) and the Technical Enabler System (TES) showed a positive link. A high implementation of the MES is accompanied with a high implementation of the TES. The MES dimensions *Management Commitment & Company Culture*, *Employee Involvement & Continuous Improvement*, and *Functional Integration & Qualification* have a significant impact on the TES. However, the last two dimensions

showed a higher impact on the TES. A positive relation between the enablers and QC lab effectiveness exists for the majority of the data basis. This applied to both the TES and MES. However, the TES showed a stronger link with QC lab effectiveness compared to the MES. A subset of QC labs was identified that did not support the positive enabler QC lab effectiveness relation. These QC labs characterize a high enabler implementation combined with a low QC lab effectiveness. Chapter 5 further investigates this subset of labs. QCHPs have a significantly higher implementation of all enablers, the MES, and TES. In the 9 out of 13 enabler dimensions *Technology Assessment & Usage, Housekeeping, Process Management, Standardization & Simplification, Pull Approach, Layout Optimization*, *Planning Adherence, Employee Involvement & Continuous Improvement*, and *Functional Integration & Qualification* QCHPs have a significantly higher implementation. The most integrated enabler dimensions for QCHPs are *Standardization & Simplification* and *Functional Integration & Qualification.* On the contrary, QCLPs have a scattered enabler dimension implementation. QCLPs focus on implementing single enabler dimensions. Overall, QCHPs show a much higher integration of the enabler dimensions compared to QCLPs. Table 55 depicts an overview of the conclusions of the research hypotheses.

Table 55: Conclusions regarding research hypotheses

No.	Conclusion
H1	QCHPs have a significantly higher QC lab effectiveness compared to QCLPs.
H1a	QCHPs have a significantly higher quality performance compared to QCLPs.
H1b	QCHPs have a significantly higher service performance compared to QCLPs.
H2a	The implementation of the MES has a positive impact on the implementation of TES.
H2b	Management Commitment & Company Culture, Employee Involvement & Continuous Improvement, and Functional Integration & Qualification have a partly significant impact on the implementation of the TES.
H3	The TES has a positive impact on the QC lab effectiveness.[1]
H4	The MES has a positive impact on the QC lab effectiveness.[1]
H5	Both the TES and MES have a significant impact on QC lab effectiveness. However, the interaction does affect the overall impact. Further research needed with non-time-centric data.
H6a	QCHPs have a significantly higher implementation in the aggregation of all enablers, the TES and MES. However, not all individual enabler dimensions within the TES and MES show a significantly higher implementation for QCHPs compared to QCLPs.
H6b	The QCHPs have a significantly higher integrated system enabler implementation compared to QCLPs. QCLPs show a scattered enabler implementation focusing on implementing single enabler dimensions.

[1] A subset of QC labs does not show this relation. Chapter 5 focuses on understanding the QC labs that do not support this hypothesis.

5 Application of Performance Measurement Model

This chapter is focused on providing explanation to the findings of the quantitative analysis in chapter 4. The main objective is to better understand the context of the three identified clusters of QC labs regarding their QC lab effectiveness enabler relation (cf. chapter 4.3.4). To enhance the findings of the quantitative analysis with context information, case study research is employed. Multiple case studies are presented to explain the phenomenon of the three distinct clusters.

Chapter 5.1 describes the applied research methods to investigate the performance enabler relation, cluster characteristics, and the cluster operating context. Chapter 5.2 depicts the in-depth analysis of the selected case studies, followed by the cross-case analysis in chapter 5.3. The chapter closes with a summary of the findings in chapter 5.4.

5.1 Methods

In the following, the applied research methods of the model application are described. The performance enabler relation constitutes the focus of the model application. Incorporating the operating context of QC labs frames the model application. Two methods are applied, i.e. quantitative descriptive statistics and qualitative case studies.

The quantitative analysis in chapter 4.3.4 concluded with three distinct clusters of QC labs. These three clusters showed a differing QC lab effectiveness enabler relation. Only two of the clusters find support in the Operations Management (OM) literature (cf. chapter 2.2.2). The first cluster includes those QC labs with a low QC lab effectiveness and low enabler implementation. The second cluster represents those QC labs with a low QC lab effectiveness but high enabler implementation. The third cluster summarizes all QC labs with a high QC lab effectiveness and a high enabler implementation. Clusters 1 and 3 support the scholars' understanding of building superior performance on a high implementation level of enablers (cf. chapter 2.2.2). Cluster 2 contradicts this understanding and needs further investigation.

The case study research approach was selected to provide a rich context to the cluster analysis. This cannot be gained with the quantitative analysis of time-centric data that was employed in chapter 4. The subsequent research is investigating a time-dependent relation of the enabler implementation and performance outcome of QC labs. Scholars have demanded case study research for analyses related to time-dependent relations in the past (Samson & Terziovski, 1999). Furlan et al. (2011) suggest to employ case study research to understand the organizational context of enabler implementation.

To conclude, a major focus of the subsequent analysis is why cluster 2 is contradicting the common understanding in OM literature. The objective of the model application is to analyze why these QC labs show a high enabler implementation but do not achieve a corresponding high QC lab effectiveness. To gain a better understanding of cluster 2, clusters 1 and 3 also need to be further investigated and contrasted.

The application of the research methods is sequenced. First, the descriptive statistical analyses introduce the characteristics of the identified clusters. The descriptive statistical analyses of this chapter are based on all 50 QC labs that collected data after the pilot data collection (cf. chapter 4.1.1). The three QC labs of the pilot cannot be included as the pilot

data collection template did not include an enabler section at the time of data gathering. Second, three case studies are tied to the clusters to explore and explain the relation between QC lab effectiveness and enabler implementation.

Chapter 5.1.1 provides a fundamental understanding of case study research approach. It also depicts how the case study research is applied to this research. In chapter 5.1.2 the three identified clusters are described in detail. A descriptive statistical analysis is employed in this chapter. The analysis intends to reveal commonalities and differences regarding the QC lab effectiveness and enabler implementation of the three clusters. In chapter 5.1.3 the operating context of the three clusters is described. A second descriptive statistical analysis is employed in this chapter. To conclude chapter 5.1 the case selection process is outlined in chapter 5.1.4.

5.1.1 Case Study Research

Survey methods cannot provide rich context understanding (Stuart, McCutcheon, Handfield, McLachlin, & Samson, 2002). On the contrary, case study research allows understanding phenomena by systematically analyzing one or multiple cases (Meredith, 1998). In case study research conclusions are drawn from within- and cross-case analyses (Eisenhardt, 1989). Case study research can be used to provide context description, test theory, or to generate theory (Eisenhardt, 1989).

Stuart, McCutcheon, Handfield, McLachlin, and Samson (2002) emphasize case study research as a method not only at preliminary stages of research but also to extend existing concepts. In contrast to quantitative statistical analyses case study research helps to explain *why* and *how* a phenomenon occurs (Stuart et al., 2002). Case study research is often chosen to understand how the context of a phenomenon influences the outcome (Ellram, 1996). Eisenhardt (1989) suggests to avoid biased findings in case studies by omitting hypotheses building. However, the author emphasizes that a priori specified constructs help to focus the research. The authors have in common to stress that some up-front specification prior to the case study research sharpens the theory building process (Eisenhardt, 1989; Ellram, 1996; Stuart et al., 2002).

Stuart et al. (2002) outline a five-step case study research process. The first step is focused on defining the research question. After setting the research focus the second step constitutes the instrument development. A study protocol allows providing a trail of evidence generating reliable results. The third step represents the actual data gathering. During the fourth step, the researcher analyzes and condenses the gathered data. The fifth and last step is focused on disseminating the findings.

Possible case study designs range from single- to multiple-case studies (Eisenhardt, 1989; Yin, 2018). A thorough case study design helps to build a stronger argumentation (Yin, 2018). Yin (2018) distinguishes four different case study designs: a holistic single-case, an embedded single-case, a holistic multiple-case design, and an embedded multiple-case design. The holistic and embedded nature of cases addresses two different research approaches. The holistic approach considers and analyzes the overall unit at once (Yin, 2018). The embedded approach distinguishes the unit into different subunits and analyzes each subunit individually (Yin, 2018). According to Yin (2018), a single-case design is most suitable to determine whether existing theory in a very specific context can be expanded

to a new context. It also allows studying critical, unusual, common, revelatory, or longitudinal cases[33] (Yin, 2018). A multiple-case design is most suitable to compare findings of a number of individual cases. (Yin, 2018). The objective to compare multiple cases is either to find similar results (literal replication) or to find contrasting results (theoretical replication) (Yin, 2018). In a multiple-case study design often cases with maximum context difference are included to understand phenomena better (Stuart et al., 2002). The proposed number of cases in a multiple-case design varies by authors (Eisenhardt, 1989; Stuart et al., 2002; Yin, 2018). Eisenhardt (1989) stresses an upper limit of cases that is not defined but reached when theoretical saturation is met and every new case would not add substantially new findings.

Triangulation ensures validity and reliability of the research findings (Jick, 1979). Using multiple data source allows limiting the risk of not meaningful findings (Stuart et al., 2002). To strengthen evidence of the findings different data collection methods should be combined (Eisenhardt, 1989). Eisenhardt and Bourgeois (1988) combine quantitative and qualitative data to build theory. Eisenhardt (1989) emphasizes that qualitative data of case study research may allow understanding relations of quantitative data better.

Applying case study research to the present thesis allows understanding the phenomenon of a differing relation regarding QC lab effectiveness and the enabler implementation of QC labs disclosed in chapter 4. The case study research approach is selected to extend the previous finding of three distinct clusters of QC labs (cf. chapter 4.3.4) by explaining *why* the QC labs perform differently and *how* a multitude of factors influence the relation of QC lab effectiveness and enabler implementation. Consequently, the identified clusters in the quantitative analysis in chapter 4 serve as the up-front specification of the case studies in this research. A holistic multi-case study design is selected to explain the phenomenon. To ensure validity and reliability of the research findings the researcher included six different data sources into the case study research: benchmarking data (1), individual and group interviews (2), public and confidential company material (3), workshop results (4), personal notes and emails (5), and on-site lab observations (6). Table 56 summarizes the above-mentioned key aspects of case study research, how it is applied to this research, and the reasoning.

[33] Yin (2018) outlines critical cases as those cases most relevant to confirm, challenge, or extend theory within conditions it is considered as true; an unusual case describes a case that shows extreme conditions that are different from the reference standard; the common case represents the opposite describing an ordinary situation; a revelatory case builds on a new social situation that allows studying a phenomenon that was inaccessible before; a longitudinal case studies the same phenomenon at different points in time.

Table 56: Case study approach of this research

Aspect	Details	Reasoning
Phenomenon	Differing relation regarding QC lab effectiveness and enabler implementation	Outcome of quantitative analysis (chapter 4)
Research Stage	Extend existing concept	Findings of quantitative analysis need further investigation
Research Focus	Why and how?	Why and how cannot be addressed with quantitative analysis
Up-front Specification	Three distinct clusters	Outcome of quantitative analysis (chapter 4)
Case Study Design	Multiple-case (holistic)	Cluster 1, 2, 3 (chapter 4)
Data Source	Benchmarking data, individual and group interviews, publicly available and confidential company material, workshop results, personal notes and emails, and on-site lab observations	Triangulation, combination of quantitative and qualitative data

5.1.2 Cluster Characteristics

The quantitative analysis in chapter 4 concluded with a positive relation between QC lab effectiveness and the enabler implementation. However, the positive relation does not apply to all QC labs of the data basis. This chapter aims at describing the characteristics of the identified clusters (cf. chapter 4.3.4) with the available quantitative data (cf. chapter 4.1.4). The descriptive statistic aims at highlighting the differences and commonalities between the three identified clusters. Figure 24 exhibits the three clusters related to the overall enabler implementation and QC lab effectiveness. The scale of both dimensions is normalized between 0 (worst value) and 1 (best value).

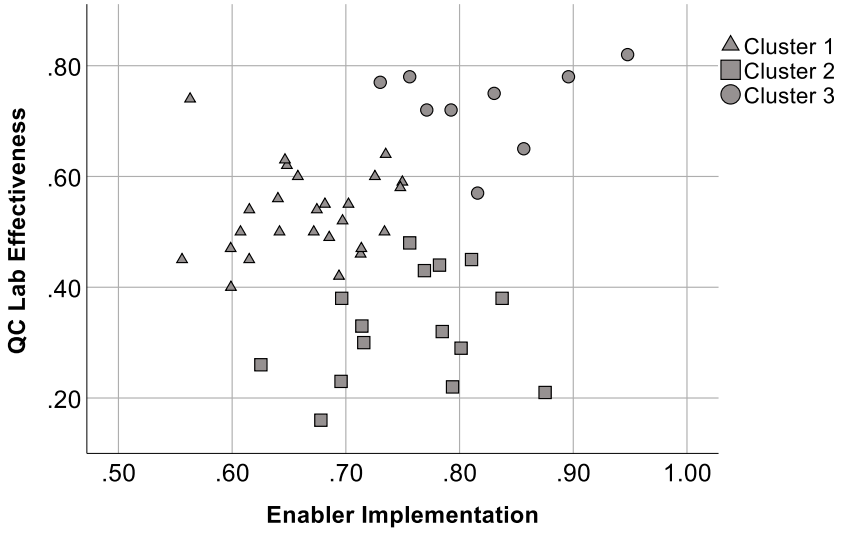

Figure 24: Scatter plot of clusters 1, 2, and 3

Cluster 1 includes 26 QC labs with a low QC lab effectiveness and low enabler implementation. Cluster 2 represents 15 QC labs with a low QC lab effectiveness but high

enabler implementation. The third cluster comprises nine QC labs with a high enabler implementation and high QC lab effectiveness. To ensure consistency with the wording of the preceding quantitative analysis in chapter 4.3.4 referring to a low QC lab effectiveness in cluster 1 in the subsequent analyses this wording is not changed to medium QC lab effectiveness in cluster 1 to avoid misunderstanding. It should be noted that the QC lab effectiveness of cluster 1 is higher than for cluster 2 that has the lowest QC lab effectiveness.
In the following chapter an overview of the differences between the clusters regarding QC lab effectiveness is provided. Then, the enabler implementation of clusters 1, 2, and 3 is discussed.

5.1.2.1 QC Lab Effectiveness of Clusters 1, 2, and 3

This chapter examines the QC lab effectiveness of the three clusters with differing performance and enabler implementation. First, the analysis depicts the differences related to the overall QC lab effectiveness performance. Second, the performance differences related to all individual indicators that build the overall QC lab effectiveness are presented.
The average QC lab effectiveness of the three clusters ranges between 0.33 (cluster 2) and 0.73 (cluster 3). Cluster 1 shows a QC Lab effectiveness of 0.53. The overall variation of the individual performance indicators is the highest in cluster 1. Cluster 3 shows a lower variation of the performance indicators compared to clusters 1 and 2.
Comparing each cluster separately reveals those performance indicators in which the cluster performs well. Cluster 1 shows the best performance in *Analytical Right First Time*, *Lab Deviation Rate*, and *Product Re-Tests due to Complaints*. The worst performance in cluster 1 is linked to *Adherence to Schedule*. The highest variation in cluster 1 is linked to *Product Re-Test due to Complaints*. Cluster 2 performs well regarding *Lab Corrective Action and Preventive Action (CAPAs) Overdue*, *Product Re-Tests due to Complaints*, and *Adherence to Schedule*. The lowest performance in cluster 2 is linked to *Analytical Right First Time*. As in cluster 1 the *Product Re-Tests due to Complaints* shows the highest variation in cluster 2. Cluster 3 shows the highest performance in *Product Re-Test due to Complaints*, *Customer Complaints Investigation Rate*, and *Lab Investigation Rate*. Different to clusters 1 and 2 the highest variation is linked to *Lab CAPAs Overdue*. *Product Re-Test due to Complaints* shows no variation in cluster 3. All QC labs in this cluster have no re-test due to complaints. It should be noted that cluster 3 performs better in all performance indicators compared to clusters 1 and 2.
Comparing clusters 1 and 2 with cluster 3 discloses those performance indicators that show the highest difference between the three clusters. A closer look at clusters 1 and 3 shows that cluster 3 is substantially better in *Product Re-Tests due to Complaints*, *Adherence to Schedule*, and *Customer Complaint Investigation Rate*. All performance gaps between clusters 2 and 3 are substantially higher compared to the gaps between clusters 1 and 3. In addition, 6 out of 10 indicators show a higher performance gap between clusters 2 and 3 compared to the highest performance gap between clusters 1 and 3. Compared to cluster 2, cluster 3 shows a substantially better performance in *Customer Complaint Investigation Rate*, *Product Re-Test due to Complaints*, and *Lab Investigation*

Rate. The smallest performance gap between clusters 1 and 3 is linked to *Lab Deviation Rate*. Clusters 2 and 3 show the smallest performance gap for *Lab CAPAs Overdue*. The largest performance variation gap between clusters 1, 2, and 3 is linked to *Product Re-Tests due to Complaints.* Cluster 3 has a substantially lower variation of this performance indicator compared to clusters 1 and 2. Table 57 summarizes the performance and its variation for clusters 1, 2, and 3 regarding all indicators of QC lab effectiveness.

Table 57: QC lab effectiveness of clusters 1, 2, and 3

Performance Indicator	Cluster 1 (n=26)		Cluster 2 (n=15)		Cluster 3 (n=9)	
	Score[1]	Std. Dev.	Score	Std. Dev.	Score	Std. Dev.
Adherence to Lead Time	.47	.26	.29	.27	.77	.20
Adherence to Schedule	.45	.31	.36	.20	.78	.14
Analytical Right First Time	.58	.27	.26	.25	.62	.27
Customer Complaint Investigation Rate	.52	.28	.27	.21	.85	.23
Invalidated OOS Rate	.55	.24	.35	.24	.79	.30
Lab CAPAs Overdue	.46	.34	.46	.24	.63	.30
Lab Deviation Rate	.57	.29	.34	.24	.57	.30
Lab Investigation Rate	.55	.26	.31	.25	.79	.25
Product Re-Tests due to Complaints	.57	.40	.45	.38	1.00	.00
Recurring Lab Deviations	.55	.34	.30	.24	.69	.27
Average		.30		.25		.23

[1] The score is a value between 0 and 1. It represents the average of all quantile ranks of the QC labs in the respective cluster. The higher the value the better the cluster performs related to the respective performance indicator.
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

5.1.2.2 Enabler Implementation of Clusters 1, 2, and 3

In this chapter the enabler implementation of the three clusters is examined. The analysis focuses on the overall enabler implementation, the enabler system implementation, and the enabler dimension implementation.

The analysis reveals that clusters 2 and 3 have a much higher implementation in all enabler dimensions compared to cluster 1. All three clusters show a relatively consistent implementation of the enabler systems. Comparing the average enabler system implementation for each cluster separately, the Technical Enabler System (TES) and the Management Enabler System (MES) do not show much variation. Regarding the enabler dimensions, all three clusters show the highest implementation rate in *Housekeeping*. The enabler dimension with the lowest implementation rate differs between the clusters. Cluster 1 has the lowest implementation rate in *Set-up Time Reduction*. Clusters 2 and 3 have the lowest implementation rate in *Technology Assessment & Usage*. A closer look at cluster 1 reveals that *Technology Assessment & Usage* is the enabler dimension with the second lowest implementation. Table 58 depicts the average implementation level of

clusters 1, 2, and 3 for the enabler systems and the enabler dimensions. The enabler implementation level is measured on a scale from 1 (worst value) to 5 (best value).

Table 58: Enabler dimension implementation of clusters 1, 2, and 3

Enabler System and Dimension	Implementation Level[1]		
	Cluster 1 (n=26)	Cluster 2 (n=15)	Cluster 3 (n=9)
All Enablers	3.33	3.78	4.11
Technical Enabler System	3.29	3.67	4.06
Preventive Maintenance	3.41	3.59	3.94
Technology Assessment & Usage	2.85	3.19	3.41
Housekeeping	3.74	4.17	4.58
Process Management	3.52	3.85	4.17
Standardization & Simplification	3.67	3.98	4.51
Set-up Time Reduction	2.75	3.29	3.85
Pull Approach	3.06	3.62	4.15
Layout Optimization	3.31	3.40	3.96
Planning Adherence	3.41	3.68	4.22
Visual Management	3.13	3.97	3.83
Management Enabler System	3.37	3.88	4.16
Mgmt. Commitment & Company Culture	3.71	4.04	4.25
Employee Involvement & CI	3.02	3.62	3.77
Functional Integration & Qualification	3.39	3.98	4.44

[1] Enabler implementation is measured on a 5-point Likert scale (1: lowest implementation, 5: highest implementation)
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The following paragraphs highlight which individual enablers of each enabler dimension show an especially high implementation rate for clusters 1, 2, and 3. The focus is set to commonalities and differences of clusters 1, 2, and 3. The wording describing the individual enabler implementation matches the enabler 5-point Likert scale wording in the data collection template at the identified average implementation rate for each cluster (cf. table 58). Individual enablers showing differences of at least 0.5 points on the Likert scale between clusters 1 and 2 as well as 2 and 3 are mentioned. In addition, most and least implemented individual enablers are highlighted. The enabler section of the data collection template with the Likert scale wording can be found in appendix 6.

In *Preventive Maintenance* QC labs of all three clusters particularly rely on formal programs for maintaining the lab instruments that are strictly adhered to and updated regularly. In addition, all three clusters regularly document maintenance jobs, plans, checklists, and post them close to the instruments. All clusters have identified bottleneck instruments and supply them with spare parts. However, clusters 1 and 2 show an uneven supply of spare parts. Clusters 1 and 2 have in common to dedicate limited resources to failure analyses. Cluster 3 continuously optimizes the maintenance program based on dedicated failure

analyses across the lab. QC labs in clusters 2 and 3 involve analysts regularly when buying new instruments. QC labs in cluster 1 only sometimes consult analysts during the decision making process of buying new instruments. Comparing proactive and reactive activities across the QC labs cluster 3 stands out with more than 80 % of activities focused on proactivity. Cluster 2 shows 60 to 80 % proactive maintenance activities. Cluster 1 has around 60 % proactive activities.

Regarding *Technology Assessment & Usage* QC labs in clusters 2 and 3 consider themselves as QC labs that sometimes seek to incorporate leading edge technology. Cluster 1 rarely incorporates leading edge technology. While cluster 1 rarely screens the market for new technology, cluster 2 sometimes assesses new technology. Cluster 3 regularly screens the market and assesses new technology. Consequently, the three clusters show differences in how effectively they use new technology. Cluster 1 is interested in improving technology but does not devote much capital expenditure to it. Cluster 2 devotes some capital expenditures and cluster 3 devotes a significant proportion of capital expenditures to new technology. All three clusters have more than 60 % vendors' instruments. This matches with the fact that proprietary process technology and instruments are not used to gain a competitive advantage across all three clusters. The emphasis on smart lab system implementation differs between the three clusters. While clusters 1 and 2 put some emphasis on it, cluster 3 has an increased emphasis on it. However, cluster 3 also rarely reviews new smart solutions.

In *Housekeeping* QC labs of all three clusters spend significant time on keeping the lab neat and clean. Employees see housekeeping as a major part of the improvement initiatives. Housekeeping checklists exist and are visible to all employees in all three clusters. However, the clusters show differing adherence. While cluster 1 adheres unevenly, cluster 2 adheres across the lab. Cluster 3 adheres across the lab and regularly updates the checklists.

To improve *Process Management* all three labs enforce strict documentation and regular updates of direct and indirect processes. Clusters 2 and 3 have dedicated process owners with responsibility for planning, managing, and sometimes improving. On the contrary, cluster 1 has dedicated process owners with less responsibility attached. All three clusters have less than 40 % of the instruments under statistical process control. Standardized tools regularly used for root cause analysis exist in clusters 2 and 3. Cluster 3 sees it as a core part of their training program. Cluster 1 has fewer standardized tools in place and uses them unevenly.

In *Standardization & Simplification* all three clusters focus the most on documenting operating procedures to standardize processes. All QC labs show regular adherence to the documentation. In contrast to clusters 1 and 2, cluster 3 more strictly adheres to the documentation and regularly updates it. In cluster 1 optimized lab operating procedures are documented but not rolled out through the whole quality organization. Cluster 2 documents optimized operating procedures but only achieves an uneven rollout through the quality organization. Cluster 3 achieves successful practice sharing of optimized procedures across the quality organization. However, the successful practice sharing is not done regularly. Standardized functional descriptions inform the vocational training for new employees across all clusters. However, only clusters 2 and 3 are able to reduce the

time spent on training to some extent. Most of the instruments of QC labs in clusters 1 and 2 are standardized. QC labs in cluster 3 have all instruments standardized. Pursuing to standardize instruments and consumables allows clusters 1 and 2 to reduce material costs a little. Cluster 3 achieves a more significant reduction of material costs through standardization.

In the dimension *Set-up Time Reduction* all three clusters schedule large proportion of the instrument set-ups to avoid disruption of testing. Clusters 1 and 2 schedule around 40 to 60 % of set-ups. Cluster 3 schedules up to 80 % of set-ups. Continuously working on lowering time spent on set-up and cleaning is only a small part of the improvement initiatives of cluster 1. Clusters 2 and 3 dedicate reasonable resources on lowering time spent on set-up and cleaning as part of their continuous improvement initiatives. Optimized set-up and cleaning procedures are documented but rolled-out unevenly across the QC lab in cluster 1. Cluster 2 achieves to share the optimized set-up and cleaning procedures across the whole lab. Cluster 3 shares the optimized set-up and cleaning procedures across the whole lab on a regular basis.

All QC labs of the three clusters follow the *Pull Approach* to some extent. Clusters 1 and 2 do most of their testing according to forecast to get maximum capacity utilization. Cluster 3 also tests according to forecast but it can still react flexibly to short-term changes. Only clusters 2 and 3 already operate with a pull system for consumables. QC labs in cluster 1 currently focus on introducing a pull system for consumables. None of the clusters has tools installed for both demand and FTE capacity analyses. However, cluster 3 has one of the IT tools. Cluster 2 is currently rolling-out IT tools related to demand and FTE capacity. Cluster 1 intends to introduce these tools soon.

All three clusters put most emphasis on classifying testing substances and products into groups with similar processing requirements to enable *Layout Optimization*. While clusters 1 and 2 have between 60 and 80 % of substance and products classified, cluster 3 has more than 80 % classified. In accordance with the classification in clusters 1 and 2 most processes are located closely together. In QC labs of cluster 3 related processes are located close together across the whole lab. To facilitate low inventory and fast throughput clusters 1 and 2 have optimized the layout in some parts of the lab. Cluster 3 optimized the layout in most parts of the lab. To match the classification according to specific requirements all clusters have resembled dedicated testing areas in some (cluster 2) or most parts of the QC lab (clusters 1 and 3). Continuous flow from incoming testing material to release with almost no interruptions is a reasonable part of the lab objective in clusters 1 and 2. For cluster 3 continuous flow is a significant part of their lab objective. Although all clusters focus on *Layout Optimization* the standardized method value stream mapping (VSM) to visualize and optimize processes is rarely used in clusters 1 and 3. Cluster 2 sometimes uses VSM.

The focus on *Planning Adherence* allows all three clusters to meet the daily lab testing plans for more than 80 % of the working days. Clusters 1 and 2 have a good view on the root causes for variance in the lab working schedule. Both clusters regularly work on eliminating them. Cluster 3 has a clear view of the root causes and continuously works on eliminating them. A flexible shift model for most employees in the lab allows QC labs in cluster 3 to adjust labor capacity according to demand changes. Clusters 1 and 2 have

fewer employees with a flexible shift model. For testing peak loads clusters 2 and 3 regularly assign extra resources or outsource activities. Cluster 1 only sometimes assigns extra resources or outsources activities. All three QC labs aim at finding the optimal balance between increasing productivity and short lead times.

Regarding *Visual Management* the QC labs show some differences. QC labs in cluster 2 and cluster 3 have performance charts to show weekly, monthly, and annual performance objectives across all key processes. Cluster 1 only has these performance charts across a majority of processes. The same pattern applies to the current performance charts. Clusters 2 and 3 monitor the current performance with charts across all key processes. Cluster 1 only has current performance charts across a majority of processes.

Overall the *Management Commitment & Company Culture* in clusters 1, 2, and 3 does not differ substantially. Cluster 1 traces most problems to their root cause. Clusters 2 and 3 show a more rigorous approach examining all problems to identify root causes. In clusters 1 and 2 the head of quality and the management seek to regularly empower employees to continuously improve processes and reduce failures. Cluster 3 the head of quality and the management are even more actively seeking to empower their employees on a continuous basis. In QC labs of cluster 1 the employees strive to reduce process waste in some processes. For example, they try to reduce waste of time and consumables. In QC labs of clusters 2 and 3 employees not only focus on some processes but most processes to reduce waste. Clusters 2 and 3 show a balance between corporate improvement programs and site improvement initiatives. Cluster 1 aims at finding this balance.

Regarding the *Employee Involvement & Continuous Improvement* the three cluster show some differences. QC labs in clusters 2 and 3 implement multiple tools and methods supporting Continuous Improvement (CI). QC labs in cluster 1 only have some of these tools and methods implemented. All clusters are regularly (clusters 1 and 2) respectively extensively (cluster 3) involving analysts in developing standard operating procedures. In cluster 1 employees are sometimes engaged in suggestion programs. In clusters 2 and 3 the lab employees actively engage the suggestion programs. Cross-functional project teams to solve problems in the QC lab are regularly utilized in clusters 2 and 3. QC labs in cluster 1 use these teams less often. All QC labs in the three clusters follow a vision based approach with qualitative objectives not always including quantitative measurable objectives. In contrast to cluster 1, clusters 2 and 3 include constraints into their vision. A QC lab certification program is not yet common across all QC labs. The majority of QC labs in cluster 1 do not have a lab certification program and is not planning to have it soon. On the contrary, in clusters 2 and 3 some of the organizations already have a lab certification program or are launching it soon.

In *Functional Integration & Qualification* the overall implementation differs between the three clusters. All QC labs focus on cross-training of analysts to meet the required level. A majority of QC labs in cluster 1 have some cross-trained lab analysts but less than the required level. In cluster 2 QC labs have a higher number of cross-trained analysts but still less than the required level. In cluster 3 QC labs have found the optimal balance between cross-trained analysts and the required level. The skill evaluation of official feedback meetings is only sometimes used in further trainings in cluster 1 QC labs. In clusters 2 and 3 most of the information is used for additional trainings.

All three clusters have dedicated development and qualification programs for the lab employees. However, only QC labs in cluster 3 continuously seek to improve the training and qualification programs. In cluster 1 the cross-trained analysts only sometimes rotate to perform different tasks, whereas in clusters 2 and 3 analysts rotate regularly. In table 59 the individual enabler with the largest difference between clusters 1, 2, and 3 are illustrated. All individual enablers that show a major average implementation difference between at least two clusters of above 1.0 point on the 5-point Likert scale are highlighted. The average enabler implementation of all clusters related to all 68 individual enablers can be found in appendix 7.

Table 59: Individual enabler implementation with largest difference between clusters

Enabler Dimension	Individual Enabler	Difference between		
		C1 & C2	C1 & C3	C2 & C3
Preventive Maintenance	To what degree is the maintenance program continuously optimized based on a dedicated failure analysis?		●	●
Preventive Maintenance	To what degree is your preventive maintenance effort focused on proactive activities rather than reactive activities?	○	●	○
Technology Assessment & Usage	To what degree do you screen the market for new production technology and assess new technology concerning its technical and financial benefit?	○	●	○
Technology Assessment & Usage	To what degree is the lab effectively using new technology?	○	●	○
Housekeeping	To what degree are housekeeping checklists used to continuously monitor the condition and cleanness of our equipment?	○	●	○
Process Management	To what degree are standardized tools in place for root cause analysis, to get a deeper understanding of the influencing factors (e.g. DMAIC)?	○	●	○
Standardization & Simplification	To what degree are optimized lab operating procedures (e.g. shortened set-ups) documented as best-practice processes and rolled-out throughout the whole quality organization?	●	●	
Standardization & Simplification	To what degree are standardized functional descriptions used to reduce the period of vocational training for new employees?	○	●	○
Set-up Time Reduction	To what degree do you continuously work to lower set-up and cleaning times in your lab?	●	●	
Set-up Time Reduction	What proportion of equipment set-ups are scheduled so that the testing process is not affected (e.g. to shorten lead time)?		○	●
Set-up Time Reduction	To what degree are optimized set-up and cleaning procedures documented as best-practices and rolled-out throughout the whole lab?	●	●	○

Enabler Dimension	Individual Enabler	Difference between		
		C1 & C2	C1 & C3	C2 & C3
Pull Approach	Do you use a pull system (Kanban squares, containers, or signals) for your consumables?	○	●	
Pull Approach	To what degree do you test according to forecast?		●	○
Pull Approach	To what degree do you have instruments installed for a regular demand and FTE capacity analysis?	○	●	○
Planning Adherence	To what degree does your lab have flexible working shift models to easily adjust labor capacity according to current demand changes?		●	○
Planning Adherence	Beyond flexible working shifts, do you assign extra resources within the lab for testing during peak loads or do you outsource activities?	○	●	
Employee Involvement & CI	To what degree does your site form cross-functional project teams to solve problems in your lab?		●	○
Employee Involvement & CI	To what degree does your lab follow a vision based approach to continuous improvement integrating constrains into the vision rather than an incremental approach?	●	●	
Funct.Integration & Qualification	To what degree is information and skill-evaluation from official feedback meetings used in further training?	○	●	○
Funct. Integration & Qualification	To what degree does your site invest in the training and qualification of your lab employees?		●	○
Funct. Integration & Qualification	To what degree do your cross-trained analysts rotate on the job performing different tasks?	○	●	

● Difference of implementation rate equal to or greater than 1.0 points on 5-point Likert scale
○ Difference of implementation rate smaller than 1.0 points on 5-point Likert scale but equal to or greater than 0.5
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

To conclude, the detailed analysis of the individual enabler implementation above showed that all three clusters mostly focus on the same enablers with some substantial differences depicted in table 59. Most notable differences exist between the implementation rate of cluster 1 and cluster 3. Some differences exist between cluster 1 and cluster 2 as well as clusters 2 and 3 regarding the implementation rate. Reemphasizing that cluster 3 shows a much higher QC lab effectiveness compared to cluster 2 further investigation is needed.

5.1.3 Cluster Operating Context

In preparation of the case studies a descriptive statistical analysis was conducted to identify differences of the operating context between clusters 1 (low enabler implementation, low QC lab effectiveness), 2 (high/low), and 3 (high/high). To identify differences between the clusters the relative proportion of individual context characteristics within each cluster is compared between clusters (e.g. proportion of QC labs from Europe). A major difference is defined as equal to or greater than 25 % difference between two clusters. A minor difference is defined as equal to or greater than 15 % difference between

two clusters. No variations below 15 % difference are highlighted. The analysis reveals that *Geographical Location*, *Portfolio Complexity*, and *Regulatory Approval* show major differences. Minor differences relate to *Organizational Scale*, *Economy of Scale*, and *Technology & Innovation* structure. No considerable differences were linked to the *Test Allocation Strategy*. Due to the limited sample size no statistical hypotheses testing for significant differences was conducted to disclose differences of the operating context between the clusters. The disclosed differences of the operating context enabled the researcher to raise specific questions in the semi-structured interviews of the case study research.

The analysis of the *Geographical Location* focused on the regional distribution and the cost location. The country allocation analysis was excluded due to the low number of QC labs per country and cluster. The analysis concludes that in clusters 2 and 3 the proportion of QC labs from Europe with 87 % and 78 % respectively is higher than in cluster 1 (62 %). In clusters 2 and 3 European QC labs have a higher relative representation compared to the overall sample (72 %) including all three clusters. Regarding the cost location, no considerable difference can be observed.

The *Portfolio Complexity* analysis focuses on differences regarding drug substance type, drug product type, and number of different final drug product types tested. In the following a chemical and a biological drug substance testing lab refers to a QC lab exclusively focused on one of the two drug substances. A biological drug substance testing QC lab does not test any chemical drug substance. A chemical drug substance testing QC lab does not test any biological drug substance. The analysis reveals a much higher concentration of chemical drug substance QC labs in clusters 1 and 2. Around 50 % of clusters 1 and 2 are QC labs testing chemical drug substance. Only 11 % of cluster 3 are chemical drug substance testing QC labs. 44 % of the overall sample test chemical drug substance. Cluster 3 includes many more biological drug substance QC labs. Comparing clusters 1, 2, and 3 the proportion of QC labs testing biological drug substance in cluster 3 is almost the same as chemical drug substance QC labs in clusters 1 and 2. 44 % of the QC labs in cluster 3 are testing biological drug substance. In clusters 1 and 2 the proportion of biological drug substance QC labs is below 15 %. The high proportion of biological drug substance testing QC labs in cluster 3 exceeds the proportion of biological drug substance testing QC labs to the overall sample substantially (44 % vs. 18 %). More than half of the QC labs in clusters 1 and 2 test multiple drug product types. The proportion of mixed drug product QC labs in these two clusters exceeds the proportion in cluster 3 (33 %) considerably. In addition, cluster 3 shows a much higher percentage (22 %) of QC labs with no drug substance testing compared to clusters 1 (12 %) and 2 (7 %). All available non-sterile liquids testing QC labs belong to cluster 3. Regarding the number of final drug product types tested, cluster 3 shows a substantially higher concentration of QC labs (89 %) with less than 50 final drug product types compared to clusters 1 (54 %) and 2 (40 %). Cluster 2 depicts the highest concentration of QC labs (53 %) with above 100 different final drug product types tested. No QC lab with more than 100 final drug product types tested belongs to cluster 3.

The *Organizational Scale* only shows minor differences. The analysis focused on the number of QC FTEs and site FTEs. Regarding the number of QC FTEs, cluster 1 has a

high concentration of QC labs (62 %) at the lower end with below 60 FTEs. More than half of the QC labs in cluster 3 show above 60 number of FTEs. In cluster 2 the number of QC labs below and above 60 FTEs is almost equally distributed. Regarding the number of site FTEs, no considerable difference was observed.

In the category *Economy of Scale* clusters 1, 2, and 3 were analyzed regarding the number of batches processed and the total number of tests conducted. While cluster 1 shows an almost equal distribution of QC labs with above and below 8,000 batches processed, the other two clusters do not show this distribution. Cluster 2 includes 60 % of QC labs processing below 8,000 batches. In cluster 3 78 % of QC labs are below this threshold. A similar relation between clusters 1, 2, and 3 exists for the number of tests conducted. Comparing the proportion of QC labs with a lower number of tests it increases from clusters 1 and 2 to 3. Clusters 1 and 2 show an almost identical proportion of 69 % respectively 73 % of QC labs that conduct below 200,000 tests. In cluster 3 89 % of the QC labs conduct less than 100,000 tests.

In *Technology & Innovation* the analysis focuses on the age of instruments and methods as well as the level of automation. Clusters 1, 2, and 3 show no considerable difference for the age of instruments and methods. Regarding the level of automation in cluster 3, more than half (56 %) of the QC labs have a high automation level. In clusters 1 and 2 more than half of the QC labs (65 % and 67% respectively) have a low level of automation. The level of automation in cluster 3 exceeds the level of automation of the overall sample substantially.

The *Regulatory Approval* distinguishes the US, Europe, China, and Japan. Regarding the approval in China and Japan, clusters 1, 2, and 3 show differences. Cluster 1 and 3 have an almost equal distribution of QC labs with and without Chinese approval, whereas in cluster 2 the QC labs with no Chinese approval represent the majority. In cluster 3 a majority of 78 % of the QC labs have the Japanese approval. A smaller proportion of QC labs in clusters 1 (58 %) and 2 (47 %) have the Japanese approval. No considerable difference can be identified for the US and European approval.

Table 60 shows a summary of the operating context and the difference between the three clusters. A more detailed quantitative overview of each characteristic can be found in appendix 8. It depicts the actual distribution of each cluster regarding all operating context factors.

Table 60: Comparison of clusters 1, 2, and 3 operating context

Category	Dimensions	Difference between			Comment
		C1 & C2	C1 & C3	C2 & C3	
Geographical Location[1]	Regional Distribution	●	○		C2 & C3 > C1 in Europe
	Cost Location				
Portfolio Complexity	Drug Substance (DS) Type		●	●	Chemical DS: C1 & C2 > C3 Biological DS: C1 & C2 < C3
	Drug Product (DP) Type		○	○ / ●	Non-sterile liquids: C1 & C2 < C3 Mixed DP: C1 & C2 > C3 No DP: C3 > C2
	No. of final DP Types Tested	○	●	●	C3 < C1 < C2
Test Allocation Strategy	Centralization				
	Degree of Centralization				
Organizational Scale	QC FTEs		○		C1 > C3
	Site FTEs				
Economy of Scale	No. of Batches processed		○	○	C1 > C3, C2 > C3
	No. of Tests		○	○	C1 > C3, C2 > C3
Technology & Innovation	Age of Instruments				
	Age of Methods	○			C1 > C2
	Automation		○	○	C1 < C3, C2 < C3
Regulatory Approval	US Approval				
	EU Approval				
	China Approval	○		○	C1 > C2, C2 < C3
	Japan Approval		○	●	C1 < C3, C2 < C3

[1] Dimension country not illustrated due to the limited number of QC labs per cluster and country
● Cluster comparison showed major difference for a specific characteristic (difference of the QC lab proportion within each cluster was equal or greater than 25 % between the two clusters)
○ Cluster comparison showed major difference for a specific characteristic (difference of the QC lab proportion within each cluster was equal or greater than 15 % between the two clusters)
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

5.1.4 Case Selection

Only two of three identified clusters of QC labs support the common understanding of the performance and enabler relation in OM literature. To analyze this result of the quantitative analysis further the three clusters build the a priori specification for the case study research. The case study design of multiple holistic cases allows comprehending why not all QC labs support the OM literature understanding. Stuart et al. (2002) emphasize that cases should be selected by diversity. Eisenhardt (1989) stresses the need to control the variation by selecting an appropriate population that defines the limits of generalizing the findings. The theoretical sampling approach is preferred over a random selection of cases (Eisenhardt, 1989). Theoretical sampling aims at cases that are likely to replicate or extend

theory (Eisenhardt, 1989). The author argues that selecting a case with an extreme situation may enhance the findings (Eisenhardt, 1989).

The main objective of the case selection of this research was to find a set of representative cases to explain why the clusters 1, 2, and 3 show a different enabler implementation and QC lab effectiveness relation. Cluster 2 was in the center of case selection process as it contradicts the OM literature (cf. chapter 2.2.2). The selected cases should allow investigating why QC labs in cluster 2 show a high enabler implementation but a low QC lab effectiveness. To get a clear understanding of cluster 2, the remaining cluster 1 and 3 should be contrasted. Consequently, the selected cases should allow investigating how cluster 3 achieves a high enabler implementation and a high QC lab effectiveness, and what differentiates cluster 1 from both the other two clusters. Linking the case selection process to the identified clusters in the quantitative analysis in chapter 4 addresses the requirement of Stuart et al. (2002) to select cases by diversity. It also concurs with Eisenhardt's (1989) theoretical sampling approach to control variation by selecting from an appropriate population. In addition, the research design focusing on multiple cases allows finding contrasting results (theoretical replication) (Yin, 2018). The following paragraph outlines the case selection process.

The quantitative analysis of the QC lab effectiveness and enabler implementation relation resulted in three distinct clusters. Cluster 1 with a low QC lab effectiveness and low enabler implementation includes 26 QC labs. Cluster 2 with a low QC lab effectiveness but high enabler implementation represents 15 QC labs. Cluster 3 comprises nine QC labs with a high enabler implementation and high QC lab effectiveness. A three-step case selection approach was employed. The above outlined requirements of Stuart et al. (2002) and Eisenhardt (1989) related to theoretical sampling framed the step-wise approach. To select representative cases the researcher generated a list of QC labs and corresponding companies for each cluster. Ten companies were identified for cluster 1. Cluster 2 included nine companies. Five different companies represented cluster 3. First, companies with less than three QC labs within the same cluster were excluded due to the limited representation for the respective cluster. This step reduced the number of possible case companies from 17 to four. Second, the more recent datasets were prioritized to ensure accessibility. This prioritization concluded with three remaining case companies. Third, the QC labs of the three selected companies that were excluded due to the threshold in step 1 were reintegrated. These QC labs enhance the case studies because they allow deepening potential differences between QC labs in different clusters but within the same company. To conclude, the three-step approach resulted in three representative companies with a total of 22 representative QC labs distributed across clusters 1, 2, and 3. The 22 QC labs represent 44 % of all available QC labs of this research that provided both performance and enabler data. Table 61 illustrates the three-step case selection process and its outcome after each step.

Table 61: Three-step case selection process

Cluster	Cluster Companies	Step 1: Exclusion	Step 2: Prioritization	Selected Companies	Step 3: Reintegration
		Companies (n_i<3)	Companies (n_i, %)		Companies (n_i, %)
C1	10	4	PharmaCo A (4, 50%), PharmaCo B (5, 50 %)	PharmaCo A, PharmaCo B, PharmaCo C	PharmaCo A (4, 50%), PharmaCo B (5, 50 %)
C2	9	2	PharmaCo B (3, 30 %), PharmaCo C (3, 75 %)		PharmaCo B (3, 30 %), PharmaCo C (3, 75 %)
C3	5	1	PharmaCo A (4, 50 %)		PharmaCo A (4, 50 %), PharmaCo B (2, 20 %, PharmaCo C (1, 25 %)

n_i = Number of labs per company
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The identified PharmaCo A, B, and C and their available QC labs per cluster are representative. Table 62 depicts an overview of the companies and QC lab allocation to clusters 1, 2, and 3. All available QC labs of PharmaCo A are equally distributed across clusters 1 and 3. Consequently, PharmaCo A represents cluster 1 and cluster 3. 50 % of all available QC labs of PharmaCo B are in cluster 1. Consequently, PharmaCo B also represents cluster 1. In addition, PharmaCo B allows comparing all clusters within one case study as the other half of PharmaCo B's QC labs is distributed across clusters 2 and 3. 75 % of all available QC labs of PharmaCo C belong to cluster 2. Therefore, PharmaCo C is representative for cluster 2. The link between the PharmaCos and its representativeness for the individual clusters is highlighted in bold in table 62. All other available QC labs of PharmaCo B and C that were reintegrated in the third step of the case selection process (cf. table 61) are used to enhance the case studies. In both case studies these QC labs are used to generate additional insight by contrasting them among all available QC labs and clusters within the organization.

Table 62: Selected cases and QC lab cluster allocation

Company	Company Type[1]	C1	C2	C3
PharmaCo A	US pharmaceutical company with above 40,000 employees worldwide and a revenue above 20 bn US dollars.	**4**	0	**4**
PharmaCo B	German biopharmaceutical company with above 50,000 employees worldwide and a revenue above 10 bn US dollars.	**5**	**3**	2
PharmaCo C	US biopharmaceutical company with above 90,000 employees worldwide and a revenue above 50 bn US dollars.	0	**3**	1

[1] Information retrieved from annual report 2017 of the respective company or other sources (e.g. bloomberg.org or different company material) if annual report was not public
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The QC lab proportion of the selected case QC labs of all QC labs in the clusters ranges between 35 and 78 %. In the case studies cluster 1 is represented by QC labs of

PharmaCo A and B. The two companies together represent 35 % of all available QC labs in cluster 1. Cluster 2 is represented by PharmaCo B and C. In this cluster PharmaCo B and PharmaCo C cover 40 % of all QC labs. In cluster 3, PharmaCo A, B, and C together substitute 78 % of all QC labs within this cluster. Figure 25 exhibits the relation between QC lab effectiveness and enabler relation highlighting the representative QC labs of the selected case companies for each cluster.

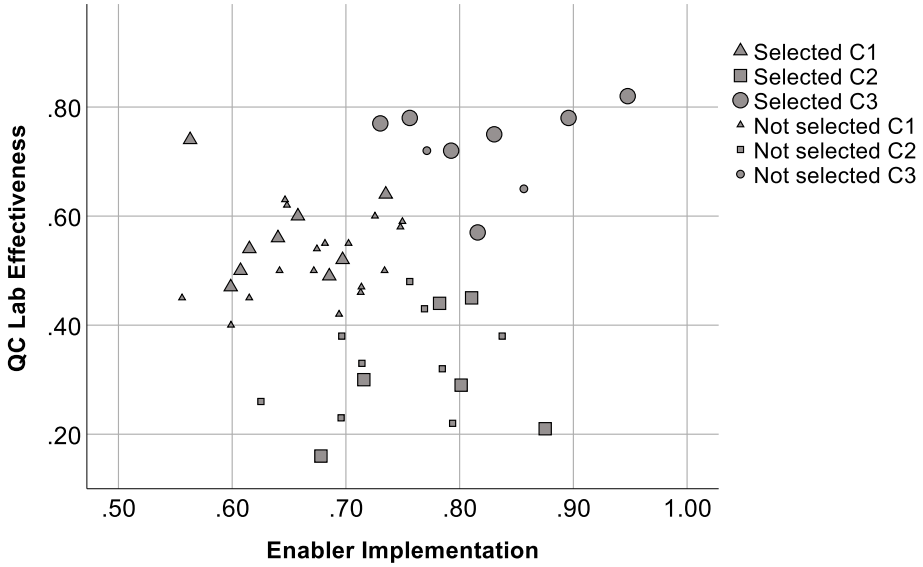

Figure 25: Scatter plot highlighting QC labs representing clusters 1, 2, and 3

Regarding the QC lab effectiveness, the case clusters, represented by the QC labs of the three selected PharmaCos, and original clusters do not differ substantially. While the original cluster 1 has an average QC lab effectiveness of 0.53, the case cluster 1 has an average QC lab effectiveness of 0.56. The original cluster 2 shows an average QC lab effectiveness of 0.33. The case cluster 2 QC labs reach a QC lab effectiveness of 0.31. Cluster 3 reaches an average QC lab effectiveness of 0.73. The case cluster 3 perform at a QC lab effectiveness of 0.74. In all three comparisons between the original cluster and the case cluster the performance difference ranges between -0.02 and 0.03. As the QC lab effectiveness represents a relative performance value the variation is between -2 and +3 %. Table 63 depicts an overview of all individual performance indicators of QC lab effectiveness and the difference between the original clusters and the case clusters 1, 2, and 3. The maximum difference shows *Recurring Lab Deviations* between cluster 2 and the selected QC labs for case cluster 2. The difference for all indicators between the selected QC labs for the case clusters 1 and 3 compared to the original clusters 1 and 3 is substantially smaller. In case cluster 1 *Customer Complaint Investigation Rate* matches the complaint rate of the original cluster 1. The three performance indicators *Analytical Right First Time*, *Product Re-Tests due to Complaints*, and *Recurring Lab Deviations* show the exactly the same performance in case cluster 3 as in the original cluster 3. All other performance indicators across the case clusters only show minor variation compared to the original clusters 1, 2, and 3.

Table 63: QC lab effectiveness of case QC labs representing clusters 1, 2, and 3

Performance Indicator	Case C1 (n=9)		Case C2 (n=6)		Case C3 (n=7)	
	Score[1]	Delta C1	Score	Delta C2	Score	Delta C3
Adherence to Lead Time	.50	+.02	.11	-.18	.74	-.03
Adherence to Schedule	.51	+.06	.32	-.05	.74	-.03
Analytical Right First Time	.43	-.15	.23	-.03	.61	+.00
Customer Complaint Investigation Rate	.53	+.00	.24	-.02	.82	-.03
Invalidated OOS Rate	.67	+.12	.30	-.06	.87	+.08
Lab CAPAs Overdue	.49	+.03	.49	+.03	.72	+.10
Lab Deviation Rate	.47	-.09	.38	+.04	.48	-.08
Lab Investigation Rate	.70	+.15	.28	-.03	.90	+.11
Product Re-Tests due to Complaints	.63	+.05	.32	-.13	1.00	+.00
Recurring Lab Deviations	.69	+.14	.54	+.24	.68	+.00
Average		+.03		-.02		+.01

[1] The score is a value between 0 and 1. It represents the average of all quantile ranks of the QC labs in the respective case cluster. The higher the value the better the case cluster performs related to the respective performance indicator.
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

Table 64 shows the enabler implementation rate of the selected case clusters 1, 2, and 3 QC labs. The delta columns for C1, C2, and C3 show that the case clusters are not substantially different from the original clusters. On the 5-point Likert scale the average difference between the case clusters and the original clusters implementation ranges between -0.07 and +0.11. On a relative scale the variation ranges between -1.75 and +2.75 %. A few of enabler dimensions differ up to a maximum of 9 % (cf. table 64).
To conclude, the good match of the QC labs included in the case studies with only minor differences regarding QC lab effectiveness and enabler implementation justifies these labs to be a representative set of QC labs for the original clusters 1, 2, and 3.

Table 64: Enabler dimension implementation of case QC labs and original clusters

Enabler System and Dimension	Implementation Level[1]					
	Case C1 (n=9)	Delta C1	Case C2 (n=6)	Delta C2	Case C3 (n=7)	Delta C3
All Enablers	3.22	-.11	3.89	+.11	4.12	+.01
Technical Enabler System	3.26	-.03	3.78	+.11	4.10	+.04
Preventive Maintenance	3.17	-.24	3.69	+.10	3.85	-.09
Technology Assessment & Usage	2.93	+.07	3.33	+.14	3.38	-.03
Housekeeping	3.58	-.16	4.54	+.38	4.61	+.02
Process Management	3.80	+.28	4.09	+.24	4.27	+.10
Standardization & Simplification	3.31	-.36	4.12	+.14	4.46	-.04
Set-up Time Reduction	2.61	-.14	3.54	+.25	3.74	-.11
Pull Approach	3.22	+.16	3.61	-.01	4.29	+.14
Layout Optimization	3.33	+.02	3.53	+.13	4.26	+.30
Planning Adherence	3.36	-.05	3.44	-.24	4.26	+.03
Visual Management	3.28	+.14	3.92	-.05	3.93	+.10
Management Enabler System	3.19	-.19	3.99	+.11	4.14	-.02
Mgmt. Commitment & Comp. Culture	3.46	-.25	4.14	+.10	4.22	-.03
Empl. Involvement & CI	2.90	-.11	3.79	+.17	3.72	-.05
Functional Integration & Qualification	3.19	-.20	4.04	+.06	4.46	+.02
Average		-.07		+.11		+.02

[1] Enabler implementation is measured on a 5-point Likert scale (1: lowest implementation, 5: highest implementation)
C1: Low enabler implementation, low QC lab effectiveness
Case C1: Representative set of QC labs for cluster 1.
C2: High enabler implementation, low QC lab effectiveness
Case C2: Representative set of QC labs for cluster 2.
C3: High enabler implementation, high QC lab effectiveness
Case C3: Representative set of QC labs for cluster 3.

5.2 Case Studies

This chapter is focused on an in-depth analysis of the QC labs of the three case companies. The case studies are composed of six different data sources: company-specific quantitative benchmarking data (1), individual and group interviews with corporate and local QC and OPEX senior executives (2), confidential and publicly available company material (3), workshop outcomes (4), personal notes and emails (5), and on-site lab observations (6). Due to changing accessibility to the three case companies over the period of this research, the composition of the six data sources shows minor variation between the case studies. Each chapter of the subsequent case studies highlights the data sources that were used to compile the content. Despite the changing accessibility to the case companies the researcher ensured data source triangulation in all case studies.

In the final phase of the case study research three semi-structured interviews were conducted with senior executives from each of the three identified case companies (cf. chapter 5.1.4). The interviews were conducted in a face-to-face setting or via telephone due to geographical distance. The researcher conducted two individual interviews and one group interview. Each interview was scheduled for 120 minutes. A semi-structured

interview approach allowed asking the same open-ended questions to all interview partners with flexibility to follow-up on relevant topics raised by the interview partner. The interview guideline focused on the company's corporate strategy to OPEX in QC labs and questions related to the enabler implementation of their QC labs in clusters 1, 2, and 3. For the latter the researcher prepared an overview of preliminary research results regarding the identified QC lab clusters as interview input for each company. A short overview of the up-front specification of the case studies was shared with the interview partners in advance to the interview to allow them gathering relevant information. The preliminary research results served as a starting point for the explanatory part of the interview related to the QC lab cluster allocation. The interviews closed with context questions related to previous findings in chapters 3 and 4 of this thesis. The sequenced interview schedule gave the researcher enough time to analyze each interview in detail before conducting the next interview. This sequenced approach allowed sharpening the succeeding interviews based on the generated knowledge of the preceding interviews. All interviews of the final research phase were recorded and transcribed. The transcripts were coded to allow theoretical generalization. The interview guideline can be found in appendix 9.

In the following, the case studies focus on understanding why the identified clusters of QC labs with differing enabler implementation and QC lab effectiveness exist. The main objective is to explain *how* and *why* the QC labs are different and how this is reflected in the QC lab cluster allocation. The configurational approach to explain *how* and *why* the QC labs are different is used in the in-depth case studies and the cross-case study analysis. By identifying "multidimensional constellation of […] distinct characteristics that commonly occur together" (Meyer et al., 1993, p. 1175) the configurational approach allows deriving commonalities and differences between high and low performing QC labs across the case studies.

First, each case study begins with a general introduction to the pharmaceutical company. Second, the case outlines the corporate approach and current strategy to OPEX in QC labs of the company. Third, each case study highlights observations *how* the QC labs in the different clusters are different. The observations focus on deepening the understanding of QC lab effectiveness and the enabler implementation of the available QC labs in each cluster of the respective case company. This chapter focuses on describing differences and commonalities and putting context to the observations. The research aims at disclosing specific case related influencing factors *why* the differences and commonalities regarding the enabler implementation and QC lab effectiveness exist for the respective case company. Fourth, each case study concludes with a summary of the findings *why* the QC labs are performing differently related to QC lab effectiveness and the enabler implementation.

5.2.1 Case 1: PharmaCo A

PharmaCo A is a US pharmaceutical company with above 40,000 employees worldwide and a revenue above 20 bn US dollars. The company group has multiple business units with products marketed in more than 100 countries. The products are manufactured in more than five different countries across America, Europe, and Asia. About 20 % of the

employees are engaged in R&D and approximately the same proportion of the annual revenue was spent on R&D in recent years.
In total nine different points of contact contributed to compile the case study on PharmaCo A. Employees at different levels within the organization allowed generating a comprehensive understanding related to the research focus. The collaboration of the researcher and PharmaCo A on OPEX in QC labs started in July 2017 and has continued until today.

5.2.1.1 Operational Excellence Strategy in QC Labs

The OPEX strategy in QC labs regarding PharmaCo A is compiled from the comprehensive analysis of the semi-structured interview with a corporate QC and OPEX senior executive of PharmaCo A and confidential as well as publicly available company material. In addition, the researcher joined a presentation on the OPEX transformation of the QC labs held by a senior executive of PharmaCo A in September 2018.
PharmaCo A emphasizes that "Operational Excellence requires a management system that stresses the systematic application and integration of a variety of beliefs, principles, behaviors, and tools toward the sustainable improvement […]."
In the past, the QC labs of PharmaCo A acted independently and did not align their work on OPEX throughout the organization. Only those sites that had the knowledge and experience in OPEX saw its potential in QC labs and dedicated resources to it. Therefore, depending on the leadership team priorities only some sites ensured the existence of OPEX initiatives in the QC labs and drove continuity. The company started with a systematic corporate OPEX approach in manufacturing around six years ago. After seeing first benefits in the manufacturing function, the approach to OPEX in manufacturing was transferred to the QC labs. PharmaCo A extended the effort in manufacturing to the QC labs by adapting manufacturing principles in 2017. A main driver of initiating a corporate approach to OPEX in QC labs was the robust pipeline of new products at PharmaCo A and the business decision not to invest substantially in additional resources to manage the growing product portfolio in the QC labs. Consequently, PharmaCo A needed to increase the QC lab efficiency to manage the increasing workload of new products.
In the past, PharmaCo A has seen variability in the progress of OPEX initiatives throughout its QC labs. This was mainly driven by setting different priorities on corporate and local level as well as different leadership approaches. Without changing the organizational structure PharmaCo A established two new committees to ensure continuity and alignment between the corporate team and local teams across all QC labs. A corporate committee, including three vice presidents and two corporate senior managers, reviews and approves all OPEX initiatives on a monthly basis. This committee selects a lead QC lab for each initiative and develops a roadmap that includes the timing of the other QC labs to follow. One of the senior managers of the corporate committee builds the link to a second committee that includes all lab leaders of the organization. In this global committee of lab leaders the roadmap of the corporate committee is reviewed and further broken down by QC lab network[34]. The global committee of lab leaders allows them to exchange and learn

[34] PharmaCo A separates its QC labs into multiple QC lab networks with the same product range.

from each other. Harmonizing the roadmaps at QC network level with the reporting structure of the QC labs to the vice presidents ensures Continuous Improvement (CI).The standardized way of starting and monitoring all QC lab OPEX initiatives in PharmaCo A has improved the attention on OPEX in QC labs. Additionally, it has stopped initiatives that were started by individuals in the past but were not adding value to the business.

The lean lab transformation of PharmaCo A aims at improving efficiency, increasing agility, and competitiveness. The company emphasizes its lab transformation as a journey of changing behaviors and adopting a CI mindset. The focus moved away from implementing specific tools to transforming all different levels of the organizational from lab analysts to the leaders. The transformation comprises five pillars: education (1), standard work (2), visual management (3), leadership (4), and others (5). The education element focuses on lean basics, fostering lean understanding among leaders, and problem solving. At PharmaCo A a standardized educational workshop is a key activity to start OPEX initiatives in all QC labs. Moreover, employee development is used as a tool for CI. The standard work element addresses process standardization and techniques to improve orderliness of the workspace. The visual management element aims at providing visual feedback on workflow and process performance. The leadership element emphasizes coaching, first-hand shop floor presence, and daily meetings. The remaining fifth element combines additional techniques that reinforce the lean transformation and support the transformation pillars education, standard work, visual management, and leadership.

At PharmaCo A a corporate team primarily drives the QC lab transformation. However, the corporate team incorporates the knowledge and experience of the local teams into the standardization effort. Lead QC labs for each OPEX initiative are selected based on the potential business impact that can be generated by improving the QC lab. PharmaCo A has worked considerably on developing the lab leadership in the past few years. In the lead QC lab selection process the company also considers whether the QC lab has the appropriate leadership showing enthusiasm and perseverance. To start an OPEX initiative in a lead QC lab, a standardized workshop introduces the initiative to the selected QC lab. Based on the success in the lead QC lab the company rolls out the initiative across all QC labs of the organization. The company assigned a corporate expert on OPEX in QC labs to conduct all initial OPEX initiative kick-off workshops across the organization. For different geographical regions project managers were selected that ensure consistency for the regional rollout.

The lean transformation is expected to provide an improved understanding of the current process performance by measuring standardized performance indicators. On a corporate level trends for individual QC labs and the networks of QC labs are monitored. A direct comparison between QC labs is not included in the corporate monitoring process to avoid driving unfavorable behaviors. Through reporting network performance to the corporate level PharmaCo A aims at a collaborative competitiveness between the QC labs. By monitoring the aggregation of performance indicators across all QC labs within one network each QC lab is encouraged to share successful practices with the other labs of its network to improve the overall network performance. In addition, PharmaCo A intends to leverage employee development through short-term assignments of lab supervisors or

analysts to share successful practices with other QC labs in- and outside the QC lab network.

PharmaCo A QC lab transformation aims at organizational knowledge through extensive use of standard work and employee involvement in the standard work definition process. The goal is to improve the understanding of the main barriers and bottlenecks and to encourage the exchange between QC lab analysts in daily stand-up meetings. In addition, the time spent by leaders in the lab is increased to enhance direct support and setting directions of improvement. Incremental improvements should always be integrated into the normal day-to-day operations. The transformation expects everyone to be involved in CI.

In 2017 and 2018 PharmaCo A participated in the St. Gallen QC Lab OPEX Benchmarking. The benchmarking in 2017 served as a starting point of OPEX in QC labs. The goal of PharmaCo A was to clean up the performance measurement and to initiate standardizing the displayed metrics across all QC labs. During the benchmarking the company identified many inconsistencies within its QC labs. The metrics, definitions and performance scorecards in the different QC labs were not standardized. Consequently, in the recent past PharmaCo A defined a desired state of a balanced QC scorecard including five dimensions: safety (1), quality (2), cost & productivity (3), delivery (4), and people (5). Currently, the company is working on implementing the balance scorecard on lab team level (daily monitoring), site level (monthly monitoring), and network level (quarterly or semi-annual monitoring). In the future, PharmaCo A aims at putting an electronic dashboard in place that can be monitored at different levels of the organization. To identify the requirements of the dashboard both corporate and local employees were involved in the development process. The future dashboard will be automatically generated based on the available performance data of the standardized systems of all QC labs. PharmaCo A intends to give flexibility to its local teams for customization of the dashboard in the QC lab. The QC labs will have the ability to define themselves what to measure and how frequently to measure. Additionally, the QC lab will have flexibility how to visualize the results. Nevertheless, PharmaCo A expects to have selected key performance indicators collected and shared automatically with the corporate level that are significant to the business and need visibility. To achieve the automated generation of the dashboard, PharmaCo A invests in standardizing the system architecture and data management across its QC labs.

Along the first steps of the QC lab transformation PharmaCo A has seen success building its OPEX initiatives on a business case and return of investment within a six-month time horizon. The company assesses the benefits of OPEX initiatives on site and network level. Additionally, passionate leaders at local and corporate level have driven CI of the QC labs of the organization.

To conclude, PharmaCo A started a systematic OPEX approach in QC labs about a year ago. Most of the approach was developed internally. External parties were primarily involved to verify and confirm planned actions. Currently, the company is in an early transformational stage. A major focus of the current OPEX effort of PharmaCo A is focused on replicating successful practices across the QC labs. Therefore, the company has compiled a roadmap how to rollout the corporate approach to all QC labs across the organization. At this point, the rollout progresses and first benefits are realized. In the

future, PharmaCo A wants to address the challenge between replication and innovation. Once the impact of innovation is large enough, the company wants to move away from replicating successful practices. In addition, the company aims at putting a QC lab certification program in place to reward and sustain the discipline of the QC labs to work on CI.

5.2.1.2 Observations

The observations regarding PharmaCo A summarize the comprehensive analysis of the available company specific performance and enabler benchmarking data, the semi-structured interview with a corporate QC and OPEX senior executive of PharmaCo A, confidential as well as publicly available company material, and on-site lab observations of one of PharmaCo A's QC labs.

In the following, the observations of the four QC labs in cluster 1 with a low enabler implementation and a low QC lab effectiveness are compared with the four QC labs in cluster 3 with a high enabler implementation and a high QC lab effectiveness. None of the available QC labs of PharmaCo A showed the contradicting relation to OM literature of a high enabler implementation with a low QC lab effectiveness (cluster 2). However, the comparison of clusters 1 and 2 of PharmaCo A informs the research by identifying how the CI effort in the different clusters deviates. Figure 26 highlights the available QC labs of PharmaCo A.

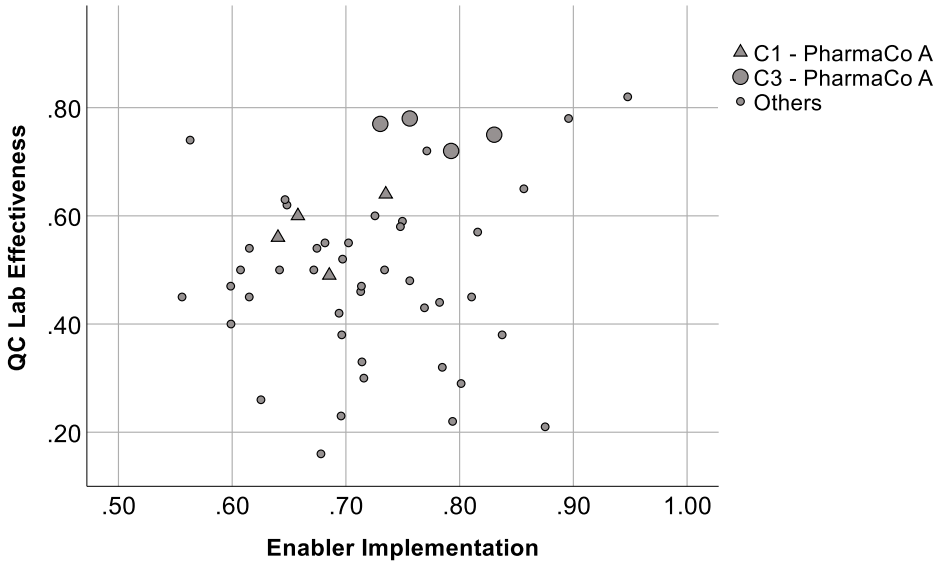

Figure 26: QC lab effectiveness and enabler plot highlighting PharmaCo A QC labs

The following paragraphs investigate the QC lab effectiveness of PharmaCo A's QC labs. The observations focus on commonalities within both clusters as well as differences between the two clusters. The QC lab effectiveness performance builds on service and quality performance (cf. chapter 4.1.5). At PharmaCo A within clusters 1 and 3 the service and quality performance are almost equally high. However, in both dimensions cluster 3 shows a substantially higher performance. The performance gap is smaller for the service performance compared to the quality performance.

In the following, the three indicators showing the highest performance levels are described for cluster 3. In addition, the three indicators with the lowest performance levels of cluster 1 are highlighted. For cluster 3 the order of performance indicators is descending starting with the indicator showing the highest performance. For cluster 1 the order of the performance indicators is ascending starting with the indicator showing the lowest performance level. In cluster 3 the QC labs of PharmaCo A have a high performance regarding *Product Re-Tests due to Complaints*, *Lab Investigation Rate*, and *Lab CAPAs Overdue*. Investigating cluster 3 of PharmaCo A reveals that none of the QC labs in this cluster needs to conduct product re-tests due to complaints. Consequently, PharmaCo A does not have any performance variation regarding this performance indicator in cluster 3. All other performance indicators across both clusters show at least some variation. In cluster 1 the QC labs show the lowest performance in *Lab Deviation Rate*, *Invalidated OOS Rate*, and *Customer Complaint Investigation Rate.*

Comparing the indicators showing the highest performance in cluster 3 with the indicators showing the lowest performance in cluster 1 and the largest performance gap reveals that the performance indicators overlap. The largest performance gaps between cluster 1 and cluster 3 of PharmaCo A exist regarding the three indicators ranked in descending order: *Product Re-Tests due to Complaints*, *Invalidated OOS Rate*, and *Customer Complaint Investigation Rate*.

The variation of the performance level within clusters 1 and 3 of PharmaCo A differs substantially. In cluster 1 the variation is almost twice as high as in cluster 3. Table 65 summarizes the observations related to QC lab effectiveness of the QC labs of PharmaCo A.

Table 65: QC lab effectiveness observations PharmaCo A

Category	Observations PharmaCo A	
	C1	**C3**
Service & Quality Performance	S ~ Q	S ~ Q
Performance Gap	S < Q	
Highest Performance		Product Re-Tests due to Complaints, Lab Investigation Rate, Lab CAPAs Overdue
Lowest Performance	Lab Deviation Rate, Invalidated OOS Rate, Customer Complaint Investigation Rate	
Largest Performance Gap	Product Re-Tests due to Complaints, Invalidated OOS Rate, Customer Complaint Investigation Rate	
Performance Variation	C1 >> C3	

~ Almost equal, A < B: A is smaller than B, A << B: A is substantially smaller than B
C1: Low enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The following paragraphs investigate the enabler implementation of PharmaCo A's QC labs. Cluster 1 differs from cluster 3 when the implementation level of the Technical

Enabler System (TES) and the Management Enabler System (MES) are compared. Cluster 1 shows a higher implementation of the TES, whereas cluster 3 has an almost equally high implementation level for both systems. The system implementation gap between the two clusters of PharmaCo A is higher in the MES compared to the TES. However, the QC labs of PharmaCo A in both clusters achieve some degree of integration between the various enabler dimensions. The variation of the enabler implementation level is below 12 % for all enabler dimensions in all available QC labs of PharmaCo A.

Comparing the three enabler dimensions with the highest implementation for each cluster for all QC labs of PharmaCo A some commonalities but also differences occur. It should be noted that cluster 3 has a higher absolute implementation in all enabler dimensions. Consequently, in this paragraph a high implementation means a high implementation relative to the implementation of the other enabler dimensions in the same cluster. Both clusters show a high implementation of *Housekeeping.* However, only for QC labs in cluster 3 a MES dimension (*Functional Integration & Qualification*) belongs to the three enabler dimensions with the highest implementation level. Apart from *Housekeeping* and *Function Integration & Qualification*, cluster 3 QC labs of PharmaCo A also show a high implementation in *Standardization & Simplification*. Next to *Housekeeping* cluster 1 QC labs of PharmaCo A have a high implementation in *Layout Optimization* and *Process Management.*

Standardization & Simplification, *Set-up Time Reduction*, and *Functional Integration & Qualification* are the three enabler dimensions in which cluster 3 QC labs of PharmaCo A have the most differing implementation level compared to their QC labs in cluster 1. The QC labs in cluster 3 exceed the implementation of the QC labs in cluster 1 in all three dimensions considerably. Table 66 summarizes the enabler observations at PharmaCo A.

Table 66: Enabler observations PharmaCo A

Category	Observations PharmaCo A	
	C1	**C3**
System Implementation	TES > MES	TES ~ MES
System Implementation Gap	TES < MES	
Highest Implementation Level	Layout Optimization, Housekeeping, Process Management	Housekeeping, Functional Integration & Qualification, Standardization & Simplification
Largest Enabler Dimension Impl. Gap (vs. C3)	Functional Integration & Qualification, Set-up Time Reduction, Standardization & Simplification	
Variation of Enabler Implementation	C1 ~ C3	

~ Almost equal, A < B: A is smaller than B
C1: Low enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The QC labs of PharmaCo A in cluster 1 with a low QC lab effectiveness and a low enabler implementation show a high business complexity. At the time of the analysis none of the

QC labs in cluster 1 already participated in the corporate OPEX initiative for QC labs. Consequently, all these QC labs worked on their own priorities. Most often these priorities were linked to direct business needs and not CI. Because there was no corporate sponsoring of the OPEX initiative they were not able to allocate the resources to CI. The QC labs of PharmaCo A in cluster 1 are characterized by substantial changes of their business in the last years. All of these QC labs are involved in the launch of new products. One of the QC labs is a lab at a commercialization site that had ten new products launched in the past two years. The product launches are usually not evenly distributed but happen to regularly disturb the routine. Additionally, the business complexity is driven by the amount of testing for other sites within and outside the organization in one of the QC labs. The degree of centralization led to a substantially higher planning and work scheduling effort. Another QC lab in this cluster changed its leadership team during the reporting period as it was not supporting the QC lab transformation. The leadership change allowed a restart but was not yet showing improvements in the performance and enabler implementation at the point of analysis. Additionally, the majority of the PharmaCo A's QC labs in cluster 1 did not embrace the introduction of a new method execution system. The adverse mindset of these QC labs toward new technology led to a refusal of the new system that was supposed to reduce their day-to-day effort.

The QC labs with a high QC lab effectiveness and high enabler implementation in cluster 3 show a high homogeneity of the types of testing. One of the QC labs has already undergone the QC lab transformation and shows first improvements. This QC lab was selected due to its key role as a lab at a commercialization site as an early adopter of the OPEX transformation. The transformation helped this QC lab to manage the complexity related to new product launches. Another QC lab in this cluster is characterized by the possibility of a frequent repetition of its tests showing a low complexity. Although one of the QC labs in this cluster also went through a drug product type change in the recent past, the type of testing did not change. Consequently, the business change did not cause complex changes in the mode of operation of this lab. Another lab of cluster 3 refurbished their entire QC lab to prepare for adding a second drug product type to it. As part of this set-up change the QC lab focused on work flow optimization and standardization. The QC labs of PharmaCo A in cluster 3 show different reasons for their high QC lab effectiveness and high enabler implementation. All QC labs in this cluster have in common that the business is not complex or the business complexity was already addressed in the past and has been transformed into a manageable business complexity until today.

Contrasting clusters 1 and 3 of PharmaCo C with selected performance-unrelated quantitative data of the QC lab benchmarking allows deepening the business complexity of the different QC labs. Cluster 1 is characterized by a more than three times higher testing volume compared to cluster 3. In addition, QC labs in cluster 1 also test more final drug product types than cluster 3. The combination of both aspects emphasizes that the majority of QC labs in cluster 1 are confronted with a high business complexity compared to a low business complexity of most QC labs in cluster 3.

Regarding the organizational structure and the employee development, the QC labs in both clusters of PharmaCo A show differences and commonalities. With few exceptions all analyzed QC labs have four reporting layers. In addition, in PharmaCo A the average

span of control ranges between nine (cluster 3) and 11 (cluster 1) employees reporting to one superior. The level of cross-trained analysts in clusters 1 and 3 differs substantially. In cluster 1 only 60 % of analysts are cross-trained, whereas in cluster 3 almost all employees are cross-trained. The lower level of cross-training does not match the higher business complexity in cluster 1 compared to cluster 3. Across both clusters the QC labs organize themselves to increase testing efficiency with a substantial amount of group work. More than two thirds of all analysts are involved in group work in both clusters. In cluster 1 the QC labs have almost twice as many training days per employee and year compared to the QC labs in cluster 3. On average, every employee spends 17 days per year on training in QC labs in cluster 1.

5.2.1.3 Conclusion

PharmaCo A has worked on OPEX in QC labs since 2017. The company is in the early phase of the QC lab transformation. Currently, they focus on rolling out the QC lab OPEX initiatives across the organization. Some of the QC labs have already undergone the transformation and shown first benefits. Other QC labs follow on a continuous basis. In the first half of 2019 all QC labs will have conducted the OPEX kick-off workshop and introduced the first phase of OPEX initiatives.

PharmaCo A has QC labs with a low QC lab effectiveness and a low enabler implementation as well as QC labs with a high QC lab effectiveness and a high enabler implementation. All QC labs of PharmaCo A focus on service and quality performance. However, the performance variation is substantially higher for the QC labs with a low QC lab effectiveness and low enabler implementation.

The in-depth analysis of PharmaCo A has shown that not all QC labs have a systematic approach to the enabler implementation and that the enabler focus differs. The analysis has also shown that the main drivers for the cluster allocation within PharmaCo A are business complexity related to changing business requirements, different leadership approaches, and the heterogeneity respectively homogeneity of testing.

The organizational structure between the available QC labs is similar. However, the employee development approach between the QC labs of PharmaCo A shows some differences beside commonalities. A major difference exists in the level of cross-trained analysts. Well performing QC labs with low business complexity have a higher degree of cross-trained analysts compared to the low performing QC labs of PharmaCo A with a high business complexity. In addition, the well performing QC labs invest considerably less time per employee in training but the training must be more effective as these QC labs do not suffer from fewer training days.

5.2.2 Case 2: PharmaCo B

PharmaCo B is a German biopharmaceutical company with above 50,000 employees worldwide and a revenue above 10 bn US dollars. The company group has multiple business units and operates in more than 50 different countries. In the pharmaceutical and biopharmaceutical business, the product portfolio encompasses a wide range from prescription drugs. The products are manufactured in more than five different countries

across America, Europe, and Asia. PharmaCo B has spent around 15 % of the annual revenue on R&D in recent years.
In total ten different points of contact contributed to compile the case study on PharmaCo B. The researcher worked together with employees from corporate and local level to receive a broad understanding of the company's work on OPEX in QC labs. The collaboration of the researcher and PharmaCo B on OPEX in QC labs started in May 2017 and has continued until today.

5.2.2.1 Operational Excellence Strategy in QC Labs

The OPEX strategy in QC labs regarding PharmaCo B is based on the comprehensive analysis of the semi-structured interview with a corporate QC and OPEX senior executive of PharmaCo B and confidential as well as publicly available company material. In addition, senior executives of PharmaCo B presented the OPEX strategy in QC labs to the researcher at three meetings between May 2017 and September 2018.
PharmaCo B started working on OPEX in QC labs in 2011. The company emphasizes OPEX as "a mindset through which the company is able to focus on meeting customer needs and expectations using strong leadership, process, and teamwork." At the same time the company stresses OPEX as an enabler to achieve "growth […] due to greater focus on improving value to the customer, increased operations efficiency, and […] administration." PharmaCo B stresses that "Operational Excellence is not a department but […] mindset and behavior for everyone every day."
Three major phases of OPEX in QC labs at PharmaCo B can be distinguished. Phase 1 was terminated in 2012. Phase 2 was terminated recently but useful tools and methods have informed the launch of the currently on-going phase. Phase 3 started at the beginning of 2018. In the first phase, a globally driven OPEX transformation was initiated with a local deployment roadmap supported by an external consultancy. PharmaCo B followed a top-down approach during phase 1 primarily focused on efficiency improvements. The top-down approach did not include any effectiveness or enabler focus. In this phase PharmaCo B improved the performance of QC labs by around 15 %, but a major challenge after phase 1 was to sustain these improvements over time and support the changing business.
In the second phase from 2017, PharmaCo B reversed the approach to OPEX of phase 1 introducing a bottom-up approach led by the individual QC labs focused on local improvements. The focus shifted to a more internally and locally driven OPEX acceleration of each individual QC lab supported by the global team. The bottom-up approach developing individual site- and lab-specific solutions reached a high acceptance rate of the QC lab employees on each site. Consequently, the locally owned and driven transformation substantially drove the lean maturity at the sites. PharmaCo B invested a lot into training and certification of its employees during this phase. The company achieved to build a common understanding of efficiency, effectiveness and enablers throughout the quality organization. However, a major challenge was to harmonize the transformation between different sites. The ability to share successful practices within the network of QC labs was not used in this phase. Consequently, the bottom-up approach led to a considerable amount of redundancies in PharmaCo B.

The third phase started at the beginning of 2018 and is based on concepts of the preceding OPEX acceleration (phase 2). It combines the bottom-up approach of phase 2 with a systematic top-down approach. The third phase expands the past OPEX transformation to address three major pillars: quality operations network, digitalization and lean lab. The combination of a bottom-up and top-down approach addresses the difficulty of harmonizing the Continuous Improvement (CI) effort across sites in phase 2. Compared to phase 2 the OPEX transformation driver changed from the individual site to corporate level.

In phase 3 the global quality organization currently drives the transformation and receives support from the local OPEX teams. To achieve maximum harmonization between the different QC labs the global team developed excellence guidelines together with selected lead QC labs of the network. Based on these excellence guidelines all QC labs systematically identify and evaluate gaps. For all identified gaps measures are defined and an implementation roadmap is designed. The global team is supporting the action planning and monitoring this CI process. In addition, the global team challenges the improvement focus identified by the site level with the findings of the St. Gallen QC Lab OPEX Benchmarking participation of the QC lab. The St. Gallen QC Lab OPEX Benchmarking of the QC labs of PharmaCo B was initiated in 2017 by the global team in preparation of phase 3. Necessary adjustment to the improvement focuses, developed on site level, are made together with the QC lab. The St. Gallen QC Lab OPEX Benchmarking results build a baseline across the network for selected improvement initiatives of PharmaCo B's transformation in the QC labs. The developed excellence guidelines allow applying similar solutions across the QC lab network.

The on-going third phase focusing on the quality operations network, digitalization, and lean lab includes many different activities that run in parallel. The current roadmap depicts 14 different initiatives over the next four years. The roadmap distinguishes the *Defining Strategy & Pilot* phase and the post-pilot *Implementation* phase for all initiatives. About 20 % of the initiatives are linked to the quality operations network. The main objective of this focus area is to harmonize local approaches on a global network level. PharmaCo B's global quality organization centralizes locally developed solutions and ensures the deployment across the network. 50 % of the initiatives are linked to digitalization. Key aspects of the digitalization effort range from reaching a paperless lab and high automation to install a fully integrated lab information management system. About 30 % of the initiative are linked to lean. These initiatives range from successful practice sharing and QC excellence standardization to the continuation of phase 2 activities.

Different from the beginning of the OPEX transformation in 2011, PharmaCo B is not focused on short-term gains anymore. In the recent past the focus has shifted toward a sustainable transformation of the QC labs. Since the beginning of phase 3 PharmaCo B has spent a significant amount of time on defining and specifying this new phase of transformation. The current objective is to have around 80 % of the OPEX transformation initiatives implemented across the network of QC labs by 2022. However, PharmaCo B does not disconnect the OPEX transformation from the immediate business needs of its QC labs. The global team adjusts its expectations regarding improvements related to the current situation of the QC labs.

With the changing approach of OPEX in QC labs from phase 1 to phase 3 PharmaCo B has also developed its organizational structure to match the requirements of the transformation. Today, the company has a corporate head of QC lab excellence who is supported by a global OPEX manufacturing team. Each site of PharmaCo B has at least one employee that is responsible for OPEX. This person is trained in OPEX tools and methods but not dedicated to one function. In addition, some sites have OPEX-trained and certified employees in specific functions such as the QC lab. The employees outlined above on global and local level developed the QC lab excellence guidelines that build the basis of the collaborative approach of PharmaCo B in phase 3. In addition, no direct reporting between the local OPEX employees and the head of QC lab excellence ensures a supportive and collaborative working environment to improve the QC labs across the network. Clear objectives and defined improvement milestones allow monitoring the progress of each QC lab by the head of QC lab excellence in monthly meetings. These meetings are also used to communicate successful practices across the network. PharmaCo B intends to have healthy competition between its QC labs. The collaborative approach including the availability of successful practices to everyone allows avoiding unfavorable competition between the QC labs.

5.2.2.2 Observations

The observations regarding PharmaCo B summarize the comprehensive analysis of the available company specific performance and enabler benchmarking data, the semi-structured interview with a corporate QC and OPEX senior executive of PharmaCo B, and confidential as well as publicly available company material. Additionally, two benchmarking result presentations with corporate and local representatives of all QC labs of PharmaCo B discussing the individual QC lab results served as a data source.

In the following, the five QC labs of PharmaCo B in cluster 1 with a low enabler implementation and a low QC lab effectiveness are compared to PharmaCoB's three QC labs in cluster 2 showing a high enabler implementation but low QC lab effectiveness. In addition, all these QC labs are compared to the two QC labs in cluster 3 with a high enabler implementation and a high QC lab effectiveness. Figure 27 highlights the available QC labs of PharmaCo B.

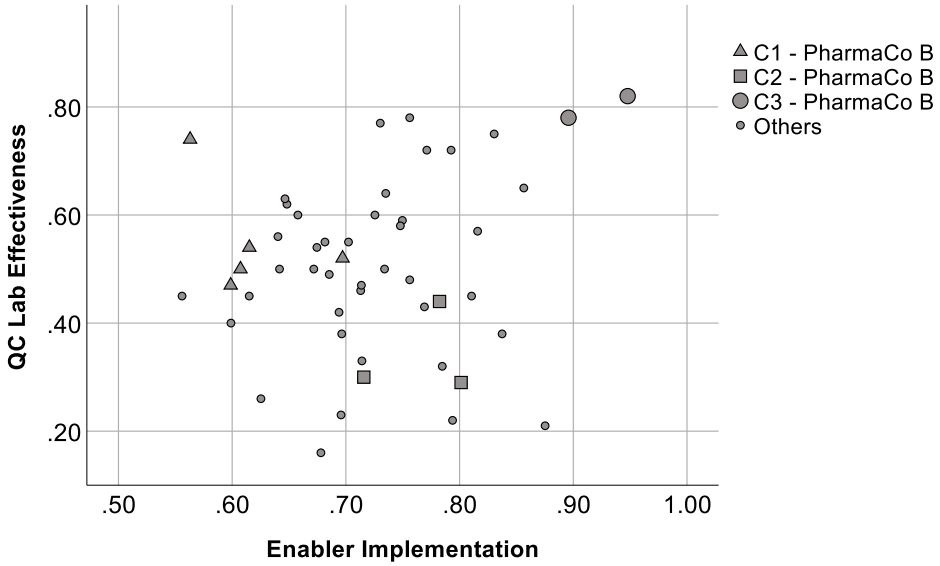

Figure 27: QC lab effectiveness and enabler plot highlighting PharmaCo B QC labs

The following paragraphs investigate the QC lab effectiveness of PharmaCo B's QC labs. The observations focus on commonalities within each cluster and differences between the three clusters. The QC lab effectiveness performance builds on service and quality performance (cf. chapter 4.1.5). It should be noted that the overall performance of cluster 2 exceeds cluster 1 and cluster 3 exceeds cluster 2. A closer look at the individual cluster reveals whether the dimension quality or service shows a higher performance. In cluster 2 and cluster 3 QC labs of PharmaCo B an equally high service and quality performance level was measured. On the contrary, PharmaCo B's QC labs in cluster 1 achieve a higher performance in quality compared to service. This fact leads to a larger performance gap regarding the service performance between cluster 1 and cluster 3 compared to the quality performance gap. Between cluster 2 and cluster 3 of PharmaCo B QC labs the performance gap for both dimensions is almost equal.

In the following, the three indicators showing the highest performance levels are described for cluster 3. In addition, the three indicators with the lowest performance levels of clusters 1 and 2 are highlighted. For cluster 3 the order of performance indicators is descending starting with the indicator showing the highest performance. For clusters 1 and 2 the order of the performance indicators is ascending starting with the indicator showing the lowest performance level. The QC labs of PharmaCo B in cluster 3 show a high performance regarding the performance indicators *Customer Complaint Investigation Rate*, *Product Re-Tests due to Complaints, Lab Investigation Rate*, and *Adherence to Lead Time.* In total, four different dimensions are outlined for cluster 3 as *Lab Investigation Rate* and *Adherence to Lead Time* share the third highest performance level. A closer look at the QC labs of PharmaCo B in cluster 3 reveals that none of the QC labs needs to conduct product re-tests due to complaints. Additionally, PharmaCo B's QC labs in cluster 3 show no performance variation in *Adherence to Lead Time*, *Customer Complaint Investigation Rate*, and *Product Re-Tests due to Complaints*. Cluster 1 shows the lowest performance related to *Adherence to Schedule*, *Analytical Right First Time*, and *Lab CAPAs Overdue*.

Cluster 2 shows the lowest performance related to *Customer Complaint Investigation Rate*, *Product Re-Tests due to Complaints*, and *Adherence to Lead Time*.
Comparing the indicators showing the highest performance in cluster 3 with the indicators showing the lowest performance in cluster 2 reveals that these performance indicators are identical. Consequently, the largest performance gaps between clusters 2 and 3 are linked to these three performance indicators ranked in descending order: *Customer Complaint Investigation Rate*, *Product Re-Tests due to Complaints*, and *Adherence to Lead Time*. Comparing the performance gaps between clusters 1 and 3 the analysis results in the same three performance indicators as outlined for the performance gap between clusters 2 and 3. However, the magnitude of the performance gap between clusters 1 and 3 is smaller compared to clusters 2 and 3.
The variation of the performance level of the QC labs of PharmaCo B within the clusters differs substantially. Within cluster 1 the QC lab effectiveness variation is higher than in the remaining clusters. However, clusters 2 and 3 do not show the same variation. Cluster 3 shows a substantially lower variation of the performance level across the indicators than the QC labs of clusters 1 and 2. As elaborated above, cluster 3 is the only cluster with no variation for a subset of performance indicators. Table 67 depicts a summary of the observations related to QC lab effectiveness of PharmaCo B.

Table 67: QC lab effectiveness observations PharmaCo B

Category	Observations PharmaCo B		
	C1	**C2**	**C3**
Service & Quality Performance	S < Q	S ~ Q	S ~ Q
Performance Gap (vs. C3)	S > Q	S ~ Q	N/A
Highest Performance			Customer Complaint Investigation Rate, Product Re-Tests due to Complaints, Lab Investigation Rate, Adherence to Lead Time
Lowest Performance	Adherence to Schedule, Analytical Right First Time, Lab CAPAs Overdue	Customer Complaint Investigation Rate, Product Re-Tests due to Complaints, Adherence to Lead Time	
Largest Performance Gap (vs. C3)	Customer Complaint Investigation Rate, Adherence to Lead Time Product Re-Tests due to Complaints		
Performance Variation	C1 > C2 >> C3		

~ Almost equal, A < B: A is smaller than B, A << B: A is substantially smaller than B
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The following paragraphs investigate the enabler implementation of PharmaCo B's QC labs. Cluster 1 and cluster 3 show a similar pattern when the implementation level of the

Technical Enabler System (TES) and the Management Enabler System (MES) are compared. Both clusters of PharmaCo B show an almost equally high implementation level of the two systems (at different degrees). On the contrary, cluster 2 has a substantially higher implementation of the MES compared to the TES.

The system implementation gap between cluster 3 and the other QC labs of PharmaCo B varies between clusters 1 and 2. Caused by the equally high implementation of both enabler systems the gap between cluster 1 and cluster 3 is almost the same for the TES and MES. Comparing clusters 2 and 3 a substantially larger system implementation gap exists for the TES compared to the MES.

The QC labs of PharmaCo B in the three clusters achieve a differing degree of integration between all enabler dimensions. Cluster 1 shows the highest variation of the implementation level of all enabler dimensions. The variation of the enabler implementation is lower in cluster 2 than in cluster 1 but not as low as it is in cluster 3. The variation of the enabler implementation of cluster 3 is lower compared to both clusters 1 and 2.

Comparing the three enabler dimensions with the highest implementation for each cluster between all QC labs of PharmaCo B some commonalities but also differences occur. It should be noted that cluster 3 has a higher absolute implementation in all enabler dimensions compared to clusters 1 and 2. Cluster 2 has a higher absolute enabler implementation compared to cluster 1. Consequently, in this paragraph a high implementation means a high implementation relative to the implementation of the other enabler dimensions in the same cluster. All three clusters of PharmaCo B have in common that one of three enabler dimensions with the highest implementation level is from the MES. Clusters 1 and 2 show a high implementation of *Management & Company Culture.* Cluster 3 shows a high implementation in *Functional Integration & Qualification.* In addition, clusters 1 and 2 have a high implementation in *Visual Management.* Clusters 2 and 3 have in common to show a high implementation in *Housekeeping.* Within cluster 1 the QC labs also have a high implementation of *Process Management*. Cluster 3 shows a high implementation related to *Pull Approach* and *Layout Optimization*. In total, four different dimensions are highlighted for cluster 3 as *Layout Optimization* and *Functional Integration & Qualification* shared the third highest implementation level.

Layout Optimization, *Set-up Time Reduction*, and *Functional Integration & Qualification* are the three enabler dimensions in which cluster 3 QC labs of PharmaCo B have the most differing implementation levels compared to their QC labs in cluster 1. The QC labs in cluster 3 exceed the implementation of the QC labs in cluster 1 in all three dimensions considerably. Clusters 2 and 3 show the largest enabler implementation gap related to *Pull Approach*, *Layout Optimization*, and *Planning Adherence*. The QC labs in cluster 3 exceed the implementation of the QC labs in cluster 2 in all three dimensions. Table 68 summarizes the enabler observations at PharmaCo B.

Table 68: Enabler observations PharmaCo B

Category	Observations PharmaCo B		
	C1	**C2**	**C3**
System Implementation	TES ~ MES	TES << MES	TES ~ MES
System Implementation Gap (vs. C3)	TES ~ MES	TES >> MES	N/A
Highest Implementation Level	Process Management, Management Commitment & Company Culture Visual Management	Management Commitment & Company Culture, Housekeeping, Visual Management	Pull Approach, Housekeeping, Layout Optimization, Functional Integration & Qualification
Largest Enabler Dimension Impl. Gap (vs. C3)	Layout Optimization, Set-up Time Reduction, Functional Integration & Qualification	Pull Approach, Layout Optimization, Planning Adherence	N/A
Variation of Enabler Implementation		C1 > C2 > C3	

~ Almost equal, A < B: A is smaller than B, A << B: A is substantially smaller than B
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

At PharmaCo B the QC labs operate in different business environments that impact the QC lab cluster allocation. The QC labs in cluster 3 with a high QC lab effectiveness and a high enabler implementation are two QC labs with limited complexity of their day-to-day business. The business type of these two QC labs is different, but none of them has changed its business in past years. One of the two QC labs is a small-scale traditional pharmaceutical QC lab with a repetitive pattern of many simple tests. The other QC lab in cluster 3 is a pure service lab doing test for other sites within the network of PharmaCo B. The complexity of a service lab is reduced within PharmaCo B as the service is limited to a very narrow portfolio. This portfolio is a predictable non-changing business in PharmaCo B's network of QC labs. The service QC lab receives many samples that are tested with the same testing method at the same time. The variability of the incoming samples is low. In the past few years this QC lab invested a lot into improving its service level. The low complexity of their business with only minor changes allows both QC labs in cluster 3 to use the available resources (FTEs and time) to systematically work on Continuous Improvement (CI). The systematic approach ensured investing effort into all enabler dimensions and performance improvements.

The QC labs in cluster 2 with a low QC lab effectiveness but a high enabler implementation are characterized by many changes made in the past few years. The majority of the QC labs of PharmaCo B in this cluster show a high business complexity. Different to cluster 3 all QC labs in this cluster are located at a manufacturing site. Next to supporting its own site one of these QC labs also acts as a service lab for the whole network of PharmaCo B. The need to balance the testing volume for the network and the company's own site results in a high business complexity. The QC labs of PharmaCo B in cluster 2 have a high day-to-day workload and are confronted with new activities on a regular basis. Regular new

product launches require these QC labs to continuously implement new methods. The third lab of PharmaCo B in cluster 2 does not have the same business complexity. However, major volume changes without adapting the analytical capacity of the site have resulted in a challenging situation of this QC lab in the past few years. Due to the demanding situation of all three QC labs of PharmaCo B in cluster 2 a higher proportion of employees is occupied with the core activities compared to the QC labs in the less challenging environment in clusters 1 and 3.

Although the OPEX transformation of PharmaCo B addresses all QC labs of PharmaCo B, the QC labs in cluster 1 with low QC effectiveness and low enabler implementation have not shown substantial benefits of the current and past work. The five QC labs of PharmaCo B in cluster 1 were identified as QC labs with a business complexity between the above described QC labs in clusters 2 and 3. These QC labs were confronted with more changes than QC labs in cluster 3 but less changes compared to the QC labs in cluster 2. In addition, some of these QC labs are partly involved in time- and effort-consuming development activities. Consequently, these QC labs have less time available to work on CI systematically.

Contrasting clusters 1, 2, and 3 of PharmaCo B with selected performance-unrelated quantitative data of the QC lab benchmarking reveals that the business complexity of QC labs in cluster 1 reaches a similarly high level as cluster 2. However, it has a different driver. In cluster 1 the QC labs show an average number of final drug product types tested that is more than three times higher compared to cluster 2 and more than ten times higher than in cluster 3. The combination of a low number of final drug product types tested and a low overall testing volume confirms the low business complexity of the QC labs in cluster 3. The business complexity of cluster 1 is primarily driven by the number of final drug product types tested, whereas in cluster 2 it is driven from the combination of the number of final drug product types tested and a substantially higher testing volume compared to both other clusters of PharmaCo B.

In addition, the difference of the organizational structure and the employee development approach between clusters 1, 2, and 3 is striking. All QC labs of PharmaCo B have between three and four reporting layers. However, cluster 1 and cluster 2 have an approximately equal span of control below 12 employees reporting to one superior. QC labs in cluster 2 show an average of 21 employees reporting to one superior. When compared with all QC labs of PharmaCo B, the QC labs in cluster 1 show the lowest number of training days per employee, the lowest proportion of employees involved in group work and the lowest level of cross-trained analysts. In the QC labs in cluster 1 PharmaCo B invests on average seven days in training of each employee per year. Approximately half of the analysts are cross-trained and around 60 % of analysts are involved in group work. In cluster 2 the QC labs show around 90 % cross-trained analysts and approximately the same proportion of analysts involved in group work. The QC labs in cluster 2 have on average nine training days per employee and year. The QC labs in cluster 3 outperform cluster 2 regarding all these indicators showing the highest rate of cross-trained analysts (100%), a higher level of group work (100%), and substantially more training days per employee and year (15 days).

5.2.2.3 Conclusion

PharmaCo B has emphasized OPEX in QC labs since 2011. All QC labs have gone through the globally driven OPEX program phase 1 and locally driven phase 2. Additionally, all QC labs are involved in the current OPEX transformation that combines the benefits of the top-down and bottom-up approaches of phases 1 and 2. However, the OPEX approach of PharmaCo B has not resulted in equal results across all QC labs.

The ten QC labs of PharmaCo B are distributed across all three clusters with differing QC lab effectiveness and enabler implementation. At PharmaCo B not all QC labs show an evenly distributed focus on service and quality performance. The performance variation is substantially lower for those QC labs with a high QC lab effectiveness and high enabler implementation compared to the QC labs with a lower QC lab effectiveness.

Apart from differences of the enabler focus, the in-depth analysis has shown that not all QC labs adopt a systematic approach to the enabler implementation. The analysis has also revealed that the main driver for the cluster allocation within PharmaCo B is the differing business complexity between the analyzed QC labs. The predictability of business showed an impact on the QC lab effectiveness enabler relation for the QC labs of PharmaCo B. Depending on the variety and alteration of the performed activities the QC labs have more or less resources available to work on improvements regarding QC lab effectiveness and enabler implementation.

The differing organizational structure and employee development approach between the QC labs of PharmaCo B is striking. The QC labs show substantial differences related to the span of control, the level of cross-trained analysts, group work, and training days per employee and year. Well performing QC labs with low business complexity have a higher degree of cross-trained analysts, group work, and more training days per employee compared to the low performing QC labs of PharmaCo B with a high business complexity.

5.2.3 Case 3: PharmaCo C

PharmaCo C is a US biopharmaceutical company with above 90,000 employees worldwide and a revenue above 50 bn US dollars. As one of the largest biopharmaceutical companies PharmaCo C has multiple business units and operates in more than 100 different countries. The company has multiple blockbuster[35] products and a substantial number of manufacturing sites across the world. In multiple R&D locations across the world PharmaCo C has spent 15 % of the annual revenue on R&D in recent years.

In total six different points of contact contributed to compile the case study on PharmaCo C. Employees from corporate and local level of the organization allowed targeting the research focus from different perspectives. The collaboration of the researcher and PharmaCo C on OPEX in QC labs started in June 2018 and has continued until today.

5.2.3.1 Operational Excellence Strategy in QC Labs

The OPEX strategy in QC labs of PharmaCo C is compiled from the comprehensive analysis of a semi-structured group interview with two corporate QC and OPEX senior executives of PharmaCo C and confidential as well as publicly available company material.

[35] A product with an annual revenue greater than 1 bn US dollars is called a blockbuster.

In addition, the research joined several meetings with corporate senior executives of PharmaCo C in which the overall OPEX strategy of the company was discussed.
PharmaCo C has worked on OPEX since 2004. The strategy has evolved from pointed improvements to a fully integrated overall excellence system. Three major phases can be distinguished.
In the early phase the company focused on applying Six Sigma allowing single point process improvements. The pointed solutions enabled higher process robustness, improved quality, better capabilities, and higher productivity. However, all improvement of this phase were spot solutions not integrated into a holistic approach and not beyond the need of the individual function. The second phase focused on value stream mapping. In this phase PharmaCo C improved flow and reduced non-value adding activities across the value chain. PharmaCo C achieved to reduce inventories and lead time and to realize cost savings. In addition, the company accelerated its lean effort by leveraging the approach of an acquired company that was ahead of PharmaCo C's lean effort at the time. The current on-going third phase focuses on a fully integrated overall excellence system. PharmaCo C started working on the integrated excellence system in 2015. The integrated excellence system comprises multiple aligned individual system units. These units range from production (e.g. drug product) to material supply to leadership. Within three years the excellence system has evolved from a production system into a management system whereby above-site functions leverage the components of the excellence system. At PharmaCo C QC represents one of the system units in the overall excellence system. The integrated approach in QC started in early 2017. However, the initial work on OPEX in QC started in 2010. The integrated approach leveraged many aspects of the past work of PharmaCo C in QC labs prior to 2017.
The objective of the integrated excellence system is an end-to-end improvement across the value chain. It addresses the main sources of gain and loss (e.g. throughput/speed, lead time variability, and robustness/losses). Therefore, each individual system unit is broken down into six standardized elements with operating standards linked to it. The operating standards are the governance for the excellence system to optimize the efficiency and effectiveness of both product and information flow. Apart from process centric teams representing the core element of each individual system unit, it includes the elements standard work, visual management, total productive management, continuous improvement and structured gemba. Furthermore, a system unit may have additional elements specific to its context.
To improve performance over time, each system unit depicts three chronological steps on multiple tier levels: plan, run, and improve. A hierarchical command and control approach does not exist. However, the tiered level approach allows clear roles and responsibilities and a cascaded two-way information flow. On each tier level the excellence system provides guidance on roles, responsibilities, performance goals, and escalation opportunities for the process centric teams. These teams are accountable for the improvements and performance. The three steps plan, run, and improve are executed and monitored by the autonomous process centric team on each tier level. The planning step focuses on defining the extent of the team's ownership, roles, and responsibilities. Additionally, this step includes preparation tasks and aligning with the tier level above. The

running step is focused on executing the defined standards, monitoring the operating unit performance and reacting to variations from the standard. The improving step combines a structured CI process with coaching support of the tier level above. The structured CI process utilizes collected data to identify, prioritize, and eliminate losses. The coaching of the tier level above leadership includes structured gemba and performance improvement support.

On the corporate level, PharmaCo C does not have an OPEX function but has built it into a corporate network design and performance team. This team is separated from the execution of the daily business but interfaces with different functions when needed. It is responsible for the design and deployment of the overall excellence system. PharmaCo C has defined a corporate design leader for each excellence system unit (e.g. QC) and regional deployment leaders that drive the implementation in their geographical region. In 2017 PharmaCo C reached 50 % of the global network with its excellence system. Thereof, 15 % just started the implementation of the excellence system in 2017 and 35 % already started the implementation earlier. Today, PharmaCo C moved away from a traditional top-down management approach to a learning organization that is embraced by leaders on every level of the organization. The initial development of the excellence system was a corporate initiative, but PharmaCo C ensured the local site involvement through selecting lighthouse sites. These lighthouse sites enable successful practice sharing within the network on a continuous basis. The company focuses on empowering its process centric teams to attain a certain degree of autonomy and providing support and guidance to them. The systematic approach of PharmaCo C intends to enable the company to link Continuous Improvement (CI) with its business needs in a structured manner. PharmaCo C stresses several success factors. During their past work on OPEX the company learned that linking the vision with the business requirements drove investments, improvement pace, and commitment of the organization. The company emphasizes that system thinking and step change has built the basis of improvements. The focus on outcome and the overall network transformation instead of pure project focus has helped to ensure defining the right priorities. Endorsement of the excellence system as a management system beyond production at the senior leadership level has helped to foster engagement and has accelerated the transformation. Creating a suitable environment and providing resources has shown to be critical for success. A philosophical shift of PharmaCo C to see QC as an operationalized element of the end-to-end material flow has allowed to change the organization’s mindset. The shift enabled PharmaCo C seeing QC a crucial contributor to success instead of seeing QC as a cost-adding support function. Finally, the holistic integration of the excellence system has allowed sustainable improvements instead of pointed solutions.

5.2.3.2 Observations

The observations regarding PharmaCo C summarize the comprehensive analysis of the available company specific performance and enabler benchmarking data, the semi-structured group interview with two corporate QC and OPEX senior executives of PharmaCo C, and confidential as well as publicly available company material. The researcher also analyzed personal notes and emails with PharmaCo C that were

exchanged during the joint benchmarking project on OPEX in QC labs between June and August 2018. Additionally, the wrap-up of a two-day workshop with corporate and local representatives of PharmaCo C discussing the benchmarking results served as a data source.

In the following, the observations of the three QC labs in cluster 2 with a low enabler implementation and a low QC lab effectiveness are compared with the one QC lab in cluster 3 with a high enabler implementation and a high QC lab effectiveness. None of the available QC labs of PharmaCo C appeared in cluster 1 with a low enabler implementation and a low QC lab effectiveness. Figure 28 highlights the available QC labs of PharmaCo C.

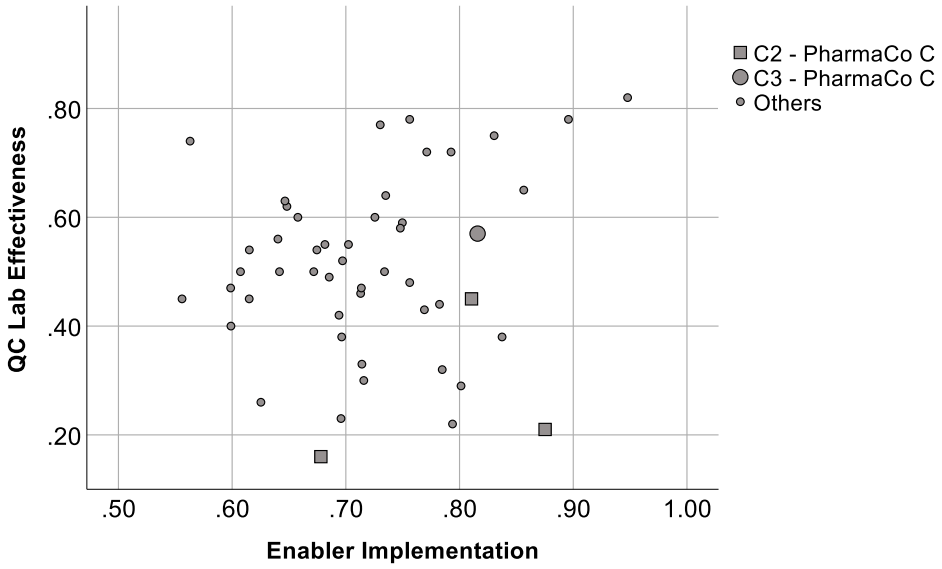

Figure 28: QC lab effectiveness and enabler plot highlighting PharmaCo C QC labs

The following paragraphs discuss the QC lab effectiveness of PharmaCo C's QC labs. The observations focus on commonalities within clusters 2 and 3 as well as differences between the two clusters. The QC lab effectiveness performance builds on service and quality performance (cf. chapter 4.1.5). Clusters 2 and 3 of PharmaCo C both show a substantially higher quality performance compared to service performance. Cluster 3 shows a substantially higher performance in both dimensions, but the performance gap for the quality and service performance between the two clusters is almost equal.

In the following, the three indicators showing the highest performance levels are described for cluster 3. In addition, the three indicators with the lowest performance levels of cluster 1 are highlighted. For cluster 3 the order of performance indicators is descending starting with the indicator showing the highest performance. For cluster 2 the order of the performance indicators is ascending starting with the indicator showing the lowest performance level. The QC labs of PharmaCo C in cluster 3 show a high performance regarding *Invalidated OOS Rate*, *Product Re-Tests due to Complaints*, and *Lab Investigation Rate.* The QC labs in cluster 2 have the lowest performance regarding *Adherence to Lead Time*, *Adherence to Schedule*, and *Invalidated OOS Rate*. A comparison of the indicators showing the highest performance in cluster 3 with the largest

performance gap between clusters 2 and 3 reveals that the performance indicators match. The largest performance gaps between cluster 2 and cluster 3 of PharmaCo C exist regarding the three indicators ranked in descending order: *Invalidated OOS Rate*, *Product Re-Tests due to Complaints*, and *Lab Investigation Rate*. A closer look at clusters 2 and 3 reveals that *Invalidated OOS Rate* stands out from the other performance indicators. It is one of the three indicators with the highest performance in cluster 3, one of the three indicators with the lowest performance in cluster 2 and among the performance indicators with the largest performance gap.

As cluster 3 is represented by one QC lab for PharmaCo C no conclusion can be made on the variation of the performance level within cluster 3. Consequently, the performance variation between clusters 2 and 3 cannot be compared. However, a closer look at cluster 2 shows that the performance variation between the QC labs within the cluster is substantial. Table 69 exhibits a summary of the observations related to QC lab effectiveness of the QC labs of PharmaCo C.

Table 69: QC lab effectiveness observations PharmaCo C

Category	Observations PharmaCo C	
	C2	**C3**
Service & Quality Performance	S << Q	S << Q
Performance Gap	S ~ Q	
Highest Performance		Invalidated OOS Rate, Product Re-Tests due to Complaints, Lab Investigation Rate
Lowest Performance	Adherence to Lead Time, Adherence to Schedule, Invalidated OOS Rate	
Largest Performance Gap	Invalidated OOS Rate, Product Re-Tests due to Complaints, Lab Investigation Rate	
Performance Variation	*Not available*	

~ Almost equal, A < B: A is smaller than B, A << B: A is substantially smaller than B
C1: Low enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The following paragraphs investigate the enabler implementation of PharmaCo C's QC labs. The QC labs of PharmaCo C in cluster 2 have an almost equally high TES and MES implementation. The QC lab in cluster 3 of PharmaCo C shows a higher implementation level of the MES compared to the TES. As the QC lab in cluster 3 shows an overall higher implementation level for both systems, it is obvious that the system implementation gap for TES is smaller compared to the MES. The QC lab of PharmaCo C in cluster 3 has a higher degree of integration between the various enabler dimensions compared to those QC labs in cluster 2. The variation of the implementation level of the enabler dimensions is lower in cluster 3 compared to cluster 2.

Regarding the highest enabler implementation, PharmaCo C shows one commonality but more differences between clusters 2 and 3. In this paragraph a high implementation means

a high implementation relative to the implementation of the other enabler dimensions in the same cluster. Both clusters show a high implementation of *Standardization & Simplification.* However, only the QC lab of PharmaCo C in cluster 3 has a MES dimension (*Management Commitment & Company Culture*) on the list of the three enabler dimensions with the highest implementation level. Apart from *Standardization & Simplification* and *Management Commitment & Company Culture*, the QC labs of PharmaCo C in cluster 3 also shows a high implementation in *Pull Approach*. Next to *Standardization & Simplification* cluster 2 QC labs of PharmaCo C have a high implementation in *Housekeeping* and *Process Management.*

The PharmaCo C QC lab in cluster 3 lacks a higher absolute implementation in all enabler dimensions. In 5 of 13 enabler dimensions this QC lab has a lower enabler implementation compared to those QC labs in cluster 2. However, it should be noted that cluster 3 is only represented by one QC lab for PharmaCo C and 3 of 5 enabler dimensions show an almost equally high implementation level. In *Housekeeping* and *Preventive Maintenance* an actual negative implementation gap between clusters 3 and 2 exist. The QC labs in cluster 2 have a notably higher implementation in these two dimensions compared to the QC lab in cluster 3. *Pull Approach*, *Planning Adherence*, and *Management Commitment & Company Culture* are the three enabler dimensions in which the QC lab of PharmaCo C in cluster 3 has the largest positive implementation gap compared to the company's QC labs in cluster 2. In all three dimensions the QC lab in cluster 3 exceed the implementation of the QC labs in cluster 2 considerably. Table 66 summarizes the enabler observations at PharmaCo C.

Table 70: Enabler observations PharmaCo C

Category	**Observations PharmaCo C**	
	C2	**C3**
System Implementation	TES ~ MES	TES < MES
System Implementation Gap	TES < MES	
Highest Implementation Level	Housekeeping, Standardization & Simplification, Process Management	Pull Approach, Standardization & Simplification, Management Commitment & Company Culture
Largest *positive* Enabler Dimension Impl. Gap (C3 > C2)	Pull Approach, Planning Adherence, Management Commitment & Company Culture	
Largest *negative* Enabler Dimension Impl. Gap (C3 < C2)	Preventive Maintenance, Housekeeping	
Variation of Enabler Implementation	C2 > C3	

~ Almost equal, A < B: A is smaller than B
C1: Low enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The QC labs of PharmaCo C in cluster 2 show a high business complexity. All of the QC labs have to fulfil a multitude of requirements testing a wide range of product categories. One of the QC labs in cluster 2 of PharmaCo C is located at a drug substance launch site. The daily business of this QC lab is characterized by regularly introducing new methods to test new drug substances introduced by PharmaCo C. Also, this QC lab is located at a site that went through divestment negotiations and a change of leadership in the past few years leading to other business priorities than CI. One site in cluster 2 combines its own manufacturing with contract manufacturing for other organizations. Consequently, the QC lab makes substantially higher planning and scheduling effort balancing the internal and external testing requirements. In cluster 2 two QC labs of PharmaCo C have employees who are unionized. The works councils have had an impact on the available resources for CI in these QC labs in the past few years. The employees of the QC lab in cluster 3 are not unionized. This QC lab is primarily involved in large-scale commercial operations. The nature of the biotechnology business of the QC lab in cluster 3 results in newer and more robust methods compared to the QC labs in cluster 2. The burden of developing new and more robust methods that have to pass approval processes of different regulatory agencies in the QC labs of cluster 2 exceeds the expected benefits. Consequently, PharmaCo C decided not to invest in new methods and technology for the QC labs in cluster 2 with comparably old products. The site of the QC lab in cluster 3 is a lead site that was one of the first sites of PharmaCo C that implemented the integrated overall excellence system. The employees in this QC lab show a proactive attitude toward change and have built the integrated excellence system on a good foundation of CI work in the past. The implementation of planning and scheduling tools and a vendor management system has helped the QC lab in cluster 3 to have resources available to work on CI systematically.

Contrasting clusters 2 and 3 of PharmaCo C with selected performance-unrelated quantitative data of the QC lab benchmarking supports differences regarding the business complexity of the different QC labs. The QC labs in cluster 2 characterize a substantially higher number of final drug product types tested and testing volume compared to cluster 3 of PharmaCo C. The QC lab in cluster 3 combines a low number of different final drug product types tested with a low testing volume. Consequently, this QC lab shows a low business complexity.

A closer look at the organizational structure and the employee development approach of PharmaCo C depicts differences and commonalities of clusters 2 and 3 regarding reporting layer, span of control, cross-trained analysts, group work, and training days per employee and year. The QC labs across both clusters have four reporting layers. However, on average the span of control differs between ten employees reporting to one superior in cluster 3 and 16 employees reporting to one superior in cluster 2. All available QC labs of PharmaCo C show a very high level of cross-trained analysts of around 85 % and all analysts are involved in group work. However, the number of training days per employee is more than twice as high in the QC lab in cluster 3 compared to the QC labs in cluster 2. On average, the QC lab in cluster 3 invests 17 days per year in training for each employee.

5.2.3.3 Conclusion

PharmaCo C has worked on OPEX in QC since 2010. The fully integrated overall excellence system is currently rolled-out across the organization. PharmaCo C intends to use the integrated excellence system to reach an end-to-end optimized value chain. The QC lab transformation is built on a philosophical shift within PharmaCo C to regard QC as a critical contributor of the material flow instead of a cost-adding support function.

The analyzed QC labs of PharmaCo C available for this research do not show the same QC lab effectiveness and enabler implementation. However, all QC labs show a stronger quality performance compared to service performance. The enabler analysis revealed that the enabler implementation approach is more systematized in the QC lab with a high QC lab effectiveness and high enabler implementation. The remaining QC labs of PharmaCo C with a low QC lab effectiveness have a relatively high enabler implementation as well but show a higher variation between the individual enabler dimensions.

The analysis has shown that the QC labs with a low QC lab effectiveness and high enabler implementation have a high business complexity compared to the well performing QC labs in both dimensions. A high variety of products results in a wide range of testing requirements driving complexity in these QC labs of PharmaCo C. Business priorities unrelated to CI can be observed in the low performing QC labs. Additionally, QC labs with a low QC lab effectiveness showed a higher rate of employees with union membership. On the contrary, a proactive attitude toward change and self-driven improvement can be observed in the well performing QC lab of PharmaCo C.

The organizational structure and employee development approach of the QC labs of PharmaCo C depicts commonalities but also differences. The number of reporting layers, the proportion of cross-trained analysts, and group work is on an equal level across all QC labs of PharmaCo C. However, the well performing QC labs have a substantially lower number of employees reporting to one superior and more than twice as many training days per employee.

5.3 Cross-case Analysis

A cross-case analysis was employed to identify commonalities and differences regarding the influencing factors of the QC lab effectiveness enabler relation across all three case studies. The cross-case analysis consolidates the observations of the in-depth analysis of PharmaCo A, B, and C and contrasts the three clusters with a different QC lab effectiveness and enabler relation. First the OPEX strategy of the three companies is compared. Second, the analysis depicts conclusions related to the clusters' QC lab effectiveness. Third, the enabler commonalities and differences of the clusters are elaborated. Fourth, the cross-analysis examines the operating context observations across the case studies and concludes influencing factors for the cluster allocation related to the business environment. Fifth, the companies' organizational structure and employee development approach in their QC labs in the different clusters are contrasted.

While PharmaCo B and C have already work on OPEX in QC labs for more than five years, PharmaCo A only started about one year ago. Despite the differing duration each PharmaCo has spent on OPEX in QC labs, today the overall approach to OPEX in QC labs is similar. PharmaCo A is currently in an early transformation stage. PharmaCo B and

C have already moved on to a later transformation stage. PharmaCo A has not yet realized all short-term gains, whereas PharmaCo B moved to a phase of sustaining the transformation across the network of QC labs. PharmaCo C is currently focused on fostering its approach of a learning organization across the network. At this point, the time horizon of PharmaCo A can be classified as short-term aiming at realizing quick wins to show the benefit of the OPEX transformation across the organization and to build enduring corporate sponsorship. The time horizon of PharmaCo B and C can be classified as long-term with established improvement roadmaps for the next few years.

Today, all three case companies focus on a balanced performance measurement by incorporating effectiveness and efficiency into their OPEX strategy in QC labs. PharmaCo B shifted the focus from pure efficiency performance toward effectiveness and efficiency after the early transformation due to lagging sustainability of the improvements. PharmaCo A already starts with a balanced performance measurement including both dimensions in the early transformation phase. PharmaCo C also has balanced effectiveness and efficiency since the beginning. All three PharmaCos stress the importance of the top-management support as a driver of the QC lab transformation.

At PharmaCo A the well-established OPEX approach in manufacturing was transferred and adapted to the QC labs. At PharmaCo B the OPEX approach for QC labs was developed within the quality organization. At PharmaCo C the OPEX approach started a company-wide fully integrated excellence system which is applied and adapted to multiple functions. Despite these differences the implementation approach of all three case companies combines the top-down driver with bottom-up support. PharmaCo A and B confirm that in the early phase of the transformation the top-down focus is stronger than in the later phase of the transformation. A strong top-down approach in phase 1 and a strong bottom-up approach in phase 2 allowed PharmaCo B to experience benefits and challenges of both isolated approaches. Today, PharmaCo B combines both approaches to benefit from synergies between the two approaches reducing the negative impact of an isolated approach. As PharmaCo A today is still in the early phase the top-down focus prevails. However, PharmaCo A has also started incorporating local team for bottom-up support. On the contrary, at PharmaCo C the company-wide excellence system enables a top-down driven learning organization with autonomous teams that have enhanced roles and accountability. Comparing PharmaCo A, B, and C the autonomy in PharmaCo C exceeds the autonomy in Pharma Co A and B.

The cross-comparison reveals that the organizational anchoring of OPEX in QC labs in PharmaCo A and B is similar. Both companies have disconnected the business reporting from the corporate QC lab OPEX leader. Disconnecting the reporting from the OPEX improvement driver on the corporate level has helped the organizations to achieve a supportive and collaborative working environment between the corporate QC lab OPEX leader and the local teams. At PharmaCo C the position of a corporate QC lab OPEX leader does not exists. Due to the magnitude of the integrated excellence system in PharmaCo C the company decided to have autonomous teams within each system unit and on each tier level focused on improvement and performance with clear cascaded support and escalation opportunities to above-tier level leaders.

All three PharmaCo's show a clear understanding of OPEX combining tools and methods with an appropriate mindset leading to a CI behavior of every employee every day. The clear understanding of OPEX has enabled all analyzed companies to avoid limiting their latest OPEX roadmaps to a narrow focus on single improvement aspects that do not capture the manifoldness of OPEX.

All three analyzed PharmaCos used the St. Gallen QC Lab Benchmarking as a strategic tool to create transparency and to anchor the improvement effort of their QC labs. PharmaCo A used the benchmarking as a starting point to develop an initial roadmap to realize short-term gains in the early phase of its transformation. PharmaCo B used the benchmarking in a later transformation phase to identify additional improvement areas to be added to the existing roadmap. PharmaCo C validated its existing roadmap from a previous benchmarking with the findings of the St. Gallen QC Lab Benchmarking.

As the QC lab transformation addressing the OPEX strategy of PharmaCo A, B, and C was not concluded and implemented at all QC labs at the point of analysis no direct link between the QC lab OPEX strategy and the cluster allocation can be made. Table 71 depicts the cross-case consolidation of the OPEX strategy of the analyzed PharmaCos.

Table 71: Cross-case consolidation of OPEX strategy in QC labs

Category	Characteristic		
	Case 1: PharmaCo A	**Case 2: PharmaCo B**	**Case 3: PharmaCo C**
Starting Point	2017	2011	2010
Current Time Horizon	Short-term focus	Long-term focus	Log-term focus
Performance Focus	Effectiveness & Efficiency	Effectiveness & Efficiency	Effectiveness & Efficiency
Top-Management Involvement	Yes	Yes	Yes
Improvement Driver	Corporate team	Corporate team	Corporate team
Cross-functional Integration	Initial approach transferred from manufacturing function	Approach built and developed within quality organization	Cross-functional development of a fully integrated excellence system
Implementation Approach	Top-down focus with some bottom-up support	Combination of top-down and bottom-up	Learning organization driven top-down with bottom-up support
Organizational Anchoring	Reporting disconnected from corporate QC lab OPEX leader	Reporting disconnected from corporate QC lab OPEX leader	Autonomous teams focused on improvement and performance with clear cascaded above-tier support
OPEX Understanding	Tools and methods, mindset and behavior	Tools and methods, mindset and behavior	Tools and methods, mindset and behavior
St. Gallen QC Lab Benchmarking	Starting point for initial roadmap development	Identification of improvement areas as an add-on to existing roadmap	Validation of existing roadmap and improvement areas

Comparing the QC lab effectiveness results across the three cases discloses a common pattern across the analyzed PharmaCos. The identified commonalities and differences related to the performance between the analyzed cases can be grouped into five categories: *Performance Focus*, *Process Robustness*, *Customer Complaints*, *Planning Adherence*, and *Performance Variation.* The following paragraph examines the characteristics of these categories and their interdependencies for the QC labs with a low QC lab effectiveness and low enabler implementation (cluster 1), the QC labs with a low QC lab effectiveness but high enabler implementation (cluster 2) and the QC labs with a high QC lab effectiveness and a high enabler implementation (cluster 3).

The QC labs in clusters 1 and 2 tend to show a higher quality performance compared to the service performance. The OPEX strategy in QC labs of PharmaCo C stresses that quality was the first priority of the early phase of the QC lab transformation. The service performance followed in a second phase of the QC lab transformation. However, *Process Robustness* and *Planning Adherence* in clusters 1 and 2 is low. The QC labs in these clusters show a high number of invalidated OOS and lab investigations. In addition, the process reliability to deliver as planned while handling unplanned tasks is not successful in clusters 1 and 2. On the contrary, cluster 3 QC labs tend to achieve an equally high service and quality performance. The improvement effort of these QC labs results in a high *Process Robustness* and a high *Planning Adherence*. The QC labs in cluster 3 show a low number of invalidated OOS and lab investigations. In addition, these QC labs adhere to the planned lead time and schedule. Regarding *Customer Complaints*, cluster 3 also stands out from the other two clusters. In clusters 1 and 2 a high number of customer complaint investigations and product re-tests due to complaints are conducted. In cluster 3 customer complaints are substantially lower. Without exception all three analyzed PharmaCos in cluster 3 have no product re-tests due to complaints. Table 72 depicts the cross-case consolidation of the observations regarding QC lab effectiveness.

Table 72: Cross-case consolidation of QC lab effectiveness observations

Category	Characteristic		
	C1	**C2**	**C3**
Performance Focus	Quality	Quality	Service & Quality
Process Robustness[1]	Low	Low	High
Planning Adherence[2]	Low	Low	High
Customer Complaints[3]	High	High	Low
Performance Variation	Very high	High	Low

[1] Low Process Robustness represents a low performance in Invalidated OOS Rate and Lab Investigation Rate
[2] Low Planning Adherence represents a low performance in Adherence to Lead Time and Adherence to Schedule
[3] Low Customer Complaints represents a low performance in Product Re-Tests due to Complaints and Customer Complaint Investigation Rate
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

Although the enabler system observations across the three cases are not identical, there seems to be a common pattern across the cases. The cross-case analysis confirms that all QC labs focus on the Technical Enabler System (TES) and the Management Enabler System (MES). However, rooted in the definition of the clusters this does not lead to a high QC lab effectiveness for all QC labs.

A more granular analysis of the enabler system implementation across the case studies revealed differences of the enabler focus for the three clusters. QC labs with a low QC lab effectiveness and low enabler implementation (cluster 1) and QC labs with a low QC lab effectiveness and high enabler implementation (cluster 2) especially focus on basic elements of the TES. Basic elements of the TES represent the foundational enabler dimensions *Housekeeping*, *Standardization & Simplification*, and *Visual Management*. The QC labs with a high QC lab effectiveness and a high enabler implementation (cluster 3) differ from two angles. First, cluster 3 QC labs show a higher implementation level for the basic elements *Housekeeping*, *Standardization & Simplification*, and *Visual Management*. Second, they also focus on more advanced elements of the TES related to *Pull Approach* and *Planning Adherence.* Cluster 3 QC labs focus especially on putting a pull system in place, analyzing capacity as well as demand, and testing according to forecast. In addition, these QC labs reserve some flexibility for peak loads and invest into eliminating root causes of variance in the lab schedule.

A closer look at the MES across the case studies reveals that the QC labs in cluster 1 work on basic elements of the MES. Clusters 2 and 3 QC labs work on these basic elements but also more advanced elements of the MES. Clusters 1 QC labs especially work on *Management Commitment & Company Culture.* These QC labs seek for a committed management and the right company culture. The QC labs in this cluster focus on empowering employees, personal involvement of leaders, open communication culture, problem solving, aligning quality standards between departments, reducing wasteful activities, and balancing corporate with local OPEX effort. Clusters 2 and 3 QC labs have enhance their effort beyond the focus on seeking for management commitment and the right company culture. These QC labs invest substantially more effort into *Employee Involvement & Continuous Improvement* and *Functional Integration & Qualification*. Among other aspects these QC labs emphasize encouraging analysts to be actively involved in definition processes, independent problem solving, cross-functional project teams, cross-training, and job rotation.

The enabler system configuration is different between all three clusters. Most successful are cluster 3 QC labs with an integrated approach to the enabler implementation. Cluster 3 QC labs do not focus on individual enabler dimensions but on the systematic implementation of a variety of different enabler dimensions. On the contrary, cluster 2 only shows little integration and cluster 1 shows no integration. QC labs in cluster 1 have a strong focus on implementing single enabler dimensions. Table 73 depicts the cross-case consolidation of the observations regarding the enablers.

Table 73: Cross-case consolidation of enabler system observations

Category	Focus		
	C1	**C2**	**C3**
Enabler System	TES & MES	TES & MES	TES & MES
Technical Enabler System	Basics	Basics	Basics & Advanced
Management Enabler System	Basics	Basics & Advanced	Basics & Advanced
Enabler System Configuration	Single Dimension	Low Integration	High Integration

TES: Technical Enabler System
MES: Management Enabler System
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

The cross-case analysis of the observations made by the interviewed senior OPEX executives of PharmaCo A, B, and C reveals that the business environment, mindset, behavior, and consequently the OPEX state of the QC labs across the three clusters differs.

Highlighted by PharmaCo C the nature of business is notably different in clusters 2 and 3. A subsequent analysis of the other PharmaCo's in all three clusters reveals that the available case QC labs in cluster 3 have a substantially higher number of QC labs exclusively working on new (biological) drug substances compared to QC labs in clusters 1 and 2. In these clusters the available QC labs primarily focus on traditional (chemical) drug substance or both drug substances.

The QC labs with a high QC lab effectiveness and a high enabler implementation in cluster 3 are characterized by homogeneity of their testing. The homogeneity is primarily driven by a low variety and alteration of activities. In addition, the business of the QC labs in cluster 3 often shows a high predictability regarding the testing activities. The nature of business as well as the non-changing portfolio of these QC labs has enabled the QC labs to continuously improve their routines. This resulted in available resources to work on CI systematically. A proactive attitude toward change has helped them to adapt corporate-driven initiatives. A closer look at two QC labs that have already undergone the QC lab transformation in PharmaCo A and C shows that these QC labs belong to cluster 3. Within the organizations these QC labs are seen as lead QC labs of the CI effort.

The QC labs with a low QC lab effectiveness but a high enabler implementation in cluster 2 show a high business complexity and many changes in recent years. In these QC labs testing requirements change constantly due to new products launched on a regular basis. Additionally, the degree of company-wide centralization, and partly contract testing, complicates harmonizing the testing workload. Volume changes without adapting the analytical capacity have reduced the ability to achieve a high QC lab effectiveness. Setting business priorities unrelated to CI has prevented them to benefit from a good CI foundation. Cluster 2 QC labs have less available resources to work on CI systematically compared to the other clusters. Additionally, a higher rate of unionized employees characterizes in this cluster. Although the enabler implementation level is higher than in cluster 1 the CI effort is not as systematized as in cluster 3.

The QC labs with a low QC lab effectiveness and a low enabler implementation in cluster 1 are confronted with a similar business complexity as those QC labs in cluster 2. Substantial business changes and frequent launches of new products have stopped these labs to establish a long-term routine. The QC labs in this cluster allocate all resources to the core activities. Missing corporate sponsorship in some of these QC labs that have not started the corporate OPEX initiatives has resulted in no CI progress. Moreover, PharmaCo A had to change the leadership team in one of their QC labs of this cluster as it was not supportive for the QC lab transformation. A culture of not embracing change and working on individual priorities has prevented QC labs in cluster 1 from major improvements. Table 74 exhibits the cross-case consolidation of the observations regarding the business environment of the QC labs across the three clusters and cases.

Table 74: Cross-case consolidation of business environment observations

Category	Characteristic		
	C1	C2	C3
Business Nature[1]	Traditional and New	Traditional and New	New
Homogeneity	Low	Low	High
Predictability	Low	Low	High
Type of Site/QC Lab	Follower	Follower	Pioneer
Transformation Stage	Early	Early	Late
New Product Launches	Frequently	Constantly	Infrequently
People	Partially not embracing change and limited resources to work on CI	Limited resources to work on CI	Proactivity and sufficient resources available to work systematically on CI

[1] The business nature is characterized as traditional in case at least 75 % of case QC labs of this cluster focus exclusively on chemical drug substance. It is classified as new in case at least 75 % of case QC labs of this cluster focus exclusively on biological drug substance. In case the QC labs in one cluster focus on both drug substances the cluster is classified as traditional and new.
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

Contrasting the QC labs across all case companies with selected performance-unrelated quantitative data of the St. Gallen QC Lab OPEX Benchmarking confirms differences regarding the business complexity of the different clusters. All three case companies depict QC labs in cluster 3 with a low business complexity showing a low testing variety and a low testing volume. QC labs in clusters 1 and 2 are confronted with a higher business complexity. For PharmaCo A in cluster 1 the business complexity is driven by the number of final drug product types tested and the testing volume. For PharmaCo B the complexity in cluster 1 is mainly driven by the number of final drug product types tested. PharmaCo B and C link the high business complexity in cluster 2 to the combination of a high number of final drug product types tested and a high testing volume.

A closer look at their organizational structure and the employee development approach depicts differences between the investigated companies and QC labs. While all three clusters show an average of four reporting layers, the span of control is different between

the clusters. PharmaCo A and B depict that clusters 1 and 3 have approximately the same number of employees reporting to one superior. On the contrary, all available QC labs of PharmaCo B and C in cluster 2 reveal a substantially higher number of employees reporting to one superior.

An increase in the number of training days per employee and year can only be linked to an increasing business complexity in PharmaCo A. PharmaCo B and C show more training days per employee in those QC labs with a lower business complexity. Consolidating the results of the QC labs of all companies across the three cases a common pattern can be derived. QC labs in cluster 3 with a low business complexity have a higher level of training days than QC labs in cluster 2 with a high business complexity. The QC labs in cluster 1 with a high business complexity meet the average number of training days of all analyzed QC labs.

Furthermore, the QC labs do not show a directional positive relation between the business complexity and the level of cross-training. PharmaCo A and B show a higher level of cross-training in QC labs in cluster 3 with a lower business complexity compared to cluster 1 with a higher business complexity. The QC labs of PharmaCo B and C correspond to this pattern in cluster 3. The QC labs with a high business complexity (cluster 2) show an equal (PharmaCo C) or lower level of cross-trained analysts (PharmaCo B) compared to the QC labs with a low business complexity (cluster 3). However, consolidating the results based on the average cross-training level of all QC labs across the three cases a common pattern can be identified. QC labs in clusters 2 and 3 show a high cross-training level above the average of all analyzed case QC labs. QC labs in cluster 1 show a low level of cross-training below the average.

Across the case companies the degree of group work does not increase with an increase in business complexity. PharmaCo A and C depict an equally high level of group work independent from the QC lab cluster allocation. PharmaCo B's QC labs employ less group work in clusters 1 and 2 compared to cluster 3. Consolidating the proportion of employees involved in group work for all PharmaCos in each cluster with the average of all analyzed case QC labs a common pattern can be identified. Cluster 1 depicts a lower level of group work compared to clusters 2 and 3.

Regarding the organizational structure and employee development approach the cross-case analysis reveals that all PharmaCos show improvement potential to better align the span of control, the level of cross-training, group work, and training days per employee and year with the business requirements. Table 75 consolidates the cross-case observations regarding the QC labs' organizational structure and employee development approach of the QC labs across the three clusters and cases.

Table 75: Cross-case consolidation of organizational and development observations

Category	Average (n=22)	Characteristic[1]		
		C1	C2	C3
Testing Variety[2] [No.]	99	High	High	Low
Lab Volume[3] [No.]	6,901	High	High	Low
Reporting Layers [No.]	4	Average	Average	Average
Span of Control [No.]	13	Low	High	Low
Training per Employee [days/year]	12	Average	Low	High
Cross-training [%]	81	Low	High	High
Group Work [%]	89	Low	High	High

[1] The characteristics of clusters 1, 2, and 3 are characterized as average in case the cluster matches with the average of all analyzed 22 case QC labs. It is characterized as low in case the value is below the average and high in case the value is above the average of all analyzed 22 case QC labs.
[2] Testing variety is measured based on the number of final drug product types tested
[3] Lab volume is measured based on the number of processed batches
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

5.4 Summary of Findings

The application of the OPEX performance measurement model (PMM) allowed investigating the performance enabler relation of QC labs in detail. The in-depth case study analyses followed by a cross-case analysis provided context to the disclosed phenomenon of three distinct clusters with a differing performance enabler relation. This summary follows Stuart et al. (2002) dissemination phase of case study research. In addition, the summary addresses Eisenhardt (1989) concluding steps of case study research to reflected the research results with literature before reaching closure.

All three case companies emphasize the importance to measure effectiveness and efficiency performance (cf. chapter 5.3). This corresponds to the developed PMM in this research (cf. chapter 3) and existing PMMs in the context of excellence (Cross & Lynch, 1988; EFQM, 2012; Kaplan & Norton, 1992; Keegan et al., 1989; Kickuth, 2005; MBNQA, 2017; Neely et al., 2001). Across the analyzed companies the top-management involvement is seen as fundamental to drive the QC lab transformation (cf. chapter 5.3). In a different context focusing on the manufacturing function, early work by Skinner (1969) as well as Hayes and Wheelwright (1985) also emphasized the importance of management involvement and leadership for success. The strategy of the early QC lab transformation phase of the analyzed companies in this research reflects a traditional hierarchical top-down strategy formulation process (Fine & Hax, 1985; Leong, Snyder, & Ward, 1990; Skinner, 1969) The combination and balance of a top-down and bottom-up approach in the later QC lab transformation phase corresponds to more recent work on the strategy formulation process (Y. H. Kim, Sting, & Loch, 2014).

The case study research revealed that QC labs of cluster 3 that perform well regarding QC lab effectiveness and the enabler implementation focus on the Technical Enabler System (TES) as well as the Management Enabler System (MES) (cf. chapter 5.3). In both systems these QC labs rely on basic enabler dimensions and more advanced enablers (cf. chapter 5.3). Instead of focusing on single enabler dimensions the well performing QC labs are

characterized by a high level of integration of the enabler dimensions (cf. chapter 5.3). These findings correspond to previous findings of Ahmad et al. (2003) and Shah and Ward (2007). The authors stress that exploiting synergies between different enabler dimensions allows achieving a competitive advantage leading to superior performance.

A closer look at the performance of these well performing QC labs revealed that their performance variation across the individual performance indicators of QC lab effectiveness is substantially lower than of all other QC labs in the clusters with a low QC lab effectiveness (cf. chapter 5.3). The well performing QC labs do not depict any individual performance indicator of QC lab effectiveness that shows a substantially worse performance compared to the remaining indicators. The link of a high level of integration of the enabler dimensions and superior performance regarding multiple performance goals corresponds to earlier findings of Shah and Ward (2007). The authors stressed that individual enabler dimensions drive selected performance goals but only the synergy of the integrated implementation allows superior performance regarding multiple performance goals. In this research, the same relation was disclosed for pharmaceutical QC labs.

The in-depth case study analyses and the cross-case analysis also showed that the complexity of the business environment of QC labs with a high QC lab effectiveness and low QC lab effectiveness as well as high and low enabler implementation differs (cf. chapter 5.2 and 5.3). The business nature of well performing QC labs is mainly characterized by new drug substances (cf. chapter 5.2.3 and 5.3). On the contrary, the business nature of the QC labs with a low QC lab effectiveness (independent from the enabler implementation) is characterized as a combination of traditional and new drug substance (cf. chapter 5.2.3 and 5.3). The more homogeneity the QC labs show the higher was their performance (cf. chapter 5.2.1 and 5.3). The predictability of business as well as the variety and alteration of the performed activities influence the performance enabler relation (cf. chapter 5.2.2 and 5.3). Additionally, no corporate sponsorship and uncooperative site leadership teams have prevented OPEX initiatives to be successful (cf. chapter 5.2.1 and 5.3). Business priorities unrelated to CI has stopped several QC labs from benefiting from a good CI foundation (cf. chapter 5.2.3 and 5.3). The cross-case analysis revealed that the business environment of all QC labs with a low QC lab effectiveness (independent from the enabler implementation) is similarly complex (cf. chapter 5.3). Characterized by frequent changes these QC labs do not achieve to work on CI systematically (cf. chapter 5.3). The complexity of their business results in a strategy to invest all available resources in the core business activities (cf. chapter 5.3). Additionally, QC labs with a low QC lab effectiveness and a low enabler implementation partially have not embraced CI. While the well performing QC labs belong to the pioneers across the analyzed companies, the QC labs with a low performance and enabler implementation can be classified as followers (cf. chapter 5.3). Finally, the case studies reveal improvement potential regarding the organizational structure and employee development approach. Both aspects show gaps between the organizational set-up and the business requirements of all analyzed case companies. In the majority of analyzed QC labs an increasing business complexity is not closely related to the level of cross-trained analysts, group work, and training days per employee and year (cf. chapter 5.2.1, 5.2.2 and 5.2.3).

In addition, the initial comparison of clusters 1, 2, and 3 highlighted substantial differences of the operating context of the three disclosed clusters (cf. chapter 5.1.3). This is supported by the observations of the interviewed senior executives that link the nature of business to differing QC lab effectiveness (cf. chapter 5.2.3 and 5.3). Also, it corresponds to previous findings of White et al. (1999) and Shah and Ward (2003) who found evidence for an impact of the operating context on the enabler implementation. Moreover, existing PMMs in Operations Management (OM) address the operating context among other dimensions (Kickuth, 2005; MBNQA, 2017; Neely et al., 2001). Some authors found no evidence for an impact of the operating context (Cua et al., 2001; Furlan et al., 2011). However, Cua et al. (2001) stress that future studies should re-evaluate the impact of the operating context on the performance enabler relation. Furlan et al. (2011) agree and emphasize a qualitative case study approach as suitable method to analyze the impact of the operating context. The approach of the present research using multiple case studies to explain the phenomenon of three distinct clusters with a differing performance enabler relation complies with the suggestion of Furlan et al. (2011) to employ case studies to investigate the impact of the operating context.

To conclude, the multitude of quantitative and qualitative data sources of the presented case studies indicates that the operating context can explain differences of QC lab effectiveness and enablers. In addition, findings of this research regarding the configuration of the enabler implementation and its link to performance confirm previous findings in OM literature in a new unit of analysis.

6 Conclusion and Outlook

The concluding chapter focuses on summarizing the findings of this research and providing an outlook on further research. Chapter 6.1 summarizes the research results of the model development (chapter 3), the quantitative data analysis (chapter 4), and the case studies (chapter 5). Chapter 6.2 depicts the theory contribution, followed by the practice contribution in chapter 6.3. Chapter 6.4 outlines the limitations of this research and closes with further research opportunities in the context of this research.

6.1 Research Results

The introduction of this thesis stressed that existing research in the field of Operational Excellence (OPEX) Performance Measurement (PM) primarily discusses the manufacturing function. In recent years, the QC lab as an integral part of the value chain of a pharmaceutical drug manufacturer with its critical role in the effective and efficient release of drugs has gained attention (cf. chapter 1.1.1). However, practitioners had no means to identify their state of QC lab OPEX capabilities relative to the industry peer-group to learn how to improve the QC lab OPEX performance. Consequently, the research at hand aimed at conceptualizing performance measurement for OPEX in pharmaceutical QC labs. In addition, the research addressed the demand of practitioners to allow direct comparisons of different QC labs. To close the identified research gap (cf. chapter 1.1.3) the thesis at hand was guided by the main-research-question outlined below.

MRQ: How can OPEX performance be measured in pharmaceutical QC labs?

In the course of this thesis three sub-research-questions were framed and discussed. The first sub-research-question was theoretically driven and focused on how OPEX performance can be conceptualized. The operationalization addressed with the second sub-research-question ensured the applicability of the theoretical concept to the unit of analysis of this research. Driven by the demand of practitioners the third sub-research-question aimed at understanding the link between the operating context, OPEX enablers, and performance in QC labs. The following paragraphs highlight the sub-research-questions, followed by a summary of the research results.

SRQ 1: How can OPEX performance be conceptualized in pharmaceutical QC labs?

The triangulation of OPEX and PM literature with industry project and workshop results allowed building a conceptual abstraction of OPEX performance measurement in QC labs (cf. chapter 3.2). The theoretical grounding of the research in the resources-based view (RBV) supported the selection of categories of the OPEX performance measurement model (PMM). Considering performance, enablers, and operating context ensured consistency with existing PM approaches. Utilizing the competitive priorities as performance dimensions of the PMM met the requirement of a multidimensional performance definition addressing efficiency and effectiveness. Tailoring three of the four existing competitive priorities allowed better alignment with the target system of the unit of

analysis and a directional positive phrasing in the context of this research (cf. chapter 3.2.1). Productivity, quality, service, and cost efficiency build the performance dimensions of the PMM. The conceptual abstraction reflects the OPEX enablers understanding in literature and practice combining technical and managerial enablers. In total, ten different technical and three different managerial enabler dimensions are incorporated into the PMM (cf. chapter 3.2.2). Due to the mixed evidence in literature related to the relevance of environmental contingencies and organizational context factors for the enabler implementation and performance level, these factors are also considered in the PMM (cf. chapter 3.2.3).

SRQ 2: How can OPEX performance in QC labs be operationalized?

In chapter 3.3 the developed OPEX performance measurement model (PMM) for QC labs was operationalized. As specific literature related to performance indicators and the operating context in QC labs is scarce, the researcher relied especially on industry experts to operationalize the PMM. Multiple iterations with practitioners, regulators, and researchers allowed identifying multiple representative performance indicators for each performance dimension. In total, 15 performance indicators were incorporated in the PMM to measure QC lab OPEX performance (cf. chapter 3.3.1). Existing available enabler scales were adapted to meet the requirements of the unit of analysis of this research. In total, 68 different enablers were summarized in 13 enabler dimensions (cf. chapter 3.3.2). The relevant factors to distinguish the operating context were derived from peer-group filter characteristics identified during individual benchmarking projects with practitioners. In total, 17 different factors were identified to distinguish the environmental and organizational characteristics of QC labs (cf. chapter 3.3.3).

SRQ 3: What is the relation between the model dimensions, context factors, and the OPEX performance in QC labs?

A quantitative analysis (chapter 4) and qualitative case study approach (chapter 5) allowed understanding the link between the operating context, OPEX enablers, and performance in QC labs. Due to the available time-centric data basis of this research, QC lab effectiveness was used as the QC lab performance (cf. chapter 3.4).
Portfolio Complexity, *Test Allocation Strategy*, *Organization Scale*, and *Technology & Innovation* show an impact on QC lab effectiveness (cf. chapter 4.2). No evidence was found for *Geographical Location*, *Economy of Scale*, and *Regulatory Approval*. (cf. chapter 4.2). QC Lab Effectiveness High Performers (QCHPs, above median performing QC labs) have a significantly higher QC lab effectiveness compared to QC Lab Effectiveness Low Performers (QCLPs, below median performing QC labs) (cf. chapter 4.3.2). The QCHPs also have a significantly higher quality and service performance (cf. chapter 4.3.2).
The implementation of the Management Enabler System (MES) has a positive impact on the implementation of the Technical Enabler System (TES) (cf. chapter 4.3.3). *Management Commitment & Company Culture*, *Employee Involvement & Continuous*

Improvement, and *Functional Integration & Qualification* have a partly significant impact on the implementation of the TES (cf. chapter 4.3.3).
The majority of QC labs confirmed a positive impact of the TES and MES on the QC lab effectiveness (cf. chapter 4.3.4). In addition, the same group of 35 QC labs (70 % of the data basis) showed that QCHPs have a significantly higher implementation in the aggregation of all enablers, the TES and MES (cf. chapter 4.3.5). However, not all enabler dimensions within the TES and MES show a significantly higher implementation for QCHPs compared to QCLPs within these 35 QC labs (cf. chapter 4.3.5). For the outlined majority of QC labs the QCHPs have a significantly higher integrated system enabler implementation compared to QCLPs (cf. chapter 4.3.5). QCLPs focus on single enabler dimensions, whereas the QCHPs achieve a systematic implementation of a variety of different enabler dimensions (cf. chapter 4.3.5). However, a subset of 15 QC labs (30 % of the data basis) did not support the findings related to the positive link between the TES, MES, and QC lab effectiveness outlined above. This minority of QC labs was contrasted to the remaining QC labs in three in-depth case studies in chapter 5.
The multitude of quantitative and qualitative data sources in these in-depth case studies indicate that the operating context can explain differences of QC lab effectiveness and enabler implementation. The within- and cross-case study analysis showed that the relation of QC lab effectiveness and enablers is driven by a number of different factors. The complexity of the QC lab business environment, the nature of business, the work homogeneity, and the business predictability showed an impact on QC lab effectiveness (cf. chapter 5.2 and 5.3). Constant business changes resulted in changing work requirements and consequently low QC lab effectiveness (cf. chapter 5.2 and 5.3). QC labs with infrequent business changes have shown a competitive advantage relative to the other QC labs (cf. chapter 5.3). Business priorities unrelated to CI have prevented these QC labs to benefit from a well-structured corporate approach to OPEX in QC labs (cf. chapter 5.3). In addition, the variation and alteration of activities in the QC labs influenced the available resources of the QC labs to continuously work on improving the QC lab effectiveness and the enabler implementation (cf. chapter 5.2 and 5.3). QC labs at a later stage of the lean transformation have shown higher performance than those at an early stage of the QC lab transformation (cf. chapter 5.3). The lead QC labs of the analyzed companies have benefited from their role showing a high performance and enabler implementation. Being a pioneer of the transformation effort resulted in a competitive advantage for these QC labs at the point of analysis (cf. chapter 5.3). Furthermore, missing corporate sponsorship and uncooperative site leadership have prevented OPEX initiatives to be successful (cf. chapter 5.2 and 5.3).
A comparison of the three case studies revealed a differing *Performance Focus*, *Process Robustness*, *Customer Complaint* level, and *Planning Adherence*. Independent from the enabler implementation level QC labs with a low QC lab effectiveness show a low *Process Robustness*, a low *Planning Adherence*, and a high level of *Customer Complaints*. QC labs with a high QC lab effectiveness and a high enabler implementation combine a high *Process Robustness*, a high *Planning Adherence*, and a low level of *Customer Complaints*. In addition, the cross-case study analysis disclosed a higher performance variation for QC labs with a low QC lab effectiveness and low enabler implementation. These QC labs are

not able to address the multidimensional target of their businesses related to quality and service performance. QC labs with a high QC lab effectiveness and high enabler implementation have a much lower performance variation. Consequently, these QC labs meet the business goal to perform well regarding the multidimensional performance target related to quality and service performance. The cross-case study analysis also depicts that the enabler configuration of the subset of QC labs contradicting the OM literature is less integrated and more focused on basic elements in the TES compared to the QC labs with a high QC lab effectiveness corresponding to a high enabler implementation (cf. chapter 5.3). Well performing QC labs showing a high QC lab effectiveness and high enabler implementation exploit synergies between different enabler dimensions enabling them to achieve superior performance regarding multiple performance goals (cf. chapter 5.4).
In addition, the organizational structure and employee development approach does not always match the business requirements of the analyzed QC labs. An increasing business complexity in the analyzed QC labs is not closely related to the level of cross-trained analysts, group work, and training days per employee and year (cf. chapter 5.3).

6.2 Theory Contribution

This research contributes to the literature of Operational Excellence and Performance Measurement providing new scientific knowledge by merging the two research domains in a specific unit of analysis that has not gained much attention in past research.
This thesis follows the scholars' request to continue research in the field of performance measurement building on existing frameworks. The initial review of empirical studies for the OPEX performance measurement model (PMM) development allowed to aggregate existing knowledge on PMMs of more than 30 years of research. The PMM development of this research is framed by implications of the OPEX and PM literature. Acknowledging existing PMMs the PMM of this research is built on existing measurement models. This research transferred and adapted existing measurement approaches to the specific requirements of the pharmaceutical QC labs. Many PMMs in literature are limited to representing conceptual abstraction without direct applicability. The PMM of this research enhances the conceptual abstraction by operationalizing all dimensions of the PMM for the unit of analysis of this research.
The QC lab specific operationalization together with the empirical data collected during this research allowed conducting a comprehensive quantitative analysis. This analysis informs the research community regarding the relation of performance, enablers, and operating context. Additionally, the quantitative analysis of the relation between the PMM model dimensions extends current empirical research to a new unit of analysis. While many quantitative studies of the past were focused on OPEX enablers in the manufacturing function, the present study replicates existing knowledge from manufacturing to pharmaceutical QC labs.
The finding contradicting OM literature on the enabler performance relation for a subset of QC labs extends existing knowledge. Incorporating the operating context into the present research addressed the mixed evidence in past literature of the relevance of distinguishing the operating context. It is found as relevant to distinguish different QC labs. Both the quantitative and qualitative research analyses showed the impact of environmental

contingency factors and organizational context factors on QC lab effectiveness and the enabler implementation as well as the relation between the two dimensions of the PMM.
To conclude, the research of this thesis is rooted in OM literature and has extended existing knowledge on the enabler performance relation to a new unit of analysis. The mixed-methods research design combined a quantitative analysis with qualitative case studies. This allowed replicating empirical work to a new unit of analysis and deepening the understanding of findings contradicting OM literature within the qualitative case studies.

6.3 Practice Contribution

This research contributes a unified, research-driven, performance measurement model for OPEX in pharmaceutical QC labs. The model incorporates all aspects to enable an industry-wide comparison. It allows the comparison of the OPEX performance and enabler implementation of QC labs under consideration of their operating context.
The PMM operationalization may serve as a basis of day-to-day performance monitoring and benchmarking of QC labs in the pharmaceutical industry. The OPEX enablers may serve as a self-assessment tool for practitioners to identify their OPEX capabilities.
The quantitative analysis allowed understanding the link between the operating context, OPEX enablers, and performance in QC labs. The practice contribution of the quantitative analysis is two-fold. First, the conclusions support practitioners with new knowledge on interdependencies within QC labs. The research propositions related to existing interdependencies were widely discussed in industry prior to this research but never confirmed with quantitative analyses. Second, practitioners can use the conclusions and compare the findings with the OPEX performance and enabler implementation state in their QC labs to identify areas of improvement with the highest impact on their business.
The findings related to the impact of the operating context on QC lab effectiveness support companies to better distinguish their network of QC labs when comparing performance data. In addition, practitioners can examine how their QC labs operate in those OPEX enabler dimensions that showed significant differences between above and below median performing QC labs. Considering the positive link between a high degree of integration of all OPEX enablers and above median performing QC labs practitioners can investigate the degree of integration of enablers in their own QC labs. Based on the investigation result practitioners can adjust their CI effort regarding the enablers to exploit synergies between different enabler dimensions to strive for superior performance.
Furthermore, the data collection template and analytical tools developed as part of this research can be used for individual industry projects with pharmaceutical companies that demand a comprehensive OPEX performance assessment of their QC labs.
The case studies enable practitioners to deepen the understanding how different QC lab patterns regarding the QC lab effectiveness and OPEX enablers implementation are characterized. Also, the case studies allow deepening the understanding why QC labs show these different patterns by disclosing a multitude of influencing factors. These influencing factors help practitioners to explain performance and enabler implementation gaps that are rooted in the organizational structure, the employee development approach, corporate business decisions, and corporate as well as local leadership. Additionally, the

disclosed influencing factors provide practitioners with a basis to inform others about performance and enabler implementation gaps rooted in the nature of their QC lab business.
Incorporating the observations on the PharmaCo's strategy for OPEX in QC labs into the case studies and cross-case analysis provides the practitioners with impulses to review their own strategy and approaches related to OPEX in QC labs. Practitioners can build and improve their own OPEX initiatives on lessons learned and successful practices of the analyzed case companies.
To conclude, the developed PMM allows practitioners a well-structured comprehensive examination of OPEX in QC labs. The results of the quantitative analysis and the case studies serve as a starting point to align current industry practices in QC labs with successful practices of well performing QC labs under consideration of the disclosed influencing factors in this research.

6.4 Limitations and Future Research

The research of this thesis faces several limitations related to the research methodology. However, the limitations include potential for further research. The limitations and further research opportunities are outlined in the subsequent paragraphs.
The research design at hand cannot be classified as a longitudinal study. Although the data was gathered over a period of approximately two years the quantitative analysis was conducted on time-centric data and no long-term claims can be made. The sequential improvement of first effectiveness and then efficiency caused the focus of the quantitative analysis on QC lab effectiveness. Gathering the same data again at a future point in time about three to five years from now will allow an in-depth analysis of the relation of QC lab effectiveness and efficiency. This future analysis will allow taking into account the complete excellence perspective of performance measurement outlined in this research. In addition, it will allow building longitudinal case studies that may reveal how the development of the systematic approaches to OPEX in QC labs have changed and potentially improved both the QC lab effectiveness and the enabler implementation.
The data basis of QC labs available for this research counted 53 QC labs at the point of analysis. There existed a high density of European high cost locations with small scale QC operations existed. A higher number of QC labs in the future may level out this tendency and additionally allow applying new statistical methods. The nature of the applied statistical methods in this research can only claim correlation but not causation. A different research design in future research may allow claiming causal relations.
Due to the number of QC labs, the quantitative analysis of the operating context was limited to a descriptive statistics. The interdependencies between different operating context factors were not studied. Future research may be dedicated to the interaction of the identified operating context factors and the impact on QC lab effectiveness. In addition, due to the number of QC labs, no statistical hypotheses testing for significant differences was conducted to disclose differences of the operating context between the three identified clusters of QC labs with differing QC lab effectiveness and enabler implementation.
In this research enablers related to customer involvement and supplier management were not included in the enabler system of QC labs. Future research should deepen the

understanding of these two dimensions. The statistical analyses of this research were focused on the relation between the enabler dimensions and QC lab effectiveness. Future research should investigate the relation between individual enabler dimensions and individual performance indicators of QC lab effectiveness. This may allow further guidance for practitioners on future improvement initiatives.

Although multiple data quality mechanisms were applied to the data collection of the quantitative data, the self-assessment related to the degree of enabler implementation may be affected by the different perception of participants. The operationalization of the performance dimensions as well as the enabler dimensions cannot claim to capture the complete image of such complex constructs. Further iterations and refinement of the performance indicators and the underlying item structure of the enabler dimensions can enhance the constructs of this research.

The case studies were carefully derived from the quantitative findings ensuring validity of the analysis and reliability of the research findings. Studying the discovered phenomenon of a differing QC lab effectiveness enabler relation, the available data source allowed gaining a better understanding how and why the QC labs are different. The in-depth analysis and cross-case analysis were focused on configurational differences between the QC labs. The configurational approach of the case studies did not focus on the effectiveness of implemented measures (e.g. training) of the case companies. Future research should investigate whether the identified characteristics related to the employee development approach depict substantial conceptual differences.

In addition, at the point of analysis the OPEX strategy in QC labs has not been implemented at all available QC labs of the three case companies yet. Consequently, the case studies of this research did not attempt to make a direct link between the OPEX strategy in QC labs and the performance outcome of each QC lab. The comparison in this research cannot conclude whether the one or the other strategy of the case companies is more successful. The link between the OPEX strategy and the cluster allocation of the QC labs is a future field of research once the deployment of the OPEX strategy has been finished across all QC labs. Future case studies investigating the described phenomenon will allow deepening the understanding why QC labs do not achieve a high QC lab effectiveness and high enabler implementation although the employed OPEX strategy is similar.

Once new pharmaceutical companies participated in the St. Gallen QC Lab OPEX Benchmarking and a substantially higher number of available QC labs is reached additional case studies can be conducted. These case studies may sharpen and enhance the current research findings. Conducting a quantitative analysis at a future point in time with a larger data basis will allow strengthening and refining the results of this research further. Additionally, incorporating site performance and enabler data will enhance this research further by providing insight on the interrelations of the QC lab and the manufacturing site.

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Appendix

Appendix 1: List of recommendations for performance measures (Neely et al., 1997)

No.	Recommendation
1	Performance measures should be derived from strategy.
2	Performance measures should be simple to understand.
3	Performance measures should provide timely and accurate feedback.
4	Performance measures should be based on quantities that can be influenced, or controlled, by the user alone or in co-operation with others.
5	Performance measures should reflect the “business process” – i.e. both the supplier and customer should be involved in the definition of the measure.
6	Performance measures should relate to specific goals (targets).
7	Performance measures should be relevant.
8	Performance measures should be part of a closed management loop.
9	Performance measures should be clearly defined.
10	Performance measures should have visual impact.
11	Performance measures should focus on improvement.
12	Performance measures should be consistent (in that they maintain their significance as time goes by).
13	Performance measures should provide fast feedback.
14	Performance measures should have an explicit purpose.
15	Performance measures should be based on an explicitly defined formula and source of data.
16	Performance measures should employ ratios rather than absolute numbers.
17	Performance measures should use data which are automatically collected as part of a process whenever possible.
18	Performance measures should be reported in a simple consistent format.
19	Performance measures should be based on trends rather than snapshots.
20	Performance measures should provide information.
21	Performance measures should be precise – be exact about what is being measured.
22	Performance measures should be objective – not based on opinion.

Appendix 2: St. Gallen operational excellence research group participants 2016

Company	Origin	Position
PharmaCo A	US	Executive Director Operations Performance Excellence & Quality Excellence
PharmaCo B	DE	Global Roll out Manager of Integrated Production System
PharmaCo C	IT	Head of Business Development – Industrial Process Solutions Division
PharmaCo D	CH	Global Lead Technical Operations Performance Program
PharmaCo E	FI	Development Manager
PharmaCo F	US	Vice President Network and Operational Excellence
PharmaCo G	CH	Global Operational Excellence Lead
PharmaCo H	FR	Head Lean Implementation
PharmaCo I	CH	Head Supply Chain Drug Products
PharmaCo J	US	Head of Continuous Improvement Program Office

Appendix 3: St. Gallen QC lab exchange platform participants 2018

Company	Origin	Position
PharmaCo 1	DE	Head of Bulk Production & Operational Excellence, 2x Head of Quality Control
PharmaCo 2	US	Director Operational Excellence Center of Excellence, Quality Control Process Development Team Member
PharmaCo 3	DE	Director Quality Control Standards & Services, Executive Director Quality Control Services, Executive Director Quality
PharmaCo 4	US	Analytical Quality Research Fellow
PharmaCo 5	FR	3x Quality Control Manager
PharmaCo 6	BE	2x Senior Director Quality Control
PharmaCo 7	DE	Head of Quality Control Laboratory Excellence, Team Leader Global Quality & Compliance IT
PharmaCo 8	CH	Global Head Operational Excellence Quality Organization
PharmaCo 9	DK	Director Biopharma Quality Control, 2x Director Quality Control
PharmaCo 10	FI	Director Chemical Quality Control, Senior Development Manager Supply Chain Development Team
PharmaCo 11	US	Senior Director Quality Assurance/Quality Control Design Lead - Production Systems
PharmaCo 12	CH	Head Global Quality Control Business Support and Improvement, 2x Global Quality Control Business Support and Improvement Team Member
PharmaCo 13	FR	Global Head Chemistry, Manufacturing and Control Large Biomolecules
PharmaCo 14	CH	Global Head of Operational Excellence
PharmaCo 15	JP	Global QC Lab Excellence Leader, Local QC Lab Excellence Leader
PharmaCo 16	DE	3x Director Quality Control

Appendix 4: St. Gallen QC lab exchange platform performance measurement workshop task 2018

Workshop	Task
1: Commonalities and Difference of Performance Measurement Approaches	1. Individual work: Collect commonalities and differences of your performance measurement approach. *(During presentations of performance measurement approaches of other companies.)* 2. Company discussion: Compare commonalities and differences of your company's performance measurement approach in QC labs to the approaches presented today. 3. Company presentation: Present commonalities and differences of your performance measurement approach in QC labs to the group.
2: KPIs for Performance Measurement	1. Group work: Identify KPIs for OPEX Performance Measurement in QC labs. Add a high-level definition and reasoning. Think of common performance dimensions across the KPIs. 2. Rotation – Group discussion: Discuss KPIs of the other group and comment in the respective column of the template. Please use standardized symbols. 3. Group presentation: Elaborate on your group's results taking into account the feedback received from the other groups.

Appendix 5: QC Lab OPEX performance measurement workshop task 2016

Workshop	Task
1: Differentiating Factors	Determine differentiating factors of QC labs which ensure the comparability of metrics and which can be used within an analysis to build meaningful peer-groups.
2: QC Benchmarking Metrics	Review the metrics of the current St. Gallen QC Lab OPEX Benchmarking questionnaire draft with the focus on meaningfulness, sensitivity, clear understanding and measurability.
3: Performance Measurement	Define performance for QC labs to distinguish high and low performing QC labs.
4: Enabler Assessment	Analyze the relevance of St. Gallen OPEX Benchmarking enabler dimensions and determine further enabler dimensions leading to better performance in QC labs.

Appendix 6: Final data collection template

Version 18. Jun 18

Institute of Technology Management
University of St.Gallen
Switzerland

Benchmarking in the Pharmaceutical Industry
for Quality Control Labs

The Project

Since 2004, the Institute of Technology Management at the University of St.Gallen (ITEM-HSG), Switzerland is conducting an international benchmarking project in the pharmaceutical industry in the field of Operational Excellence. This continuous benchmarking project deals with the implementation of Lean Thinking and other basic principles of Operational Excellence.
In 2016 ITEM-HSG introduced a new benchmarking that aims for an analysis of Quality Control Labs in pharmaceutical companies in order to enable the participating companies to position their Quality Control Lab against a broad range of other pharmaceutical companies.

Your Commitment

Your participation is vital to the success of this unique study. Filling out the questionnaire takes about 30 minutes. The time to collect the data (e.g. performance indicators) differs from company to company.

Your Benefits

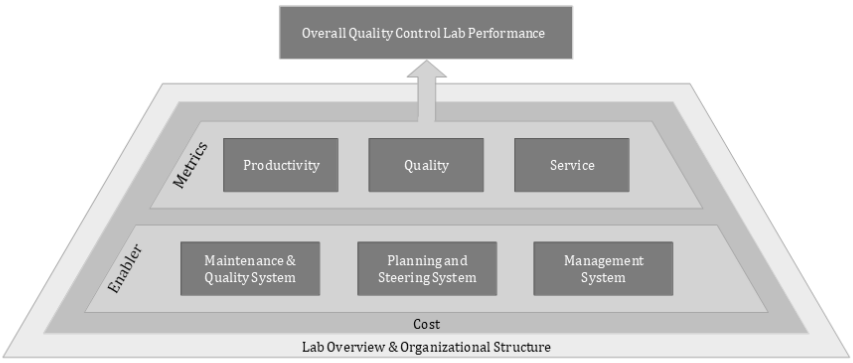
The questionnaire has been developed in cooperation with leading pharmaceutical companies under supervision of Prof. Dr. Thomas Friedli. This will help you to position your lab on the basis of our database.

The Confidentiality of the Data

The benchmarking project will be conducted according to the International Benchmarking Code of Conduct, that ensures ethical activities of all participants. The company data will be handled with upmost discretion. Company-specific data will not be used without prior approval of the respective company.

Thank you very much for your participation!

Please find below the benchmarking framework that is the basis for the questionnaire structure



How to complete the form:

Please enter the figures for the respective metric.* All metrics should be average values for the year the data is collected for.

* If you are unable to provide a figure, please insert "n/a".

If you have any questions regarding the project please contact

University of St.Gallen (HSG)
Institute of Technology Management (ITEM-HSG)
Dufourstrasse 40a
CH-9000 St.Gallen

Stephan Koehler
stephan.koehler@unisg.ch
Tel.: +41 (0) 71 224 72 71

General Information

Please provide some general information of your company below.

A01	LastName	
A02	FirstName	
A03	Position or Role	
A04	Company Name	
A05	Benchmarking Lab	
A06	Country Lab is situated	
A07	Telephone	
A08	Email	
A09	Address	

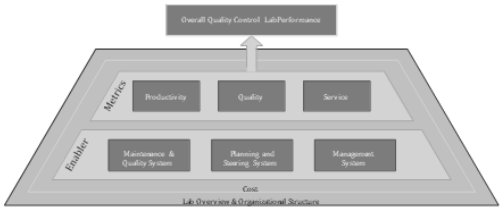
Please fill in the year your data is collected for. This should always match a full calendar year (e.g. 2016).

A10	Year	

Please chose which currency you use for filling in this questionnaire from the dropdown menu below.

A11	Currency	

Lab Overview



Lab Type / Technologies

Please indicate for which technologies/products your QC Lab is performing tests for.

	Drug Substance		
B01a	Chemicals (API)	○ Yes	○ No
B01b	Biologics	○ Yes	○ No
	Formulation, Filling and/or Packaging (Primary and Secondary)		
B01c	Solids	○ Yes	○ No
B01d	Creams	○ Yes	○ No
B01e	Suppositories	○ Yes	○ No
B01f	Sterile liquids	○ Yes	○ No
B01g	Non-Sterile liquids	○ Yes	○ No
B01h	Patches	○ Yes	○ No
B01i	Inhalers	○ Yes	○ No

Lab Focus

Pleas indicate what kind of purpose your QC Lab has.

B02a	☐	Multi-purpose lab (if more than one DP or DS is tested, please consider yourself as a multi-purpose lab)
B02b	☐	Low volume lab
B02c	☐	High volume lab

Lab Role

Please indicate the degree of centralization of the QC Lab.

B03a	○	Our lab is only responsible to conduct testing for the site where the lab is located.
	○	Our lab is responsible to conduct testing for multiple sites.

	If the lab is responsible to conduct testing for multiple sites, please indicate to what degree this lab does testing for other sites.	Unit	Figure
B03b	Proportion of tests for other sites to overall number of tests within QC Lab.	%	

Mutual Recognition Agreement (MRA)

Please indicate if you do re-testing for batches produced in another country with no MRA in place and thus batches from these countries must undergo batch re-testing.

B04a	○	Yes, batch re-testing is done at our QC Lab for our own production in a third-country.
	○	No, batch re-testing is done by another company (CMO re-testing) or another location of our company.

If yes, please indicate to what degree in-country batch re-testing is conducted.	Unit	Figure
B04b Proportion of batch re-testing to overall amount of testing within QC Lab.	%	

Regulatory Approval

Please indicate if your lab has regulatory approval. Regulatory approval means any approvals by health authorities in a country or organization (e.g. FDA).

B05a	☐	Food & Drug Administration (FDA)
B05b	☐	European Medicines Agency (EMA)
B05c	☐	Pharmaceuticals and Medical Devices Agency in Japan (PMDA)
B05d	☐	China Food and Drug Administration (CFDA)
B05e	☐	World Health Organization (WHO)
B05f	☐	Other approval, please specify below
B05g		

Age of Testing Methods

Please indicate if new testing methods (not an update of an existing methods) have been introduced to the lab. All categories below should sum up to 100%.

	Unit	Figure
B06a Testing methods which were introduced less than 3 years ago	%	
B06b Testing methods which were introduced between 3 and 5 years ago	%	
B06c Testing methods which were introduced between 6 and 10 years ago	%	
B06d Testing methods which were introduced more than 10 years ago	%	

Active vs. Inactive Testing Methods

Please indicate the proportion of active methods that are regularly used in your lab. Inactive methods are those methods that are still in the system but are not used anymore (e.g. due to expiration, termination of products tested with this method).

	Unit	Figure
B07 Proportion of active methods that are regularly used within QC Lab	%	

Age of Equipment

Please indicate the age of your lab equipment. All categories below should sum up to 100%.

	Unit	Figure
B08a Lab instruments which are less than 3 years old	%	
B08b Lab instruments which are between 3 and 5 years old	%	
B08c Lab instruments which are between 5 and 10 years old	%	
B08d Lab instruments which are more than 10 years old	%	

Level of Automation

Please indicate the level of automation in your lab. Please include instruments in sample preparation as well as testing. All categories below should sum up to 100%.

	Unit	Figure
B09a Percentage of instruments that are manually operated (supervision at anytime is needed)	%	
B09b Percentage of instruments that are operated with IT-support (temporary supervision is sufficient)	%	
B09c Percentage of instruments that are fully automated (without supervision)	%	

No. of Products tested & Countries filed

Please indicate the total number of products tested and the number of countries that your lab runs tests for (e.g. one product tested with two different methods and/or specifications for country specific regulatory = 2).

	Unit	Figure
B10a Total number of products tested	No.	
B10b Total number of countries filed	No.	

FTE Structure

Please include all FTEs working on your site, in your Quality Control Lab and your Quality Assurance department (on-site & network) independent from being on your payroll. If you are unable to provide a figure please insert "n/a".

	Name	Definition	Unit	Figure
	Total Site FTEs			
B11a	Site Permanent FTEs	Number of permanent site FTEs.	**No.**	
B11b	Site Temporary FTEs	Number of temporary site FTEs.	**No.**	
B11c			**Total**	n/a
	Quality Control (QC) FTEs			
B12a	QC Permanent FTEs	Number of permanent Quality Control FTEs.	**No.**	
B12b	QC Temporary FTEs	Number of temporary Quality Control FTEs.	**No.**	
B12c			**Total**	n/a
	Quality Assurance (QA) FTEs			
	Site Level			
	Site Level includes all QA FTE that are on-site supporting on-site QA activities.			
B13a	QA Permanent FTEs	Number of permanent Quality Assurance FTEs.	**No.**	
B13b	QA Temporary FTEs	Number of temporary Quality Assurance FTEs.	**No.**	
B13c			**Total**	n/a
	Network Level On-Site			
	Network Level On-Site includes all QA FTE that are on-site supporting off-site QA activities.			
B14a	QA Permanent FTEs	Number of permanent Quality Assurance FTEs.	**No.**	
B14b	QA Temporary FTEs	Number of temporary Quality Assurance FTEs.	**No.**	
B14c			**Total**	n/a
	Network Level Off-Site			
	Network Level Off-Site includes all QA FTE that are off-site supporting on-site QA activities.			
B15a	QA Permanent FTEs	Number of permanent Quality Assurance FTEs.	**No.**	
B15b	QA Temporary FTEs	Number of temporary Quality Assurance FTEs.	**No.**	
B15c			**Total**	n/a

Lab Volumes

Please include all processed batches independent from where these batches were produced and if batches were actually tested (e.g. number of batches from other sites that are processed at your lab should be included.)

B16	Drug Substance Batches	Total number of drug substance batches processed in the last year.	**No.**	
B17	Intermediate Batches	Total number of intermediate batches processed in the last year.	**No.**	
B18	Raw Material Batches	Total number of raw material batches processed in the last year.	**No.**	
B19	Stability Batches	Total number of stability batches processed in the last year.	**No.**	
B20	Drug Product Batches	Total number of drug product batches (completed all processing stages up to, but not incl. final packaging) processed in the last year.	**No.**	
B21	Packaged Product Batches	Total number of packaged product batches processed in the last year.	**No.**	
B22	Component & Packaging Material Batches Receipts	Total number of component & packaging material batches receipts in the last year.	**No.**	
B23			**Total**	n/a

Comment

Organizational Structure

Please fill in the respective figures below. If you are unable to provide a figure please insert "n/a".

	Name	Definition	Unit	Figure
	General metrics			
C01	Span of Control	Number of employees to supervisors (employees directly reporting to this supervisor).	No.	
C02	Reporting Layers	Number of management levels from analyst to the highest ranking quality manager at the site (e.g. Worker - Supervisor - Manager of the department - Quality Head = 4 Levels).	No.	
C03	Qualified Technicians	Employees with prior work related qualification in your lab as a percentage of all lab employees (e.g. trained/certified employees at previous company who do not require re-training in your organization). If your organization does re-train certified employees = 0 %)	%	
C04	Employees Fluctuation	Employees leaving your lab due to personal reasons, terminations, expired work contracts, retirements etc. as a percentage of all lab employees.	%	
C05	Cross-trained Analysts	Proportion of employees to total lab employees that are cross-trained in order to conduct various type of tests and tasks within the lab.	%	
C06	Group Work	Percentage of lab employees that are organized in teams in order to facilitate day-to-day work more efficient.	%	
C07	Training	Number of training days per lab employee (all kinds of training off- and on the job) in the last year.	Days	
C08	Sick Leave	Total time of employees absent (e.g. sick leave, maternity leave) as a percentage of the total working time.	%	
C09	Number of Suppliers for Consumables	Number of suppliers for consumables.	No.	
	QC Direct FTE Structure			
	Direct employees are all those employee that are doing directly batch-related work (e.g. testing analysis). Full-time equivalent (FTE) allows part-time workers' working hours to be standardized against those working full-time. The standardized figure is 1.0, which refers to a full-time worker. 0.5 refers to an employee that works half full-time hours.			
C10a	Drug Substance Testing FTE	Number of direct drug substance testing FTEs.	No.	
C10b	Intermediate Testing FTE	Number of direct intermediate testing FTEs.	No.	
C10c	In Process Control Testing FTE	Number of direct IPC testing FTEs.	No.	
C10d	Raw Material Testing FTE	Number of direct raw material testing FTEs.	No.	
C10e	Stability Testing FTE	Number of direct stability testing FTEs.	No.	
C10f	Drug Product Testing FTE	Number of direct drug product testing FTEs.	No.	
C10g	Packaged Product Testing FTE	Number of direct packaged product testing FTEs.	No.	
C10h	Microbial Environmental Testing FTE	Number of direct environmental testing FTEs.	No.	
C10i	Microbial Product Testing FTE	Number of direct microbial product testing FTEs.	No.	
C10j	Component & Packaging Testing FTE	Number of direct component & packaging testing FTEs.	No.	
C10k			Total	n/a
	QC Indirect FTE Structure			
	Indirect employees are all those employee that are doing indirectly batch-related work (e.g. documentation). Full-time equivalent (FTE) allows part-time workers' working hours to be standardized against those working full-time. The standardized figure is 1.0, which refers to a full-time worker. 0.5 refers to an employee that works half full-time hours.			
C11a	Drug Substance Testing FTE	Number of indirect drug substance testing FTEs.	No.	
C11b	Intermediate Testing FTE	Number of indirect intermediate testing FTEs.	No.	
C11c	In Process Control Testing FTE	Number of indirect IPC testing FTEs.	No.	
C11d	Raw Material Testing FTE	Number of indirect raw material testing FTEs.	No.	
C11e	Stability Testing FTE	Number of indirect stability testing FTEs.	No.	
C11f	Drug Product Testing FTE	Number of indirect drug product testing FTEs.	No.	
C11g	Packaged Product Testing FTE	Number of indirect packaged product testing FTEs.	No.	
C11h	Microbial Environmental Testing FTE	Number of indirect environmental testing FTEs.	No.	
C11i	Microbial Product Testing FTE	Number of indirect microbial product testing FTEs.	No.	
C11j	Component & Packaging Material Testing FTE	Number of indirect component material testing FTEs.	No.	
C11k	Management & Administration FTE	Number of QC management & administration FTEs.	No.	
C11l	Analytical Development FTE	Number of analytical development FTEs.	No.	
C11m	Other QC FTE	Number of other QC FTEs.	No.	
C11n			Total	n/a

QA FTE Structure

Site Level

Site Level includes all QA FTE that are on-site supporting on-site QA activities.

C12a	Validation FTE	Number of validation FTEs (e.g. method validation, equipment validation, process validation).	**No.**		
C12b	Batch Disposition FTE	Number of batch disposition FTEs (incl. batch record review).	**No.**		
C12c	Quality Compliance and Auditing FTE	Number of quality compliance and auditing FTEs.	**No.**		
C12d	Quality Systems FTE	Number of quality systems FTEs (e.g. responsible for Annual Product Quality Reviews, Stability Reports, Change Controls.)	**No.**		
C12e	Management & Administration FTE	Number of QA management & administration FTEs.	**No.**		
C12f	Other QA FTE	Number of other QA FTEs.	**No.**		
C12g			**Total**	n/a	

Network Level On-Site

Network Level On-Site includes all QA FTE that are on-site supporting off-site QA activities.

C13a	Quality Compliance and Auditing FTE	Number of quality compliance and auditing FTEs.	**No.**		
C13b	Quality Systems FTE	Number of quality systems FTEs.	**No.**		
C13c	Management & Administration FTE	Number of QA management & administration FTEs.	**No.**		
C13d			**Total**	n/a	

Network Level Off-Site

Network Level Off-Site includes all QA FTE that are off-site supporting on-site QA activities.

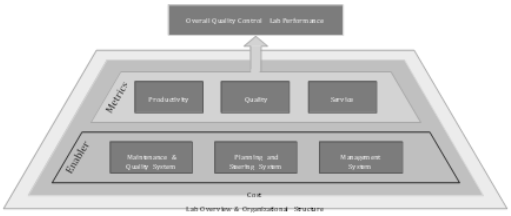
C14a	Quality Compliance and Auditing FTE	Number of quality compliance and auditing FTEs.	**No.**		
C14b	Quality Systems FTE	Number of quality systems FTEs.	**No.**		
C14c	Management & Administration FTE	Number of QA management & administration FTEs.	**No.**		
C14d			**Total**	n/a	

Overtime

C15a	QC	Proportion of spent overtime hours to total hours in QC.	%		
C15b	QA	Proportion of spent overtime hours to total hours in QA	%		

Comment

Enabler



Please rate to what degree your lab fulfils the enablers below.

	Question	1	2	3	4	5	Don't know
	Maintenance & Quality System						
	Preventive Maintenance						
D1	To what degree is there a formal program for maintaining your lab equipment?	There is no formal maintenance program	Formal program exists but is not widely visible	Formal program exists and is visible but is adhered to unevenly	Formal program is regularly adhered to but not regularly updated	Formal program strictly adhered to and updated regularly	
		○	○	○	○	○	○
D2	To what degree are maintenance jobs (e.g. calibration programs) documented, and maintenance plans and checklists posted close to instruments?	Jobs, plans, and checklists are not documented & posted	Jobs, plans, and checklists are rarely documented & posted	Jobs, plans, and checklists are sometimes documented & posted	Jobs, plans, and checklists are regularly documented & posted	Jobs, plans, and checklists are always documented & posted	
		○	○	○	○	○	○
D3	To what degree is potential bottleneck lab equipment identified and supplied with additional spare parts?	Bottleneck equipment is not identified	Bottleneck equipment is identified but not supplied with spare parts	Bottleneck equipment is supplied with spares, but unevenly across the lab	Bottleneck equipment is supplied with spare parts across the lab	Bottleneck analysis is regularly refreshed, and equipment supplied with spares	
		○	○	○	○	○	○
D4	To what degree is the maintenance program continuously optimized based on a dedicated failure analysis?	Dedicated failure analysis is not carried out	Dedicated failure analysis is carried out but not used to optimize maintenance	Failure analysis is used to optimize maintenance, but unevenly across the lab	Failure analysis is used to optimize the maintenance program across the lab	Regularly-refreshed failure analysis is used to optimize maintenance	
		○	○	○	○	○	○
D5	To what degree does the maintenance department focus on assisting analysts perform their own preventive maintenance?	Analysts receive no assistance relating to preventive maintenance	Analysts receive little assistance relating to preventive maintenance	Analysts receive some assistance relating to preventive maintenance	Analysts receive significant assistance relating to preventive maintenance	Analysts receive extensive assistance relating to preventive maintenance	
		○	○	○	○	○	○
D6	To what degree are analysts actively involved in the decision making process when buying new equipment?	Analysts are not involved in buying new equipment	Analysts are rarely consulted when buying new equipment	Analysts are sometimes consulted when buying new equipment	Analysts are regularly consulted when buying new equipment	Analysts are extensively involved in buying new equipment	
		○	○	○	○	○	○
D7	To what degree is your equipment maintained internally vs. externally?	<20% of maintenance is conducted internally	20% - 40% of maintenance is conducted internally	40% - 60% of maintenance is conducted internally	60% - 80% of maintenance is conducted internally	>80% of maintenance is conducted internally	
		○	○	○	○	○	○
D8	To what degree is your preventive maintenance effort focused on proactive activities rather than reactive activities?	<20% of activities are focused on proactive maintenance	20% - 40% of activities are focused on proactive maintenance	40% - 60% of activities are focused on proactive maintenance	60% - 80% of activities are focused on proactive maintenance	>80% of activities are focused on proactive maintenance	
		○	○	○	○	○	○
	Technology Assessment & Usage						
D9	To what degree is the lab situated at the leading edge of new technology?	We do not seek to use leading edge technology	We rarely incorporate leading edge technology	We sometimes incorporate leading edge technology	We regularly incorporate leading edge technology	We seek to stay at the frontier of leading edge technology	
		○	○	○	○	○	○
D10	To what degree do you screen the market for new production technology and assess new technology concerning its technical and financial benefit?	We do not screen for and assess new technology	We rarely screen for and assess new technology	We sometimes screen for and assess new technology	We regularly screen for and assess new technology	We are always screening for and assessing new technology	
		○	○	○	○	○	○
D11	To what degree is the lab effectively using new technology?	We have not introduced new technology in the last 5 years	We are interested in improving technology but do not devote much capex to this	We seek to introduce new technology, and devote some capex to this	We seek to introduce new technology, and devote a significant portion of capex	Our lab is used to pilot new technology within our network	
		○	○	○	○	○	○
D12	To what degree does the lab rely on vendors for its equipment?	<20% of equipment from vendors	20% - 40% of equipment from vendors	40% - 60% of equipment from vendors	60% - 80% of equipment from vendors	>80% of equipment from vendors	
		○	○	○	○	○	○
D13	To what degree is proprietary process technology and equipment used to gain a competitive advantage?	We use off-the-shelf process technology and equipment	We buy equipment on the market and use it with minimal modification	We buy equipment on the market, and carry out some modification as needed	We buy equipment on the market, and continuously modify to suit our needs	We build equipment to fit our needs - if it doesn't exist on the market we build it	
		○	○	○	○	○	○
D14	To what degree do you put an emphasize on smart lab system implementation?	We do not put an emphasize on smart lab system implementation	We put little emphasize on smart lab system implementation	We put some emphasize on smart lab system implementation	We put emphasize on smart lab system implementation but rarely review new smart solutions	We put remarkable emphasize on smart lab system implementation and regularly review new smart solutions	
		○	○	○	○	○	○

	Housekeeping						
D15	To what degree do employees strive to keep the lab neat and clean?	Housekeeping is not a core part of our improvement initiatives	Housekeeping is a small part of our improvement initiatives	Housekeeping is a reasonable part of our improvement initiatives, and a part of our training program	Housekeeping is a significant part of our improvement initiatives and training program	Housekeeping is a core part of our improvement initiatives, and we perform regular audits	
		○	○	○	○	○	○
D16	To what degree are tools and consumables put in their place (e.g. usage of a shadow board)?	We do not have formal housekeeping procedures	Formal housekeeping procedures exist but are not widely visible	Formal housekeeping procedures exist and are visible, but are adhered to unevenly	Formal housekeeping procedures are adhered to across the lab	Regularly-updated formal housekeeping procedures are adhered to across the lab	
		○	○	○	○	○	○
D17	To what degree are housekeeping checklists used to continuously monitor the condition and cleanness of our equipment?	We do not have housekeeping checklists	Housekeeping checklists exist but are not widely visible	Housekeeping checklists exist and are visible, but are adhered to unevenly	Housekeeping checklists are adhered to across the lab	Regularly-updated housekeeping checklists are adhered to across lab	
		○	○	○	○	○	○
D18	To what degree do you do a regular review of the "As-Is" situation (e.g. by doing a walkthrough) in your lab in order to identify potential improvement areas (e.g. by doing a gap analysis)?	We do not do a regular review of the "As-Is" situation	We rarely do a review of the "As-Is" situation	We sometimes do a review of the "As-Is" situation	We regularly do a review of the "As-Is" situation but do not always use tools to identify improvement areas	We regularly do a review of the "As-Is" situation and use tools to identify improvement areas	
		○	○	○	○	○	○
	Process Management						
D19	To what degree are direct and indirect processes documented?	Documentation does not exist	Documentation exists but is not widely visible	Documentation exists and is visible but is enforced unevenly	Documentation is regularly enforced but not regularly updated	Documentation strictly enforced and updated regularly	
		○	○	○	○	○	○
D20	To what degree is process quality continually measured using process metrics?	No clear definition of metrics	Few clearly defined metrics, but no regular usage	Some standardized metrics and occasional usage	Comprehensive set of standardized metrics and continuous usage	Comprehensive set of standardized metrics with leading and lagging indicators and continuous usage	
		○	○	○	○	○	○
D21	To what degree are dedicated process owners defined and responsible for planning, managing, and improving their processes?	No dedicated process owners	Some ownership of processes	Dedicated process owners, but little responsibility attached	Dedicated process owners responsible for planning & management	Dedicated process owners responsible for planning, management and improvement	
		○	○	○	○	○	○
D22	What proportion of the equipment in the lab is currently under statistical process control (SPC)?	<20% of equipment	20% - 40% of equipment	40% - 60% of equipment	60% - 80% of equipment	>80% of equipment	
		○	○	○	○	○	○
D23	To what degree are standardized tools in place for root cause analysis, to get a deeper understanding of the influencing factors (e.g. DMAIC)?	No tools in place	Some tools in placed but not standardized	Standardized tools in place, but used unevenly	Standardized tools used regularly	Standardized tools used regularly and a core part of training	
		○	○	○	○	○	○
	Standardization & Simplification						
D24	To what degree is standardization emphasized as a strategy for continuous improvement of lab processes and equipment?	We do not communicate standardization as part of our improvement program for the lab	Standardization is communicated but not emphasized in the lab	standardization is emphasized, but unevenly across the processes and equipment	Standardization is emphasized across both processes and equipment, but not core to our improvement program	Standardization is core to our improvement program for both processes and equipment	
		○	○	○	○	○	○
D25	To what degree are documented operating procedures used to standardize processes (e.g. set-ups)?	Documentation does not exist	Documentation exists but is not used to drive adherence	Documentation exists and is visible but is adhered to unevenly	Documentation is regularly adhered to but not regularly updated	Documentation strictly adhered to and updated regularly	
		○	○	○	○	○	○
D26	To what degree are optimized lab operating procedures (e.g. shortened set-ups) documented as best-practice processes and rolled-out throughout the whole quality organization?	Best practice is not documented	Best practice is documented but not rolled-out	Best practice is documented and rolled-out unevenly across the quality organization	Best practice is shared across the quality organization, but not regularly	Best practice is shared across the quality organization regularly	
		○	○	○	○	○	○
D27	To what degree are standardized functional descriptions used to reduce the period of vocational training for new employees?	Standardized functional descriptions do not exist	Standardized functional descriptions exist but are not used in training	Standard functional descriptions inform training but do not reduce the period	Standard functional descriptions inform training and reduce the period a little	Standard functional descriptions inform training and reduce the period significantly	
		○	○	○	○	○	○
D28	To what degree are standardized lab equipment (e.g. standardized design, standardized spare parts) used to achieve a high up time of the equipment?	Equipment is not standardized	A minor part of the equipment is standardized	Some equipment is standardized	Most of the equipment is standardized	Equipment is standardized throughout the lab	
		○	○	○	○	○	○
D29	To what degree do you pursue lowering material costs with the help of standardized equipment (e.g. for spare parts) and standardized consumables?	Equipment and consumables are not standardized	Little standardization of equipment and consumables exists, but reduction of material costs is not measured	Some standardization of equipment and consumables exists, but does not reduce material costs	Use of standardized equipment and consumables reduces costs a little	Use of standardized equipment and consumables reduces costs significantly	
		○	○	○	○	○	○

Planning & Steering System

Set-up Time Reduction

D30	To what degree do you continuously work to lower set-up and cleaning times in your lab?	We do not seek to continuously improve set-up and cleaning times	Continuously improving times is a small part of our improvement initiatives	Continuously improving times is a reasonable part of improvement initiatives	Continuously improving times is a significant part of our improvement initiatives	Continuously improving times is a core part of our improvement initiatives	
		○	○	○	○	○	○
D31	To what degree do analysts practice set-ups to reduce the time required?	Analysts do not practice set-ups	Analysts rarely practice set-ups	Analysts sometimes practice set-ups	Analysts regularly practice set-ups	Analysts practice set-ups extensively	
		○	○	○	○	○	○
D32	What proportion of equipment set-ups are scheduled so that the testing process is not affected (e.g. to shorten lead time)?	<20% of set-ups	20% - 40% of set-ups	40% - 60% of set-ups	60% - 80% of set-ups	>80% of set-ups	
		○	○	○	○	○	○
D33	To what degree are optimized set-up and cleaning procedures documented as best-practices and rolled-out throughout the whole lab?	Best practices are not documented	Best practices are documented but not rolled-out	Best practices are documented and rolled-out unevenly across the lab	Best practices are shared across the whole lab, but not regularly	Best practices are shared across the whole lab regularly	
		○	○	○	○	○	○

Pull Approach

D34	Do you use a pull system (Kanban squares, containers or signals) for your consumables?	We do not use a pull system for our consumables and it is not planned to introduce it	We do not use a pull system for our consumables but we want to introduce it	We are currently introducing a pull system for all our consumables	We have a pull system in place for all our consumables	We have a pull system in place for all our consumables and continuously improving it	
		○	○	○	○	○	○
D35	To what degree do you test according to forecast?	We do not test according to forecast	We do little testing according to forecast	We do some of our test according to forecast	We do most of our test according to forecast to get maximum capacity utilization	We do most of our test according to forecast but still can react flexible to short-term changes	
		○	○	○	○	○	○
D36	To what degree do you have tools installed for a regular demand and FTE capacity analysis?	We have no instruments installed to analyze demand and FTE capacity and no intend to do it in the future	We do not have any instruments installed to analyze demand and FTE capacity but intend to do it soon	We are currently rolling-out instruments to analyze demand/or and FTE capacity	We have one instrument installed demand analysis or FTE capacity analysis	We have instruments installed for both, demand analysis and FTE capacity analysis	
		○	○	○	○	○	○

Layout Optimization

D37	To what degree are your processes located close together so that material handling and consumable storage are minimized?	Related processes are not located close together	A minor part of related processes is located close together	Some related processes are located close together	Most related processes are located close together	Related processes are located close together across the whole lab	
		○	○	○	○	○	○
D38	What proportion of testing substances/products are classified into groups with similar processing requirements to reduce set-up times?	<20% of substances/products	20% - 40% of substances/products	40% - 60% of substances/products	60% - 80% of substances/products	>80% of substances/products	
		○	○	○	○	○	○
D39	To what degree does the layout of the lab facilitate low inventories and fast throughput?	Lab layout is not optimized for inventories and throughput	Layout is optimized in one or two parts of the lab	Layout is optimized in some parts of the lab	Layout is optimized in most parts of the lab	Layout is optimized across the lab	
		○	○	○	○	○	○
D40	To what degree can your lab layout be characterized as separated into "mini-labs", if testing substances/products have been classified based on their specific requirements?	Layout does not resemble "mini-labs"	Layout resembles "mini-labs" in one or two parts of the lab	Layout resembles "mini-labs" in some parts of the lab	Layout resembles "mini-labs" in most parts of the lab	Layout resembles "mini-labs" across the lab	
		○	○	○	○	○	○
D41	To what degree does you testing processes from incoming testing material to release involve almost no interruptions and can be described as a full continuous flow?	Continuous flow is not a core part of our lab objective	Continuous flow is a small part of our lab objective	Continuous flow is a reasonable part of our lab objective	Continuous flow is a significant part of our lab objective	Continuous flow is a core part of our lab objective	
		○	○	○	○	○	○
D42	To what degree do you use "Value Stream Mapping" as a methodology to visualize and optimize processes?	VSM is not used	VSM is rarely used	VSM is sometimes used	VSM is regularly used	VSM is extensively used	
		○	○	○	○	○	○

	Planning Adherence						
D43	To what degree do you meet your daily lab testing plans?	<20% of days	20% - 40% of days	40% - 60% of days	60% - 80% of days	>80% of days	
		○	○	○	○	○	○
D44	To what degree do you know the root causes of variance in your lab working schedule and continuouslytry to eliminate them?	We do not have a clear view of root causes of variation	We have some view of the root causes, but do not work on eliminating them	We have a good view of the root causes, but unevenly work on eliminating them	We have a good view of the root causes and regularly work on eliminating them	We have a clear view of root causes and continuously work on eliminating them	
		○	○	○	○	○	○
D45	To what degree does your lab have flexible working shift models in order to easily adjust labor capacity according to current demand changes?	We do not have flexible shift models	We have flexible shift models for a minor part of the employees in the lab	We have flexible shift models for some employees in the lab	We have flexible shift models for most employees in the lab	We have flexible shift models for all employees throughout the whole lab	
		○	○	○	○	○	○
D46	Beyond flexible working shifts, do you assign extra resources within the lab for testing during peak loads or do you outsource activities?	We don't have a clear strategy how to handle peak loads	We rarely follow one of the two objectives during peak loads	We do sometimes assign extra resources or outsource activities during peak loads	We regularly assign extra resources or outsource activities during peak loads	We are always assigning extra resources or outsource activities during peak loads	
		○	○	○	○	○	○
D47	To what degree do you prefer to increase productivity over short lead time or vice versa?	We don't have a clear strategy how to handle this trade-off	We only follow one of the two objectives	We try to follow both objectives but are not very successful	We aim to find the optimal balance between increasing productivity and short lead time	We found the optimal balance between increasing productivity and short lead time	
		○	○	○	○	○	○
	Visual Management						
D48	To what degree do you utilize performance charts to show weekly/monthly/annual performance objective?	We do not utilize performance charts in the lab	Performance charts are used for a few processes only	Performance charts across most processes show objectives	Performance charts across all key processes show objectives	Regularly-updated charts across all key processes show objectives	
		○	○	○	○	○	○
D49	To what degree do you utilize charts showing the current performance status (e.g. current RFT rate) in your lab?	We do not utilize current performance charts in the lab	Performance charts are used for a few processes to show current KPIs	Performance charts across most processes show current KPIs	Performance charts across all key processes show current KPIs	Regularly-updated charts across all key processes show current KPIs	
		○	○	○	○	○	○
	Management System						
	Management Commitment & Company Culture						
D50	To what degree does the head of quality and management empower employees to continuously improve processes and reduce failure?	Head of quality and management do not seek to empower lab employees	Head of quality and management promotes continuous improvement activity through other means	Head of quality and management seekto empower lab employees, but unevenly	Head of quality and management regularly seek to empower employees	Head of quality and management actively seek to empower all lab employees on a continuous basis	
		○	○	○	○	○	○
D51	To what degree are the head of quality and management personally involved in improvement projects?	Head of quality and management are not involved in improvement projects	Head of quality and management are involved in setting objectives for improvement, but no further	Head of quality and management are sometimes personally involved in improvement projects	Head of quality and management are regularly personally involved in improvement projects	Head of quality and management are personally involved in virtually all improvement projects	
		○	○	○	○	○	○
D52	To what degree does your site have an open communication culture, encourage the flow of information between the production and lab?	We always have trouble with communication between the production and lab	We often have trouble with communication between the production and lab	We sometimes have trouble with communication between the production and lab	We have an open communication culture enabling flow of info between the production and lab	We have an open communication culture, with a very good flow of info between the production and lab	
		○	○	○	○	○	○
D53	To what degree are problems (e.g. complaints) traced back to their origin to identify root causes?	We do not trace problems of this type to their origin	We rarely trace problems to their origin	We trace problems to their root cause if they repeat	We trace most problems to their root cause	We rigorously examine all problems, and identify root causes	
		○	○	○	○	○	○
D54	To what degree do you align the achievement of quality standards between production and QC/QA (e.g. shared responsibility or primarily the task of QA/QC)?	We do not seek to align the approach to achieve quality standards between production and QC/QA	We rarely align the approach to achieve quality standards between production and QC/QA	We sometimes seekto align the approach to achieve quality standards between production and QC/QA	We regularly align the approach to achieve quality standards between production and QC/QA	We always align the approach to achieve quality standards between production and QC/QA	
		○	○	○	○	○	○
D55	To what degree do your employees continuously strive to reduce waste in processes (e.g. waste of time, consumables)?	Waste reduction is not a core activity	Waste reduction is a focus for specialized employees only	Employees strive to reduce process waste in some processes	Employees strive to reduce process waste in most processes	Employees strive to reduce all kinds of waste in every process	
		○	○	○	○	○	○
D56	To what degree do you prefer improvement programs initiated and promoted by the site lab and not the global organization and vice versa?	We don't have a clear strategy how to handle this trade-off	We try to have both but initiatives are not aligned and not very successful	We aim to find a balance between corporate improvement programs and site improvement initiatives	We have a balance between corporate improvement programs and site improvement initiatives	We found the optimal balance between corporate improvement programs and site improvement initiatives	
		○	○	○	○	○	○

Employee Involvement & Continuous Improvement

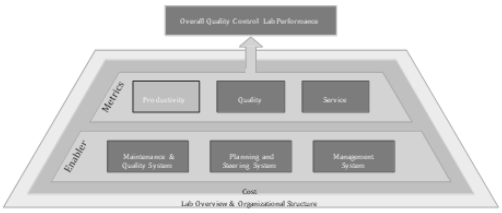
D57	To what degree have you implemented tools and methods to deploy a continuous improvement process in your lab?	We do not have a continuous improvement program	Continuous improvement processes are not supported by tools	We have some tools and methods to support continuous improvement	We have multiple tools and methods to support continuous improvement	Comprehensive tools and training in place to support continuous improvement	
		○	○	○	○	○	○
D58	To what degree are your analysts involved in writing standard operating procedures (SOPs)?	Analysts are not involved in developing SOPs	Analysts are rarely consulted when developing SOPs	Analysts are sometimes consulted when developing SOPs	Analysts are regularly consulted when developing SOPs	Analysts are extensively involved in developing SOPs	
		○	○	○	○	○	○
D59	To what degree do lab employee actively drive suggestion programs ((not excl. linked to a suggestion system in place)?	Employees do not actively drive suggestion programs	Employee engagement with suggestion programs is very limited	Employees are sometimes engaged in suggestion programs	Employees are actively engaged in suggestion programs	Employees are extensively involved in driving suggestion programs	
		○	○	○	○	○	○
D60	To what degree do your analysts have the authority to correct problems (e.g. with equipment, testing methods) when they occur without consulting a supervisor?	Problem solving is not carried out by analysts	Very few analysts have the authority to correct problems	Some analysts have the authority to correct problems	Most analysts have the authority to correct problems	Analysts have the authority to actively correct problems	
		○	○	○	○	○	○
D61	To what degree do supervisors focus on assisting analysts to perform their own problem solving?	Analysts receive no assistance relating to problem solving	Analysts receive little assistance relating to problem solving	Analysts receive some assistance relating to problem solving	Analysts receive significant assistance relating to problem solving	Analysts receive extensive assistance relating to problem solving	
		○	○	○	○	○	○
D62	To what degree does your site form cross-functional project teams to solve problems in your lab?	Our site does not utilize cross functional teams	Our site rarely utilizes cross functional teams	Our site sometimes utilizes cross functional teams	Our site regularly utilizes cross functional teams	Our site makes extensive use of cross functional teams	
		○	○	○	○	○	○
D63	To what degree does your lab follow a vision based approach to continuous improvement integrating constrains into the vision rather than an incremental approach?	We solely rely on incremental steps to continuous improvement	We mostly rely on incremental steps to continuous improvement	We folow a vision based approach with solely qualitative objectives	We folow a vision based approach with qualitative objectives integrating constrains into the vision	We folow a vision based approach with quantitative/measureable objectives integrating constrains into the vision	
		○	○	○	○	○	○
D64	Does global quality organization have a lab certification program for best performing labs?	We don't have and are currently not planning to have a lab certification program	We do not have a lab certification program but will launch it soon	We are currently launching a lab certification program	We have a lab certification program but once a lab is certified there is no review in place	We have a lab certification program and continuously review the lab certificates	
		○	○	○	○	○	○

Functional Integration & Qualification

D65	To what degree do you put emphasize on analysts cross-training to the required level so that they can fill-in for others when necessary?	We do not have cross-trained lab analysts	We have too few cross-trained lab analysts	We have some cross-trained lab analysts but less than the required level	We have a high number of cross-trained lab analysts but less than the required level	We have the optimal balance between cross-trained analysts and the required level	
		○	○	○	○	○	○
D66	To what degree is information and skill-evaluation from official feedback meetings used in further training?	The information is not used	The information is used, but not in any broad program. Employees do standard trainings	Some of the information is used in further trainings	Most of the information is used in further trainings	The information is used systematically in further training	
		○	○	○	○	○	○
D67	To what degree does your site invest in the training and qualification of your lab employees?	We do not invest in the training and qualification of our lab employees	We invest a little in training, but do not offer qualifications for lab employees	We have some trainings and offer one or two qualifications for lab employees	We have a dedicated development and qualification program for lab employees	We continuously seek to improve our dedicated training and qualification program for lab employees	
		○	○	○	○	○	○
D68	To what degree do your cross-trained analysts rotate on the job performing different tasks?	Our cross-trained analysts do not rotate	Our cross-trained analysts rarely rotate	Our cross-trained analysts sometimes rotate	Our cross-trained analysts regularly rotate	Our cross-trained analysts extensively rotate	
		○	○	○	○	○	○

Comment

Productivity

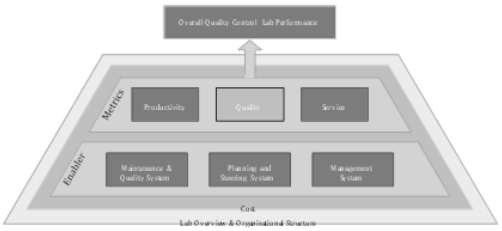


Please fill in the respective figures below. If you are unable to provide a figure please insert "n/a".

	Name	Definition	Unit	Figure
	General metrics			
E01	Handled Samples	Total number of samples managed by lab (not necessarily tested but incl. e.g. sample splitting for shipment) in the reporting period.	**No.**	
E02	Dedicated Equipment	Percentage of equipment that is dedicated to a specific product (e.g. drug product solids) that is tested.	**%**	
E03	Equipment Utilization Rate	Ratio between output that is actually achieved with the installed equipment, and the potential output which could be achieved with it, if capacity was fully used.	**%**	
E04	Number of samples per run	Number of different samples that can be tested together in one run due to same testing method (pooling).	**No.**	
E05	Stock-time for Consumables	Number of days consumables are on stock before usage for testing (e.g. solvents, reagents, gloves, filters, etc.).	**days**	
E06	SOPs	Number of Standard Operating Procedures (SOPs) or other formal written instructions (excluding the testing methods themselves) in the lab.	**No.**	
	Tests			
	Number of individual sample items (test items) analyzed is equal to number of tests. Testing multiple sample items (test items) at the same time is counted as multiple tests. If you do a purity test that leads into 10 different results for impurity this is still only counted as one test.			
E07a	Drug Substance Tests	Number of drug substance tests in the reporting period.	**No.**	
E07b	Intermediate Tests	Number of intermediate tests in the reporting period.	**No.**	
E07c	In Process Control Tests	Number of in process control tests in the reporting period.	**No.**	
E07d	Raw Material Tests	Number of raw material tests in the reporting period.	**No.**	
E07e	Stability Tests	Number of stability tests in the reporting period.	**No.**	
E07f	Drug Product Tests	Number of drug product tests in the reporting period.	**No.**	
E07g	Packaged Product Tests	Number of packaged product tests in the reporting period.	**No.**	
E07h	Microbial Environmental Tests	Number of microbial environmental tests (i.e. absence from microbes in clean rooms (e.g. on surface and personnel gear)) in the reporting period.	**No.**	
E07i	Microbial Product Tests	Number of microbial product tests (i.e. absence from microbes (e.g. bacteria and viruses) in products) in the reporting period.	**No.**	
E07j	Component & Packaging Material Tests	Number of component and packaging material tests (incl. primary and printed packaging material) in the reporting period.	**No.**	
E07k			**Total**	**n/a**
	Throughput rate			
E08a	Drug Substance Throughput rate	Number of drug substance testing samples analyzed per week in the reporting period.	**No./wk.**	
E08b	Intermediate Throughput rate	Number of intermediate testing samples analyzed per week in the reporting period.	**No./wk.**	
E08c	In Process Control Throughput rate	Number of IPC testing samples analyzed per week in the reporting period.	**No./wk.**	
E08d	Raw Material Throughput rate	Number of raw material testing samples analyzed per week in the reporting period.	**No./wk.**	
E08e	Stability Throughput rate	Number of stability testing samples analyzed per week in the reporting period.	**No./wk.**	
E08f	Drug Product Throughput rate	Number of drug product testing samples analyzed per week in the reporting period.	**No./wk.**	
E08g	Packaged Product Throughput rate	Number of packaged product samples analyzed per week in the reporting period.	**No./wk.**	
E08h	Microbial Environmental Throughput rate	Number of microbial environmental testing samples analyzed per week in the reporting period.	**No./wk.**	
E08i	Microbial Product Throughput rate	Number of microbial product testing samples analyzed per week in the reporting period.	**No./wk.**	
E08j	Component & Packaging Material Throughput rate	Number of component & packaging material testing samples analyzed per week in the reporting period.	**No./wk.**	
E08k			**Total**	**n/a**

Comment

Quality



Please fill in the respective figures below. If you are unable to provide a figure please insert "n/a".

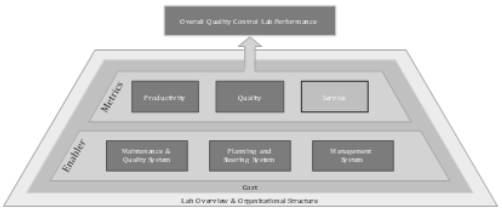
	Name	Definition	Unit	Figure
	General metrics			
F01	Lab Deviation Events	Number of events where an unexplained discrepancy from the routine processes occurs in the reporting period. Lab deviations comprise all events where an error occurs due to technical, human factors or environmental factors that caused differences from the routine processes.	**No.**	
F02	Recurring Deviations	Percentage of lab deviations that have already occurred in the reporting period. A deviation is recurring when a second deviation with the same root cause occurs within a one-year rolling period in the same process/system.	**%**	
F03	CAPAs Overdue	Proportion of CAPAs on lab deviations that went overdue in the reporting period to total number of CAPAs.	**%**	
F04	Customer Complaints Requiring Investigations	Total number of customer complaints requiring investigations in the reporting period.	**No.**	
F05	Product Re-Tests due to Complaints	Percentage of product re-tests (due to complaints by the customer) from overall number of tests in the reporting period.	**%**	
F06	Routine Product Re-tests	Number of routine product retests in the reporting period. Product retesting occurs when a material has reached the end of its initial shelf life and requires re-testing (re-analysis) to assess conformity to the registered specification(s). The test material was not progressed to formulation / further processing due to lack of demand. The intention of retesting is to prevent waste.	**No.**	
F07	Annual Product Quality Reviews (APQR)	Number of conducted verifications (reviews) that confirm the acceptability of the manufacturing and packaging processes in the reporting period.	**No.**	
F08	APQR On-Time Rate	Percentage of conducted verifications (reviews) that were on-time in the reporting period.	**%**	
F09	Stability Reports	Number of stability reports confirming stability at the time of testing and at different times during storage.	**No.**	
F10	Change Controls opened	Number of changes to product, process, equipment, testing methods and other changes which are tracked in a formal system.	**No.**	
F11	Audits	Number of audits by external parties (e.g. regulatory agencies, other companies) in the reporting period.	**No.**	
F12	Method Transfers	Number of Method Transfers in the reporting period. A method transfer is the formal process of transferring the analytical know-how from the sending unit to the receiving unit which must demonstrate the ability to do the analytical procedure(s) reliably and accurately.	**No.**	
F13	Test Method Validations	Number of test method validations performed in the reporting period.	**No.**	
	Analytical Right First Time			
F14a	Drug Substance Testing RFT	Percentage of "total number of test without any deviation" out of "total number of tests" in the reporting period. Deviation = Each test repeated not due to confirmed OOS/OOT/OOE result regardless to the reason (human error, equipment error, low method performance, etc.). Data which is not part of a formal Deviation Management system (e.g. Trackwise) has to be collected manually on a continuous basis.	**%**	
F14b	Intermediate Testing RFT		**%**	
F14c	In Process Control Testing RFT		**%**	
F14d	Raw Material Testing RFT		**%**	
F14e	Stability Testing RFT		**%**	
F14f	Drug Product Testing RFT		**%**	
F14g	Packaged Product Testing RFT		**%**	
F14h	Microbial Environmental Testing RFT		**%**	
F14i	Microbial Product Testing RFT		**%**	
F14j	Component & Packaging Material Testing RFT		**%**	
F14k			**Total Avg.**	**n/a**
	Lab Investigation			
F15a	Drug Substance Lab Investigation	Number of lab investigations in the reporting period. A lab investigation is undertaken for deviation events to understand the root cause of the error when a test result is out of specification (OOS).	**No.**	
F15b	Intermediate Lab Investigation		**No.**	
F15c	In Process Control Lab Investigation		**No.**	
F15d	Raw Material Lab Investigation		**No.**	
F15e	Stability Lab Investigation		**No.**	
F15f	Drug Product Lab Investigation		**No.**	
F15g	Packaged Product Lab Investigation		**No.**	
F15h	Microbial Environmental Lab Investigation		**No.**	
F15i	Microbial Product Lab Investigation		**No.**	
F15j	Component & Packaging Material Lab Investigation		**No.**	
F15k			**Total**	**n/a**

	Invalidated OOS			
F16a	Drug Substance Invalidated OOS	Number of occurrence when the assessment of a testing OOS result does not confirm the previous OOS result but testing results appear to be accurate in the reporting period.	No.	
F16b	Intermediate Invalidated OOS		No.	
F16c	In Process Control Invalidated OOS		No.	
F16d	Raw Material Invalidated OOS		No.	
F16e	Stability Invalidated OOS		No.	
F16f	Drug Product Invalidated OOS		No.	
F16g	Packaged Product Invalidated OOS		No.	
F16h	Microbial Environmental Invalidated OOS		No.	
F16i	Microbial Product Invalidated OOS		No.	
F16j	Component & Packaging Material Invalidated OOS		No.	
F16k			Total	n/a

	Total OOS			
F17a	Drug Substance OOS	Number of confirmed OOS in the reporting period.	No.	
F17b	Intermediate OOS		No.	
F17c	In Process Control OOS		No.	
F17d	Raw Material OOS		No.	
F17e	Stability OOS		No.	
F17f	Drug Product OOS		No.	
F17g	Packaged Product OOS		No.	
F17h	Microbial Environmental OOS		No.	
F17i	Microbial Product OOS		No.	
F17j	Component & Packaging Material OOS		No.	
			Total	n/a

Comment

Service

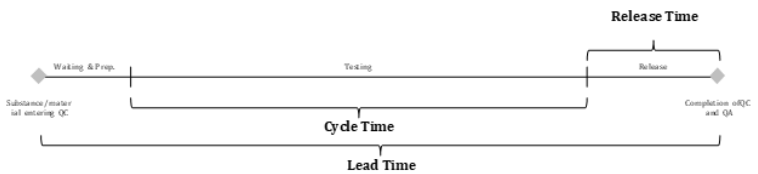


Please fill in the respective figures below. If you are unable to provide a figure please insert "n/a".

Name	Definition	Unit	Figure

Process Times

Which of the following figures are you able to provide?



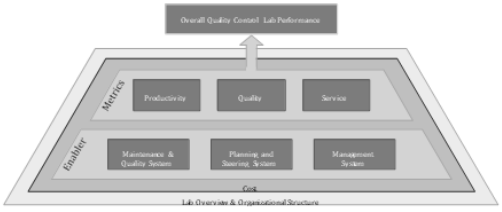
G01		Lead Time
G02		Cycle Time
G03		Release Time

	Lead Time			
G04a	DS Testing Lead Time	Time from substance/material entering QC until completion of QC and QA work, including all waiting time, storage time and order processing time.	No. of days	
G04b	Intermediate Testing Lead Time		No. of days	
G04c	IPC Testing Lead Time		No. of days	
G04d	Raw Material Testing Lead Time		No. of days	
G04e	Stability Testing Lead Time		No. of days	
G04f	Drug Product Testing Lead Time		No. of days	
G04g	Packaged Product Testing Lead Time		No. of days	
G04h	Microbial Environmental Testing Lead Time		No. of days	
G04i	Microbial Product Testing Lead Time		No. of days	
G04j	Component & Packaging Material Testing Lead Time		No. of days	
G04k			Total Avg.	n/a
	Cycle Time			
G05a	DS Testing Cycle Time	Value adding time in QC to complete the analytical tests from start to finish (incl. secondary review). Not including waiting time, storage time and order processing time.	No. of days	
G05b	Intermediate Testing Cycle Time		No. of days	
G05c	IPC Testing Cycle Time		No. of days	
G05d	Raw Material Testing Cycle Time		No. of days	
G05e	Stability Testing Cycle Time		No. of days	
G05f	Drug Product Testing Cycle Time		No. of days	
G05g	Packaged Product Testing Cycle Time		No. of days	
G05h	Microbial Environmental Testing Cycle Time		No. of days	
G05i	Microbial Product Test Cycle Time		No. of days	
G05j	Component & Packaging Material Testing Cycle Time		No. of days	
G05k			Total Avg.	n/a
	Release Time			
G06a	DS Release Time	Time after finishing testing (incl. secondary review) to release of the products including all waiting times. Secondary review should be only included in cycle time.	No. of days	
G06b	Intermediate Release Time		No. of days	
G06c	IPC Release Time		No. of days	
G06d	Raw Material Release Time		No. of days	
G06e	Stability Release Time		No. of days	
G06f	Drug Product Release Time		No. of days	
G06g	Packaged Product Release Time		No. of days	
G06h	Microbial Environmental Release Time		No. of days	
G06i	Microbial Product Test Release Time		No. of days	
G06j	Component & Packaging Material Release Time		No. of days	
G06k			Total Avg.	n/a
	Adherence to Schedule (ATS)			
G07a	Drug Substance Testing Adherence	Percentage of drug substance testing batches that were tested as scheduled in the reporting period.	%	
G07b	Intermediate Testing Adherence	Percentage of intermediate testing batches that were tested as scheduled in the reporting period.	%	
G07c	In Process Control Testing Adherence	Percentage of in process control testing batches tests that were tested as scheduled in the reporting period.	%	
G07d	Raw Material Testing Adherence	Percentage of raw material testing batches that were tested as scheduled in the reporting period.	%	
G07e	Stability Testing Adherence	Percentage of stability testing batches that were tested as scheduled in the reporting period.	%	
G07f	Drug Product Testing Adherence	Percentage of drug product testing batches that were tested as scheduled in the reporting period.	%	
G07g	Packaged Product Testing Adherence	Percentage of packaged product testing batches that were tested as scheduled in the reporting period.	%	
G07h	Microbial Environmental Testing Adherence	Percentage of microbial environmental testing batches (i.e. absence from microbes in clean rooms (e.g. on surface and personnel gear)) that were tested as scheduled in the reporting period.	%	
G07i	Microbial Product Testing Adherence	Percentage of microbial product testing batches (i.e. absence from microbes (e.g. bacteria and viruses) in products) that were tested as scheduled in the reporting period.	%	
G07j	Component & Packaging Material Testing Adherence	Percentage of packaging material testing batches (incl. primary and printed packaging material) that were tested as scheduled in the reporting period.	%	
G07k			Total Avg.	n/a

	Adherence to Lead Time (ATL)			
G08a	Drug Substance Testing ATL	Percentage of drug substance testing batches that were on time in the reporting period.	%	
G08b	Intermediate Testing ATL	Percentage of intermediate testing batches that were on time in the reporting period.	%	
G08c	In Process Control Testing ATL	Percentage of in process control testing batches tests that were on time in the reporting period.	%	
G08d	Raw Material Testing ATL	Percentage of raw material testing batches that were on time in the reporting period.	%	
G08e	Stability Testing ATL	Percentage of stability testing batches that were on time in the reporting period.	%	
G08f	Drug Product Testing ATL	Percentage of drug product testing batches that were on time in the reporting period.	%	
G08g	Packaged Product Testing ATL	Percentage of packaged product testing batches that were on time in the reporting period.	%	
G08h	Microbial Environmental Testing ATL	Percentage of microbial environmental testing batches (i.e. absence from microbes in clean rooms (e.g. on surface and personnel gear)) that were on time in the reporting period.	%	
G08i	Microbial Product Testing ATL	Percentage of microbial product testing batches (i.e. absence from microbes (e.g. bacteria and viruses) in products) that were on time in the reporting period.	%	
G08j	Component & Packaging Material Testing ATL	Percentage of packaging material testing batches (incl. primary and printed packaging material) that were on time in the reporting period.	%	
G08k			Total Avg.	n/a

Comment

Cost



Please fill in the respective figures below. If you are unable to provide a figure please insert "n/a". Please use your local currency that you indicated on the "General Information" sheet. Please insert figure in thousand (e.g. 100000 -> 100).

	Name	Definition	Unit	Figure
H01	Total QO Costs	All costs of the quality organization in the reporting period.	Thousand	n/a
H02	Total QC Costs	All costs of the Quality Control Lab in the reporting period.	Thousand	n/a
H02a	Labor	All labor costs.	Thousand	
H02b	Materials (e.g. consumables)	All materials (e.g. consumables) costs.	Thousand	
H02c	Equipment	Costs for instruments, tools and spare parts (incl. electricity).	Thousand	
H02d	Maintenance	All maintenance costs including routine and no- routine maintenance.	Thousand	n/a
H02d1	Internal Maintenance	Internal cost of maintenance of lab equipment and facilities.	Thousand	
H02d2	External Maintenance	Cost for maintenance of lab equipment and facilities that are maintained by a third-party.	Thousand	
H02e	Depreciation	All depreciation costs.	Thousand	
H02f	Services	All service costs (incl. costs for employment of external parties to provide services) that are included in QC lab expenses.	Thousand	n/a
H02f1	Contract Lab	Cost of testing carried out by a third-party lab.	Thousand	
H02f2	Sample Packaging	Cost of sample management activities (transport, weighing, packaging, labelling etc.) carried out by a third-party.	Thousand	
H02f3	Lab Glassware	Cost for collecting, washing and returning glassware to the lab.	Thousand	
H02f4	Waste Disposal	Cost of waste management activities carried out by a third-party including waste collection, packaging and disposal.	Thousand	
H02f5	Archiving	Cost of document transport and storage, carried out by a third-party.	Thousand	
H02f6	Administration	Cost of administration activities carried out by a third-party, which may include document authoring or formatting, data management and secretarial duties.	Thousand	
H02f7	Information Technology	Cost of IT services provided by a third-party.	Thousand	
H02f8	Other QC Service Costs	All other QC service costs not included in any category above.	Thousand	
H02g	Other QC Costs	All other QC costs not included in any category above.	Thousand	

H03	Total QA Costs	All costs of the Quality Assurance in the reporting period.	Thousand	
H04	Other QO Costs	All other costs of the quality organization in the reporting period.	Thousand	
H05	Site Absorption	Site absorption costs are all manufacturing costs of finished products (incl. materials, labor and manufacturing overhead) in the reporting period.	Thousand	

Comment

You have completed the survey.
Thank you very much for your participation!
Please save the survey on your hard disk and email the file to

stephan.koehler@unisg.ch

Appendix 7: Average implementation rate of individual enablers for clusters 1, 2, and 3

Individual Enabler ID and Question	Impl. Rate		
	C1	C2	C3
D1 To what degree is there a formal program for maintaining your lab equipment?	4.7	4.8	5.0
D2 To what degree are maintenance jobs (e.g. calibration programs) documented, and maintenance plans and checklists posted close to instruments?	4.5	4.9	4.6
D3 To what degree is potential bottleneck lab equipment identified and supplied with additional spare parts?	3.4	3.5	4.3
D4 To what degree is the maintenance program continuously optimized based on a dedicated failure analysis?	2.6	2.4	3.9
D5 To what degree does the maintenance department focus on assisting analysts perform their own preventive maintenance?	2.7	3.1	2.9
D6 To what degree are analysts actively involved in the decision making process when buying new equipment?	3.4	3.9	3.9
D7 To what degree is your equipment maintained internally vs. externally?	2.5	2.2	1.9
D8 To what degree is your preventive maintenance effort focused on proactive activities rather than reactive activities?	3.5	4.0	4.9
D9 To what degree is the lab situated at the leading edge of new technology?	2.7	3.5	3.6
D10 To what degree do you screen the market for new production technology and assess new technology concerning its technical and financial benefit?	2.6	3.1	3.7
D11 To what degree is the lab effectively using new technology?	2.7	3.3	3.8
D12 To what degree does the lab rely on vendors for its equipment?	4.4	4.0	3.9
D13 To what degree is proprietary process technology and equipment used to gain a competitive advantage?	1.7	2.1	1.7
D14 To what degree do you put emphasis on smart lab system implementation?	3.1	3.2	3.9
D15 To what degree do employees strive to keep the lab neat and clean?	4.0	4.3	4.8
D16 To what degree are tools and consumables put in their place (e.g. usage of a shadow board)?	3.7	4.1	4.6
D17 To what degree are housekeeping checklists used to continuously monitor the condition and cleanness of our equipment?	3.4	3.9	4.6
D18 To what degree do you do a regular review of the "As-Is" situation (e.g. by doing a walkthrough) in your lab to identify potential improvement areas (e.g. by doing a gap analysis)?	3.8	4.3	4.4
D19 To what degree are direct and indirect processes documented?	4.8	4.9	5.0
D20 To what degree is process quality continually measured using process metrics?	3.9	4.1	4.2

Individual Enabler ID and Question	Impl. Rate		
	C1	C2	C3
D21 To what degree are dedicated process owners defined and responsible for planning, managing, and improving their processes?	3.6	4.5	4.6
D22 What proportion of the equipment on the shop floor is currently under statistical process control?	1.4	1.6	2.1
D23 To what degree are standardized tools in place for root cause analysis, to get a deeper understanding of the influencing factors (e.g. DMAIC)?	3.3	3.9	4.7
D24 To what degree is standardization emphasized as a strategy for continuous improvement of lab processes and equipment?	3.7	4.2	4.4
D25 To what degree are documented operating procedures used to standardize processes (e.g. set-ups)?	4.3	4.5	5.0
D26 To what degree are optimized lab operating procedures (e.g. shortened set-ups) documented as best-practice processes and rolled-out throughout the whole quality organization?	2.9	3.9	4.3
D27 To what degree are standardized functional descriptions used to reduce the period of vocational training for new employees?	3.4	3.9	4.6
D28 To what degree is standardized lab equipment (e.g. standardized design, standardized spare parts) used to achieve a high up time of the equipment?	3.9	3.9	4.4
D29 To what degree do you pursue lowering material costs with the help of standardized equipment (e.g. for spare parts) and standardized consumables?	3.8	3.7	4.4
D30 To what degree do you continuously work to lower set-up and cleaning times in your lab?	2.5	3.5	3.4
D31 To what degree do analysts practice set-ups to reduce the time required?	2.8	2.9	3.3
D32 What proportion of equipment set-ups are scheduled so that the testing process is not affected (e.g. to shorten lead time)?	3.2	3.0	4.1
D33 To what degree are optimized set-up and cleaning procedures documented as best practices and rolled-out throughout the whole lab?	2.7	3.8	4.6
D34 Do you use a pull system (Kanban squares, containers, or signals) for your consumables?	2.8	3.5	3.8
D35 To what degree do you test according to forecast?	3.7	4.1	4.9
D36 To what degree do you have instruments installed for a regular demand and FTE capacity analysis?	2.7	3.2	3.9
D37 To what degree are your processes located closely together so that material handling and consumable storage are minimized?	3.8	3.8	4.6
D38 What proportion of testing substances/products are classified into groups with similar processing requirements to reduce set-up times?	4.0	3.9	4.9
D39 To what degree does the layout of the lab facilitate low inventories and fast throughput?	3.4	3.3	4.0
D40 To what degree can your lab layout be characterized as separated into "mini-labs", if testing substances/products have been classified based on their specific requirements?	3.7	3.5	4.2
D41 To what degree do your testing processes from incoming testing material to release involve almost no interruptions and can be described as a full continuous flow?	2.7	3.3	3.7
D42 To what degree do you use "Value Stream Mapping" as a methodology to visualize and optimize processes?	2.2	2.6	2.4
D43 To what degree do you meet your daily lab testing plans?	4.5	4.6	4.9
D44 To what degree do you know the root causes of variance in your lab working schedule and continuously try to eliminate them?	3.7	3.9	4.6
D45 To what degree does your lab have flexible working shift models to easily adjust labor capacity according to current demand changes?	2.6	2.9	3.8

Individual Enabler ID and Question	Impl. Rate		
	C1	C2	C3
D46 Beyond flexible working shifts, do you assign extra resources within the lab for testing during peak loads or do you outsource activities?	2.7	3.5	3.8
D47 To what degree do you prefer to increase productivity over short lead time or vice versa?	3.6	3.6	4.1
D48 To what degree do you utilize performance charts to show weekly/monthly/annual performance objectives?	3.2	4.0	3.9
D49 To what degree do you utilize charts showing the current performance status (e.g. current RFT rate) in your lab?	3.1	3.9	3.8
D50 To what degree does the head of quality and management empower employees to continuously improve processes and reduce failure?	3.7	4.4	4.7
D51 To what degree are the head of quality and management personally involved in improvement projects?	3.9	3.9	4.2
D52 To what degree does your site have an open communication culture, encourage the flow of information between the production and lab?	3.7	3.9	4.1
D53 To what degree are problems (e.g. complaints) traced back to their origin to identify root causes?	4.2	4.5	4.6
D54 To what degree do you align the achievement of quality standards between production and QC/QA (e.g. shared responsibility or primarily the task of QA/QC)?	3.8	4.1	4.2
D55 To what degree do your employees continuously strive to reduce waste in processes (e.g. waste of time, consumables)?	3.2	3.8	4.1
D56 To what degree do you prefer improvement programs initiated and promoted by the site lab and not the global organization and vice versa?	3.3	3.7	3.9
D57 To what degree have you implemented tools and methods to deploy a continuous improvement process in your lab?	3.2	4.1	4.0
D58 To what degree are your analysts involved in writing standard operating procedures?	3.8	4.1	4.6
D59 To what degree do lab employees actively drive suggestion programs ((not excl. linked to a suggestion system in place)?	3.4	4.1	4.1
D60 To what degree do your analysts have the authority to correct problems (e.g. with equipment, testing methods) when they occur without consulting a supervisor?	2.8	3.0	3.3
D61 To what degree do supervisors focus on assisting analysts to perform their own problem solving?	3.6	4.0	4.1
D62 To what degree does your site form cross-functional project teams to solve problems in your lab?	3.3	3.8	4.4
D63 To what degree does your lab follow a vision based approach to continuous improvement integrating constraints into the vision rather than an incremental approach?	2.7	3.8	3.8
D64 Does global quality organization have a lab certification program for best performing labs?	1.2	1.7	1.6
D65 To what degree do you put emphasis on employee cross-training to the required level so that they can fill in for others when necessary?	3.7	4.5	4.6
D66 To what degree are information and skills evaluation from official feedback meetings used in further training?	3.1	3.6	4.3
D67 To what degree does your site invest in the training and qualification of your lab employees?	3.7	4.1	4.8
D68 To what degree do your cross-trained analysts rotate on the job performing different tasks?	3.2	3.8	4.1

C1 (n=26): Low Enabler implementation, low QC Lab Effectiveness
C2 (n=15): High Enabler implementation, low QC Lab Effectiveness
C3 (n=9): High Enabler implementation, high QC Lab Effectiveness

Appendix 8: Quantitative comparison of clusters 1, 2, and 3 operating context

Category	Dimensions	Characteristic	Proportion within		
			C1 (n)	C2 (n)	C3 (n)
Geographical Location[1]	Regional Distribution	Europe	62 % (16)	87 % (13)	78 % (7)
		North America	19% (5)	7% (1)	11% (1)
		Middle & South America	12% (3)	0% (0)	11% (1)
		Asia	8% (2)	7% (1)	0% (0)
	Cost Location	High Cost	77% (20)	87% (13)	89% (8)
		Low Cost	23% (6)	13% (2)	11% (1)
Portfolio Complexity	Drug Substance (DS) Type	Chemicals	54% (14)	47% (7)	11% (1)
		Biologics	12% (3)	13% (2)	44% (4)
		Mixed	27% (7)	27% (4)	33% (3)
		No DS	8% (2)	13% (2)	11% (1)
	Drug Product (DP) Type	Solids	12% (3)	13% (2)	0% (0)
		Sterile Liquids	23% (6)	20% (3)	22% (2)
		Non-sterile Liquids	0% (0)	0% (0)	22% (2)
		Mixed	54% (14)	60% (9)	33% (3)
		No DP	12% (3)	7% (1)	22% (2)
	No. of final DP Types Tested	Up to 50	54% (14)	40% (6)	89% (8)
		51 to 100	12% (3)	7% (1)	11% (1)
		Above 100	35% (9)	53% (8)	0% (0)
Test Allocation Strategy	Centralization	Centralized	50% (13)	53% (8)	56% (5)
		Decentralized	50% (13)	47% (7)	44% (4)
	Degree of Centralization	Up to 50 %	92% (12)	88%	80% (4)
		Above 50 %	8% (1)	13%	20% (1)
Organizational Scale	QC FTEs	Up to 60	62% (16)	53% (8)	44% (4)
		Above 60	38% (10)	47% (7)	56% (5)
	Site FTEs	Up to 400	38% (9)	47% (7)	33% (3)
		Above 400	63% (15)	53% (8)	67% (6)
Economy of Scale	No. of Batches processed	Up to 8,000	54% (14)	60% (9)	78% (7)
		Above 8,000	46% (12)	40%(6)	22% (2)
	No. of Tests	Up to 200,000	69% (18)	73% (11)	89%(8)
		Above 200,000	31% (8)	27% (4)	11% (1)
Technology & Innovation	Age of Instruments	New[2]	15% (4)	27% (4)	13% (1)
		Old[3]	85% (22)	73% (11)	88% (7)
	Age of Methods	New[2]	4% (1)	20% (3)	11% (1)
		Old[3]	96% (25)	80% (12)	89% (8)
	Automation	High[4]	35% (9)	33% (5)	56% (5)
		Low[5]	65% (17)	67% (10)	44% (4)

Category	Dimensions	Characteristic	Proportion within		
			C1 (n)	C2 (n)	C3 (n)
Regulatory Approval	US Approval	Yes	69% (18)	73% (11)	78% (7)
		No	31% (8)	27% (4)	22% (2)
	EU Approval	Yes	85% (22)	80% (12)	89% (8)
		No	15% (4)	20% (3)	11% (1)
	China Approval	Yes	54% (14)	33% (5)	56% (5)
		No	46% (12)	67% (10)	44% (4)
	Japan Approval	Yes	58% (15)	47% (7)	78% (7)
		No	42% (11)	53% (8)	22% (2)

[1] Dimension country not illustrated due to the limited number of QC labs per cluster and country
[2] New is defined as more than 50 % of the instruments or methods less than five years old
[3] Old is defined as more than 50 % of the instruments or methods more than five years old
[4] High is defined as more than 50 % of instruments (partially or fully) automated
[5] Low is defined as more than 50 % of instruments manually operated
C1: Low enabler implementation, low QC lab effectiveness
C2: High enabler implementation, low QC lab effectiveness
C3: High enabler implementation, high QC lab effectiveness

Appendix 9: Case interview guideline

Institute of Technology Management
University of St.Gallen

1. Introduction

- Dissertation-Topic: QC Lab Operational Excellence Performance Measurement
- Interview-Objective: Understanding Enabler – Performance Relation (Three Clusters)

1. Corporate Approach to Operational Excellence in QC Labs

General Information

- When did your company start with OPEX/lean in QC labs? What was your first initiative and focus area? Did you start with measuring performance outcomes or building up capabilities?
- Today, do you measure performance & capabilities?
- Do you have competition or collaboration between the QC labs? (e.g. successful practices sharing across organization?)

Corporate Approach

- Do you have a central corporate approach/guidance that is applied to all labs or is it rather a decentralized approach?
- What were the major milestones since you started working on OPEX in QC labs?
- If corporate approach exists, how does your guidance look like? What flexibility do the QC labs have to build their own approach to work on Operational Excellence in QC labs?
- What are lessons learned that your company has made?
- Do you have a lean lab certification for your QC labs?
- How do you rate the current state of OPEX in QC labs across your organization? (scale from 1 to 10 with 1 = lowest maturity level and 10 = highest maturity level)

Future Activities

- What do you see as next steps on the journey to OPEX in QC labs? (e.g. performance improvements vs. capability improvements)

2. Strategy of Operational Excellence in QC Labs

- What is the purpose of your OPEX effort in the QC labs? (e.g. regulatory requirements, efficiency, effectiveness?)
- How is OPEX in QC labs anchored in the organization? (e.g. dedicated OPEX function for QC, part of a corporate OPEX team, part of the quality organization?)
- How do you judge the management importance for a successful implementation of OPEX in QC labs?
- Do you have lead OPEX QC labs within your organization in which you pilot improvement measures? Why?
- How to you ensure the rollout of OPEX across all QC labs? If not, why?
- Without taking into account actual data, do you expect difference on the current state of OPEX in QC labs across your network?
- Do you collaborate with external parties for your OPEX effort in QC labs?

3. Understanding the Enabler Implementation in Cluster 1

We found the following QC labs X, Y, Z in cluster 1: low QC effectiveness/low enabler implementation (show chart with relevant company QC labs in cluster 1 to interview partner.)

The following questions are related to labs of cluster 1 only.

- How do you assess the influence of the operating context on the allocation of the QC labs into this cluster? (e.g. geographical location, portfolio complexity, organizational scale, economy of scale, technology & innovation state)
- When did you start working on OPEX enablers/capabilities in these QC labs?
- How important is the OPEX capability building for these QC labs?
- What were the milestones since you started working on OPEX enablers?
- Did you set a focus on certain OPEX enabler dimensions (*show list of OPEX enabler dimensions.*)? If yes, why?
- How do you rate the current state of OPEX in these QC labs? (scale from 1 to 10 with 1 = lowest maturity level and 10 = highest maturity level)
- How does your roadmap for the future work regarding OPEX enablers in these QC labs? What areas of improvement regarding enablers have the greatest potential for these QC labs?

4. Understanding the Enabler Implementation in Cluster 2

We found the following QC labs X, Y, Z in cluster 2: low QC effectiveness/high enabler implementation (show chart with relevant company QC labs in cluster 2 to interview partner.)

The following questions are related to labs of cluster 2 only. (Same questions as in 3. Understanding…)

5. Understanding the Enabler Implementation in Cluster 3

We found the following QC labs X, Y, Z in cluster 3: high QC effectiveness/high enabler implementation (show chart with relevant company QC labs in cluster 3 to interview partner.)

The following questions are related to labs of cluster 3 only. (Same questions as in 3. and 4. Understanding…)

6. Miscellaneous

7. Interview Summary

Curriculum Vitae

Name	Stephan Alexander Köhler
Date & place of birth	March 11, 1990 in Iserlohn, Germany
Nationality	German

Work Experience

Since 02/2019	**University of St.Gallen – Institute of Technology Management**, *St. Gallen, Switzerland* Project Leader in the division of Production Management
Since 07/2017	**University of St.Gallen – Institute of Technology Management**, *St. Gallen, Switzerland* Head of Operational Excellence in the division of Production Management
09/2015 – 01/2019	**University of St.Gallen – Institute of Technology Management**, *St. Gallen, Switzerland* Research Associate in the division of Production Management
01/2015 – 06/2015	**Fraunhofer USA – Center for Manufacturing Innovation CMI**, *Boston, USA* Internship focusing on Project Management
07/2014 – 12/2014	**Fraunhofer Institute for Production Technology IPT**, *Aachen, Germany* Student Assistant in the field of Technology Management
10/2012 – 09/2013	**European Students of Industrial Engineering & Management ESTIEM**, *Aachen, Germany* Representative Local Group Aachen
10/2011 – 03/2012	**Daimler AG – Mercedes-Benz plant Untertürkheim**, *Stuttgart, Germany* Internship in the field of in-house Supply Chain Management

Education

09/2016 – 05/2019	**University of St.Gallen**, *St. Gallen, Switzerland* **Doctor of Philosophy in Management** focusing on Business Innovation
10/2012 – 12/2014	**RWTH Aachen University**, *Aachen, Germany* **Master of Science** in Industrial Engineering and Management Specialization: Mechanical Engineering, Production
07/2013 – 11/2013	**RMIT University**, *Melbourne, Australia* Studies abroad focusing on Business Administration
10/2008 – 09/2012	**RWTH Aachen University**, *Aachen, Germany* **Bachelor of Science** in Industrial Engineering and Management Specialization: Mechanical Engineering, Production
08/2000 – 06/2008	**Märkisches Gymnasium Iserlohn**, *Iserlohn, Germany* **Abitur** (German equivalent for A-level)