2021

Strategies Used by U.S. Biotechnology Companies to Attain FDA Quality Compliance

Peter M. Ovwiovwio
Walden University

Walden University

College of Management and Technology

This is to certify that the doctoral study by

Peter M. Ovwiovwio

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee
Dr. Irene Williams, Committee Chairperson, Doctor of Business Administration Faculty

Dr. Tim Truitt, Committee Member, Doctor of Business Administration Faculty

Dr. Brenda Jack, University Reviewer, Doctor of Business Administration Faculty

Chief Academic Officer and Provost
Sue Subocz, Ph.D.

Walden University
2021

Abstract

Strategies Used by U.S. Biotechnology Companies to Attain FDA Quality Compliance

by

Peter M. Ovwiovwio

MSc, University of San Diego, 2016

BS, Colorado Technical University, 2010

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

Walden University

December 2021

Abstract

Up to 70% of U.S. businesses in the biotech industry received Food and Drug Administration (FDA) noncompliance citations in 2015. The effective implementation of quality management strategies may lead to improved quality compliance. The purpose of this qualitative multiple case study was to explore the strategies that quality compliance managers in biotech companies use to integrate and apply FDA product quality compliance requirements into their products' quality compliance metrics. Deming's strategic models for developing and implementing quality provided the conceptual framework for the study. The study participants consisted of five biotech quality compliance managers in the West region of the United States who had successfully implemented strategies to integrate and apply FDA product quality compliance requirements into their quality compliance metrics. Data were collected from semistructured interviews and public documents. Data were analyzed according to Yin's 5-step process of compiling, disassembling, interpreting, and making conclusions. Three themes emerged from the data analysis: product quality outcomes, policies and procedures, and collaborative partnerships. A key recommendation includes compliance managers identifying collaborative quality compliance opportunities within and outside their organizations. The implications for positive social changes include the availability of needed drugs for society. Growth in the biotech industry may improve the overall health and living conditions of the public.

Strategies Used by U.S. Biotechnology Companies to Attain FDA Quality Compliance

by

Peter M. Ovwiovwio

MSc, University of San Diego, 2013

BS, Colorado Technical University, 2008

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

Walden University

August 2021

Dedication

I dedicate this study to my friends and family who stood by me throughout this process. A special thanks to my wife for her continuous support, love, and encouragement. To my mom for her prayers and my two little “rascos”, Bryan and Sharon Ovwiovwio. I hope that someday the two of you would earn a terminal degree, if not, it is just okay, you’re loved and I say thanks for being there always while I was busy trying to finish a paragraph.

Acknowledgments

I would like to acknowledge and thank my esteemed chair, Dr. Irene Williams for her patience and continued guidance. A special thanks to my SCM, Dr. Tim Truitt. Also, I would like to appreciate and thank Dr. Joe Gredler for his thorough and insightful reviews and feedback…you are all deeply appreciated.

Table of Contents

List of Tables v

Section 1: Foundation of the Study 1

Background of the Problem 1

Problem Statement 2

Purpose Statement 2

Nature of the Study 3

Research Question 5

Interview Questions 5

Conceptual Framework 6

Operational Definitions 8

Assumptions, Limitations, and Delimitations 9

Assumptions 9

Limitations 10

Delimitations 11

Significance of the Study 11

Contribution to Business Practice 11

Implications for Social Change 12

A Review of the Professional and Academic Literature 12

Application to the Applied Business Problem 12

Academic Source Utilized to Conduct the Review 13

Keywords, Phrases, and Terminologies 14

Diversity of Literature Sources 14
Conceptual Framework: Deming's Quality Management Theory 14
Create Consistency of Purpose for Improving Products and Services 15
Adopt the New Philosophy 16
Porter's Value Chain Model 22
Simons's Levers of Control Theory 24
Social Learning Theory 25
U.S. Regulatory and Public Health Policy 26
FDA's Quality Regulatory Policies 30
Quality Assurance Role in Product Quality Compliance in the Biotech Industry 36
Government Policies and the Complexity of the Biopharmaceutical Delivery Systems 38
Government Policies and the Adverse Effects on Biotech Product Quality Outcomes 41
Transition 44
Section 2: The Project 46
Purpose Statement 46
Role of the Researcher 46
Participants 48
Research Method and Design 49
Research Method 50

Research Design 50
Population and Sampling 51
Ethical Research 53
Data Collection Instruments 55
Data Collection Technique 56
Data Organization Technique 58
Data Analysis 59
Reliability and Validity 61
Reliability 61
Validity 63
Transition and Summary 65
Section 3: Application to Professional Practice and Implications for Change 66
Introduction 66
Presentation of the Findings 66
Emergent Theme 1: Product Quality Outcomes 67
Emergent Theme 2: Policies and Procedures 71
Emergent Theme 3: Collaborative Partnerships 73
Applications to Professional Practice 75
Implications for Social Change 76
Recommendations for Action 77
Recommendations for Further Research 78
Reflections 78

Conclusion 79

References 80

Appendix: Case Study Interview Protocol Checklist 98

List of Tables

Table 1. Cluster Related to the Three Emerging Themes 67

Table 2. Theme 1: Product Quality Outcomes 68

Table 3. Subthemes Related to Emerging Theme 1 of Product Quality Outcomes 69

Table 4. Theme 2: Policies and Procedures 72

Table 5. Subthemes Related to Emerging Theme 2 of Policies and Procedures 73

Table 6. Theme 3: Collaborative Partnerships 74

Table 7. Subthemes Related to Emerging Theme 3 of Collaborative Partnerships 75

Section 1: Foundation of the Study

As the biotech industry becomes increasingly larger and faster paced, the Food and Drug Administration's (FDA's) quality regulatory regime becomes even more stringent (Huang et al., 2020). Improved regulatory quality compliance strategies have become imperative for compliance managers in the biotech industry (Huang et al., 2020). As Chen et al. (2019) noted, manufacturers must think about quality compliance from the early product development phase and should also consider FDA quality compliance requirements. The lack of quality compliance accounts for failing profit in the biotech industry (Katamesh et al., 2019). Quality compliance managers should develop quality compliance strategies to attain full FDA product quality compliance requirements as best practices (Chen et al.,2019). My focus in this qualitative multiple case study was to explore the strategies used by quality compliance managers in the biotech industry to attain full FDA product quality compliance. Identifying the strategies used in the industry to attain FDA product quality compliance may result in improved compliance in the industry, may improve industry profitability, and may reduce the number of noncompliance citations received in the industry.

Background of the Problem

Biotech firms received quadrupled FDA noncompliance citations in 2015 (Katamesh et al., 2019). Katamesh et al. (2019) further noted that noncompliance with FDA product quality regulations had continued to negatively impact the industry's profitability. According to Wang et al. (2016), noncompliance with the FDA's product quality regulations in the biotechnology industry impacts the industry's profitability and

has a negative impact on future research outcomes. The FDA reported a 64% increase in the amount of current Good Manufacturing Practice (cGMP) noncompliance from 2007 to 2012 (Wang et al., 2016). Despite the development of new products in the biotech industry, financial growth rate was low due to an increase in associated product quality compliance fines and citation costs (Katamesh et al., 2019). My focus in this qualitative multiple case study was to explore the strategies used by biotech companies to integrate FDA product quality requirements into their product quality metrics.

Problem Statement

The slow growth rate and failing profit of U.S. biotechnology industry is tied to the FDA's product quality compliance and enforcement regulations (Fox et al., 2017). Noncompliance with the FDA's product quality regulation in the biotechnology industry impacts the industry's profitability and has a negative impact on future research outcomes (Katamesh et al., 2019). The FDA reported a 64% increase in the amount of current cGMP noncompliance from 2007 to 2012 (Wang et al., 2016). The general business problem was the biotech industry is unable to incorporate FDA quality compliance requirements into their operational business practices despite its impact on their profitability. The specific business problem was some quality compliance managers in the biotech industry do not have the strategies to integrate and apply FDA quality compliance requirements into their products' quality metrics.

Purpose Statement

The purpose of this qualitative multiple case study is to explore the strategies that quality compliance managers in biotech companies use to integrate and apply FDA

product quality compliance requirements into their products' quality compliance metrics. The target population consisted of five biotech quality compliance managers in the West region of the United States who had successfully implemented strategies to integrate and apply FDA product quality compliance requirements into their quality compliance metrics. The findings of this study may contribute to social change by providing the U.S. population with more rapid access to urgently needed drugs and treatment. The findings from this study may also help to mitigate FDA citation compliance violation cost incurred by the biopharmaceutical industry, which is typically passed down to the public in the form of higher drug costs.

Nature of the Study

For this study, I considered three research methods: (a) quantitative, (b) qualitative, and (c) mixed. After considering these research methods, I chose the qualitative method. Qualitative methodology is appropriate for creating a deeper understanding of a contemporary phenomenon within a real-world context (Bernard, 2013). According to Yin (2017), using the qualitative research method provides an opportunity for a better understanding of the subject of study. As Ritchie et al., (2016) opined, using the qualitative method provides the researcher with a naturalistic interpretive approach to understanding the meaning of events and phenomena. In contrast, the quantitative research method is used to test hypotheses about variables' relationships (Jacob et al., 2015). The quantitative research method was unsuitable for this study's focus on identifying and exploring the strategies used by quality compliance managers to integrate and apply FDA quality compliance requirements into their

companies' quality metrics. Quantitative methodology was rejected because I did not need to examine variables' relationships through testing a hypothesis to address my study's purpose. Researchers use mixed methods when combining qualitative and quantitative methods in one study. I rejected the mixed-methods approach because I did not need to combine quantitative and qualitative methods. I used a qualitative method because employing a qualitative method would enable a detailed analysis of the different strategies used by quality compliance managers in the biotech industry to integrate and apply FDA quality compliance requirements into their products' quality metrics.

I chose a multiple case study design for this study. A case study design was suitable for this study because using a case study design would enable me to ask *what*, *how*, and *why* questions. Researchers use multiple case study designs to understand the similarities and differences between cases (Yin,2017). Baškarada (2016) argued that researchers use the multiple case study design to generate evidence from multiple cases, which makes the study more reliable. I selected a multiple case study for this study to clarify findings and to ensure a wider discovery of evidence to answer the research question. Yin (2017) argued that using case study designs enables the researcher to answer *what*, *how*, and *why* questions more effectively than any other design. In the current study, I wanted to identify and explore the strategies used by compliance managers when formulating and integrating current FDA quality compliance requirements into their products' quality metrics. I considered other designs such as (a) narrative, (b) ethnography, and (c) phenomenology.

Researchers use the narrative design to explore research participants' personal stories. The current study focused on business strategies and not personal stories. Therefore, the narrative design was unsuitable. Researchers use the ethnographic design to study participants' daily lives, community processes, and activities in a defined study population (Small et al., 2014). Also, researchers use the ethnographic design to study social interaction and culture of a group of people (Hoeber & Shaw, 2017). I did not address any social interactions in this study; therefore, the ethnographic design was unsuitable. Phenomenology researchers seek to understand the meanings of participants' personal experiences with a phenomenon. I rejected the phenomenological design because I did not focus on identifying and exploring the personal meanings of participants' experience of a phenomenon. Rather, I focused on identifying and exploring business strategies. The multiple case study design was appropriate for this study because employing a case study design allowed me to effectively explore the strategies used by quality compliance managers to integrate and apply FDA quality compliance requirements into their products' quality compliance metrics.

Research Question

What are the strategies use by quality compliance managers in the biotech industry to integrate and apply FDA quality compliance requirements into their products' quality metrics?

Interview Questions

The following interview questions were used to answer the research question:

1. What leadership strategies do you use to embed a culture of quality and compliance within your company?
2. How does your management team formulate and adopt product quality compliance techniques?
3. How does your organization integrate quality compliance strategies into your internal and/or external quality compliance metric systems?
4. What total quality management processes and tool does your organization use to implement your quality management strategies?
5. How does your organization identify the key opportunities for quality improvement within your quality and compliance processes to ensure compliance with FDA quality requirements?
6. What, if any, supply chain management technologies do your organization use to address key barriers to integrating FDA product quality requirements into your product quality metrics?
7. What are the strategies used by your organization to monitor quality compliance throughout products' life cycles?
8. What other information can you provide about the strategies used by your organization to apply and integrate FDA's quality compliance requirements into your products' quality metrics?

Conceptual Framework

The conceptual framework governing this study is Deming's (1986) strategic models for developing and implementing quality. Although Deming's quality

management theories are based on prior research by Taylor and Stewart, Deming is the theorist responsible for four major quality implementation theories: (a) 14 points of top management; (b) seven deadly diseases that management must cure; (c) plan, do, study, act; and chain reaction quality implementation theories (Deming, 1986; Hackman & Wageman, 1995; Quality Council of Indiana, 2007). However, six of Deming's 14 points for quality implementation were expected to closely apply to this study:

1. create consistency of purpose for improving products and services;
2. adopt the new philosophy;
3. cease dependent inspection to achieve quality;
4. improve constantly every process for planning, production, and service;
5. adopt and institute leadership; and
6. remove barriers that rob people of pride of workmanship, and eliminate the annual rating and merit system.

Though other theorists such as Juran and Gryna (1988) favored a more structured approach to implementing quality control, Deming's 14-point quality implementation theory applied to this study. As Munechika et al. (2016) opined, Deming's 14-point quality implementation theory is appropriate for developing and implementing quality compliance strategies for use in mitigating costs that may arise from product quality failures. Deming's 14-point quality implementation theory provided a viable and robust study platform to explore the strategies used by quality compliance managers in the biotech industry to integrate and apply FDA quality compliance requirements into their products' quality metrics.

Operational Definitions

Biologics: These are sugars, protein, or nucleic acids or a combination of these substances or living entities such as cells and tissues that are produced by biotech methods and gene-based cutting-edge technologies (Strauss & Borenstein, 2015).

Feedback loop: Feedback loop is the transmission pathway of cause-and-effect information sequence (Strauss & Borenstein, 2015).

Good manufacturing practices: Good manufacturing practice (cGMP) refers to the regulated FDA rules that provide for systems that ensure proper design, monitoring, and quality of manufacturing processes and facilities (Hadjul & Kolinska, 2016).

Quality strategy implementation techniques: Quality strategy implementation techniques are the techniques for selecting a supply chain quality implementation strategy (Strauss & Borenstein, 2016).

Quality control samples: Quality control samples are the small product specifications used to assess the precision and accuracy of an assay and the stability of the samples (FDA, 2018).

Risk mitigation: Risk mitigation is the level of exposure to organizational uncertainties that a leader must understand and be able to efficiently manage to create values without undermining organizational values (Strauss & Borenstein, 2015).

Supplier risk metric: Supplier risk metric is a designated system of calculating inherent risks within a supplier that may create quality issues down the supply chain (Hadjul & Kolinska, 2016).

*Supply chain quality responsiv*eness: Supply chain quality responsiveness is the promptness to which supply chain quality managers address quality issues within the supply chain network (Sharma et al., 2018).

Supply chain quality risk management: Supply chain quality risk management is the simple but clear and concise process of creating and managing risks throughout the supply network (Hadjul & Kolinska, 2016).

Assumptions, Limitations, and Delimitations

Scholarly inquiries often address public views, perceptions, and realities through analysis, values, and assumptions (Denzin, 2012). Strauss and Borenstein (2015) noted that the procedures of qualitative studies may be imprecise in comparison to a quantitative study because qualitative research focuses on understanding the experiences and observations of the target population. Therefore, the targeted population behaviors and practices are drawn from assumptions.

Assumptions

In a research study, assumptions are statements the researcher believes to be true and valid though these statements may not have support (Yin, 2017). In a qualitative study, key assumptions may form the basis upon which the researcher begins the study (Yin, 2017). In the current qualitative study, I assumed that the participants would answer all interview questions honestly and truthfully and that the participants would honestly share their understanding and processes through which they form their quality compliance practices. I also assumed that the participants' experiences related to quality compliance strategies would adequately describe the phenomenon under exploration.

Further, I assumed participants had experience in FDA quality compliance processes and could articulate their experiences related to the research problem. I assumed the information given was bias free. Also, I assumed the participants would provide information that was true and represented their actual experiences rather than their guesses or expectations. A qualitative researcher should always identify emerging themes and patterns from the data received to avoid researcher biases (Lichtman, 2017). These assumptions lead to certain unavoidable research limitations.

Limitations

A limitation is a condition or restriction preventing the state of completeness (Kirkwood & Price, 2017). Limitations in a study may restrain the transferability of the findings. Also, a lack of peer-reviewed research material may limit the efficacy of a research finding. Yin (2017) noted participants' less than optimal responses and individual biases as a research limitation may influence the research reliability and validity. One limitation of the current study was the decision to use only two sites. This limitation could have negatively impacted the research reliability because it limited the number of participants who could have participated in the study. However, researchers introduce delimitations to effectively complete the study (Yin,2017). The researcher selects the research design that will accomplish the research goal and accepts limitations that are necessary to attain the research goal (Noble & Smith, 2015). In the current study, I selected a multiple case study design to mitigate possible research limitations.

Delimitations

Delimitations are the research boundaries reflecting the conscious omission and addition of elements during development of the research plan (Marshall & Rossman, 2016). Supply chain professionals, quality compliance managers, auditors, indirect suppliers, and technical leaders participated in the current study. I explored how organizations in the biotech industry develop and deploy their quality compliance strategies. The research participants had 10–20 years of experience in quality compliance management, corporate governance, and operations management in the West region of the United States.

Significance of the Study

The findings from the study may contribute to the current body of knowledge related to how biotech quality compliance managers develop and implement quality compliance strategies in response to FDA quality compliance requirements. Practitioners may use the findings in the study to fill gaps in their current quality compliance governance and strategies. The outcome of the study may serve as a reference guide for quality compliance managers in selecting a strategy for FDA quality compliance requirements. Quality compliance managers may use the recommendations in this study when responding to FDA quality compliance visitations and citations.

Contribution to Business Practice

An explorative analysis such as this study may provide a clear and succinct approach to business practice optimization such as earning quality compliance on the first FDA inspection visit. This study may provide practitioners with strategies for developing

and implementing quality compliance measures in response to FDA product quality requirements. Practitioners may use the outcome of this study to mitigate the cost of FDA product quality noncompliance enforcement.

Implications for Social Change

The implementation of the strategies discussed in the study may reduce drug shortage of urgently needed biopharmaceutical drugs. The results of the study may lead to growth in the U.S. economy by improving efficiencies in the biopharmaceutical industry. Growth in the biopharmaceutical industry may result in job creation and employment opportunities for Americans who work in biotech companies.

A Review of the Professional and Academic Literature

This literature review resulted from an exploration of peer-reviewed articles, government regulations, and business books that related to the research question addressing the strategies used by quality compliance managers in the biotech industry to apply FDA quality compliance requirements in their products' quality metrics. The conceptual framework for the examination of the research question consisted of Deming's (1986) strategic models for developing and implementing quality.

Application to the Applied Business Problem

There was a gap in the available literature for supply chain quality management strategies used by quality compliance managers in the biotech industry to attain FDA product quality compliance. I did not find any literature that directly addressed the research question. To conduct an effective review of the literature addressing the research topic, I extended the search to include all terms that described processes and practices

used by quality compliance managers in the biotech industry to formulate strategies to attain FDA quality compliance. Researchers used terms such as *compliance metrics*, *regulatory compliance*, *process improvements*, and *monitoring* to describe some organizational practices used by quality compliance managers in the biotech industry to formulate strategies in response to FDA product quality requirements (Giri & Sarker, 2017; Halldorsson et al., 2015; Kirovska et al., 2016). The literature review covers compliance metrics, process improvements, and monitoring related to practices that describe quality compliance managers' activities directed at FDA quality compliance requirements.

The literature review begins with an overview of Deming's (1986) strategic models for developing and implementing quality as the conceptual framework of the study, followed by a review of contrasting and supporting quality management theories. The literature review continues with an analysis of the U.S. regulatory and public health policies. Further, I explore the FDA's quality regulatory policy by examining the FDA's cGMP. Next, I address theories, concepts, and practices relevant to the study of FDA quality compliance requirements: (a) quality assurance role in the biotech industry, (b) government policies and the complexity of the biopharmaceutical delivery systems, and (c) government policies and the adverse effects on the biotech product quality outcomes.

Academic Source Utilized to Conduct the Review

In support of this study, I reviewed a collection of peer-reviewed articles, books, and government reports. I obtained peer-reviewed articles by searching academic databases available in the Walden University library using the following search terms:

Porter's *value chain*, Deming *management theory*, supply chain *quality management techniques*, *biologics* and quality compliance, quality *process improvements*, FDA quality compliance citations, and *supply and logistics integration.* The databases I used were Academic Search Complete, Business Source Complete, Science Direct, Life Sciences, Politics & Government, and Social Science Citation Index.

Keywords, Phrases, and Terminologies

I used the following keywords, terminologies, and phrases when searching reference databases for the literature review: *biotech* product *quality compliance* metrics, FDA product *certification metrics*, FDA quality compliance requirement for the biotech industry, supply chain management strategies in the *biotech industry*, FDA product recall requirements in the biotech industry, and quality management strategies in the biotech industry.

Diversity of Literature Sources

The research topic required the incorporation of numerous government agency publications, bylaws, congressional hearings, and federal legislation. There was a need to assess and compare government regulatory requirement documents with industry practices related to FDA product quality compliance requirements. Also, I reviewed academic and professional organizations' viewpoints and opinions.

Conceptual Framework: Deming's Quality Management Theory

In this study, I used Deming's (1986) management theory as the conceptual framework for exploring the strategies quality compliance managers in the biotech industry use to integrate FDA product quality compliance requirements into their

products' quality metrics. Deming's quality management theory has four major quality implementation theories: (a) 14 points of top management; (b) seven deadly diseases that management must cure; (c) plan, do, study, act; and (d) chain reaction quality implementation theories (Deming, 1986; Hackman & Wageman, 1995; Quality Council of Indiana, 2007;). Six of Deming's 14 points for quality implementation closely applied to this study:

1. create consistency of purpose for improving products and services;
2. adopt the new philosophy;
3. cease dependent inspection to achieve quality;
4. improve constantly every process for planning, production, and service;
5. adopt and institute leadership; and
6. remove barriers that rob people of pride of workmanship, and eliminate the annual rating and merit system.

Munechika et al. (2016) opined that Deming's 14-point quality implementation theory is appropriate for developing and implementing quality compliance strategies for use in mitigating costs that may arise from product quality failures. Deming's 14-point quality implementation theory was appropriate to explore the quality management strategies used by biotech quality compliance managers to integrate and apply FDA product quality compliance requirements into their products' quality metrics.

Create Consistency of Purpose for Improving Products and Services

Consistency of purpose as a quality improvement strategy is one of the most important aspects of quality improvement strategies. One of the core components of

Deming's (1986) 14-point quality implementation theory is create consistency of purpose for improving products and services. Other quality research and implementation experts agreed that consistency of purpose in quality implementation is at the core of any process, product, or service quality implementation (Smith & Rupp, 2016). Quality compliance managers should develop quality management strategies that are resilient to maintain consistency. According to Fawcett et al. (2016), consistency in product and service quality implementation guidelines and strategies improves stakeholder confidence in the quality implementation processes. Quality improvement strategies may take different forms, but consistency remains an important aspect in developing a sustainable product and service quality. Smith and Rupp argued that consistency in the quality implementation strategies within the organization continuously improves product quality outcomes. Deming's 14-point quality implementation theory and the core component of creating consistency of purpose for improving product and services quality could help quality compliance managers within the biotech industry create consistency in product and service quality implementation. Further, consistency of purpose should also form part of the organization's new product quality improvement philosophy. Smith and Rupp noted that consistency of purpose should be a core part of the organization's standard of operation and should form part of the organization's new philosophy.

Adopt the New Philosophy

Organizations create and adopt a new quality philosophy to attain sustainable quality implementation strategies. Deming (1986) noted that organizations must move past the notion of seeing quality improvement as a new periodic exercise but should

create and adopt the new quality implementation strategies within the organization as the new organization's philosophy. The adopted strategy becomes an integral part of the organization's overall quality mission. The adoption of quality implementation as a new organizational philosophy by everyone within the organization is key to quality improvement within the organization (Smith & Rupp, 2016). The inability to adopt quality implementation as the organization's new philosophy may impede quality improvement strategies. Quality improvement as a onetime effort is not sustainable and may be more costly in the long run (Deming, 1986). In the 14-point quality implementation management theory, Deming argued that failure to adopt quality implementation as an organizational theory creates management chaos and defects within the management, planning, and production processes. To avoid such failures, managers within the biotech industry may adopt a new philosophy of quality implementation in integrating FDA quality product quality compliance requirements into their products' quality metrics.

Improve Constantly Every Process for Planning, Production, and Service

The constant improvement of processes for planning, production, and service aspects of Deming's (1986) quality improvement strategies is relevant to product quality improvement requirements in the biotech industry. Challener (2020) stated that process improvement is a fundamental component of quality improvement in product manufacturing. Dittes et al. (2016) agreed but noted that in instances when changes would delay quality implementation, consistency is required, and process may not be improved. However, other quality implementation practitioners agreed that continuous

quality process improvement planning creates a quality metric that manufacturers in any industry can use to improve product quality requirements (Dittes et al., 2016; Vellema et al., 2016). The biotech industry as a manufacturing industry could use constant process improvements to integrate and apply full FDA product quality requirements into their products' quality metrics. Standing et al. (2016) opined that continuous process improvement is directly connected to process and planning improvement implementation. The requirement for constant process and production planning may help eliminate manufacturing quality errors that are costly (Stoica & Brouse, 2017).

By adopting Deming's (1986) recommendation to improve constantly every process for planning, production, and services, quality compliance managers in the biotech industry may develop an effective quality management strategy to integrate and apply full FDA product quality compliance requirements into their products' quality metrics. Vellema et al. (2016) argued that this aspect of Deming's quality management strategy is applicable in any manufacturing or service setting. The biotech industry as a manufacturing industry could adopt and implement Deming's quality implementation theory without dependence on inspection and certification, which is a common practice in the industry.

Cease Dependent Inspection to Achieve Quality

Though inspection is an integral part of the FDA regulatory regime, Deming's (1986) 14-point quality management theory requires little or no reliance on inspection to achieve product or process quality. The quality implementation process is the engagement of an active culture of quality and process improvement without the reliance

on inspections (Deming, 1986). Reliance on inspection as a quality process improvement strategy may impede innovation and continuous improvement (Pinto & Winch, 2016). Reliance on inspection is discouraged to avoid creating a culture of reliance on inspection, which upends a philosophy and culture of quality adherence (Ferreira, 2017). Ferreira argued that learned organizational cultures are more effective in implementing practices such as quality implementation compared to practices that are dependent on other activities such as inspections. Further, other researchers have opined that reliance on inspection to achieve quality requirement may create an environment of delay, chaos, and lack of management response to change and process improvement requirements (Belschak et al., 2016; Gunia & Kim, 2016).

Ferreira (2017) noted that dependence on inspection creates a work environment that hinders employee motivation. Dependence on inspection creates delay in process (Gunia & Kim, 2016). Ferreira further stated that quality requirement should form the operational structure upon which the organization's quality philosophy is based. Also, Wu (2017) opined that developing a quality philosophy improves quality compliance within the organization. Dependence on inspection is not enough. Organizations should develop a philosophy of quality compliance and adopt quality leadership that ensures the creation of a culture of quality compliance, not reliance on inspection (Gunia & Kim, 2016). By adopting this philosophy of compliance, the biotech industry may be able to adopt and institute quality compliant leadership within the industry that may help develop strategies to integrate and apply FDA quality compliance requirements into their products' quality metrics.

Adopt and Institute Leadership

To integrate and apply FDA product quality requirements into their products' quality metrics, organizations in the biotech industry must set an organizational tone of quality that runs through the entire management structures (Wu, 2017). By adopting organizational leadership that is quality oriented, an organization sets a tone of quality implementation and improvement (Belschak et al., 2016). Further, an organization can implement quality changes that improve overall quality performance within the organization (Belschak et.al., 2016). Escoffery et al. (2018) argued that quality implementation starts with the organization's leadership capability as leadership defines the quality metric of the organization. Whereas leadership sets the quality implementation mandate, Wu (2017) opined that leadership must do more than lay down the rules; they also must lead by example. That is one reason why Deming (1986) opined that quality improvement within the organization requires leadership with a quality improvement mindset. Quality leadership provides a roadmap for continuous quality improvement (Wu, 2017). Wu further noted that, organizations through adopted leadership must incorporate a philosophy of total quality management.

Organizations with quality conscious leadership creates an organizational culture of total quality adherents (Green et al., 2012). Smith and Rupp (2016) noted that management commitment is required to implement total quality goals. Smith and Rupp argued that organizations must select quality leadership champions within the organization to set the pace for a culture of quality within the organization. Escofferry et al. (2016) argued that, to create a culture of quality, the organizations must select quality

champions as leaders who would set the pace for the entire organization. Goedhuys and Sleuwaegen (2016) agreed. Goedhuys and Sleuwaegen noted that when leadership sets the pace, the entire workforce gets involved and pursues quality implementation as part of their work commitments. Organizations within the biotech industry may integrate and apply full FDA product quality compliance requirements into their products' quality metrics by adopting Deming's *adopt and institute leadership* quality management strategy. Companies in the biotech industry may use this theory to set up leadership responsibilities to remove all instituted forms of barriers to quality implementation within their organizations.

Remove Barriers That Rob People of Pride of Workmanship and Eliminate the Annual Rating and Merit System

Workmanship pride is a core factor in instituting total quality management within an organization. Feelings of humiliation and other morale issues such as lack of information, work-life balance and lack of incentives create barriers to quality improvement within the organization (Deming, 1987). Whereas employee recognition is encouraged as a form of employee motivation, improperly managed employee motivation may create a barrier to quality improvement strategies within an organization (Fida et al., 2016; Golparvar, 2016). Accordingly, Wu (2017) argued that quality implementation is a shared responsibility between management and employees. Also, Wu noted that quality implementation is a shared responsibility between management and employees. Other researchers agreed and opined that merit and recognition should be collectively shared as quality management is a collective responsibility. (Fida et al., 2016; Golparvar, 2016).

However, Harold et al., (2016) argued that individual recognition should be given when an employee excels in quality management commitment. Wu (2017) agreed but noted that recognition should not discourage but motivate the workforce. Deming's 14-point for quality implementation theory is supported by recent research as Deming noted that, for any organizational quality requirement strategy to be successful, management must motivate by removing barriers that robs employees of the workmanship and effort needed to maintain set quality standards. Management should emphasize workmanship pride as a core factor in instituting quality management strategies within the organization (Deming, 1987). Porter's value chain theory supports this view.

Porter's Value Chain Model

Deming's quality management theory forms the conceptual framework of this study. However, Porter's value chain theory aligns with Deming's quality management theory. Quality compliance managers, in the biotech industry, may integrate and apply FDA product quality compliance requirements into their products' quality metrics by adopting Porter's value chain model. Koc and Bozdag (2017) described the identification of processes and activities for the purpose of improving quality as a core component of Porter's value theory. Further, Porter (1985) noted that processes are all activities such as may include communication and customer engagement. Quality compliance managers, within the biotech industry, may integrate and apply FDA quality compliance requirements into their products' quality compliance metrics by identifying activities and processes that creates product quality compliance issues within their organizations. Porter noted that business leaders may use his generic value model to develop strategies within

their own industry to gain competitive advantages by identifying activities that impede value creation. This means that business leaders in the biotech industry could adopt Porter's value chain model to improve product quality compliance and avoid FDA quality noncompliance citations. Like Deming's management theory, Porter's value chain model could form the theoretical foundation for exploring the strategies used by quality compliance managers, in the biotech industry, to integrate and apply FDA product quality requirements into their products' quality metrics.

Porter's value chain model may form the basis for quality improvement within the biotech industry. McPhee (2015) noted that Porter's value model is used by organizations to create value by improving every process within the value chain. Porter's value chain model has been used as the foundation for a variety of qualitative and quantitative studies (Cygler & Debkowska, 2015; Koc & Bozdag, 2017; McPhee, 2015). McPhee argued that manufacturers could use Porter's value chain model to improve product quality by identifying the areas where defect exist within the myriad of manufacturing activities. By contrast, Cygler and Debkowska noted that, Porter's value chain model is applicable and useful in the service industry. However, Koc and Bozdag deferred and argued that Porter's value chain is applicable in a manufacturing business setting. Similarly, Prajogo et al., (2016) argued that quality practitioners could use Porter's value model to improve logistical processes and create a competitive advantage. Though the conceptual framework of this study is based on Deming's management theory, Porter's value chain theory, like Simons's Levers of Control theory could form the conceptual framework of this study.

Simons's Levers of Control Theory

Simons's lever of control (LOC) theory of strategic management is a supportable theoretical foundation for this study. Like Deming's strategic management theory, other researchers identified LOC as a strategic management tool (Martyn et al., 2016). According to Simons (1995), LOC theory consists of four major structures: (a) belief systems and core value, (b) boundary systems and risk to avoid, (c) interactive control systems and strategic uncertainty, and (d) diagnostic control systems and critical performance variables. Peters (2019) noted that, the biotech industry need to mitigate the crisis of noncompliance with a culture of compliance. Also, in support of these LOC strategic variables, Peter noted that compliance managers in the biotech industry will attain FDA compliance by effectively managing critical quality performance measures within the manufacturing process. Risk avoidance is a core part of LOC's theory of strategic management and could form the basis for exploring the strategies used by quality compliance managers, in the biotech industry, to integrate and apply FDA quality compliance requirements into their products' quality metrics. Also, Simons highlighted the examination of control systems and critical performance variables are a core tenet of Simmons's LOC strategic management theory. Peters argued that leaders in the biotech industry should develop FDA quality compliance strategies to manage activities that may create risk.

Deming's strategic management theory and Simons's LOC theory could be used as the conceptual frameworks for this study. This is the case because, quality improvement forms the basis of both theories. These theories may provide insight into

how compliance managers, in the biotech industry, integrate and apply FDA product quality requirements into their products' quality metrics. In contrast, Social Learning Theory may not provide an effective theoretical foundation for exploring the strategies used by quality compliance managers, in the biotech industry, to integrate FDA quality compliance requirements into their products' quality metrics.

Social Learning Theory

Social learning theory (SLT) is not an appropriate conceptual framework to explore the strategies used by quality compliance managers in the biotech industry to integrate FDA quality compliance requirement into their product quality metrics. Under the SLT theory, human behavior is a continuous interaction between cognitive, behaviors, and the human environmental elements (Bandura, 1978). Accordingly, Hartmann and Doree (2015) argued that SLT theory means humans learn by observing others and by obeying environmental factors and not rules. Bandura developed the SLT theory in a study while researching how to cure phobias. The focus of this study is to explore strategies and not behaviors. The SLT theory focuses on behaviors and how humans learn (Horsburgh & Ippolito, 2018).

Therefore, SLT theory is not an appropriate conceptual framework for the exploration of strategies used by compliance managers, in the biotech industry, to integrate and apply FDA quality compliance requirements into their products' quality metrics. However, several researchers have applied SLT in closely related studies. Brown et al., (2005) used SLT theory as the conceptual framework for studying leaderships and leader's ethical behavior in a manufacturing setting. The SLT concept of modeling

requires that people learn behavior through observation, imitation, and identification (Bandura, 1978). The SLT theory would be appropriate in exploring why employees look to managers for motivation in work-related matters (Kalshoven, van Dijk, & Boon, 2016). Reinforcement of ethical standards and ethical decision-making are two means via which leaders can make an impact on employees' moral principles (Kalshoven et al., 2016).

In contrast, Deming's quality management theory provides a robust platform for exploring strategies used by quality compliance managers, in the biotech industry, to integrate and apply FDA quality compliance requirements, into their products' quality metrics. One core component of Deming's management theory is that management should remove barriers such as lack of information needed to formulate quality requirement strategies. Managers in the biotech industry may remove such barriers by providing employees with current and relevant regulatory information needed to effectively incorporate government quality requirements (Peters, 2019).

U.S. Regulatory and Public Health Policy

The United States' Food and Drug Administration (FDA) is responsible for a large portion of the regulatory regimes that governs the US biopharmaceutical industry (Chabner, 2011). Biopharmaceutical policy is a sub-category of the pharmaceutical health policy with the responsibility of developing drug development process (Woodcock & Wosinka, 2013). According to Chabner, pharmaceutical policy manages the factors of use and delivery and qualifies the components of drug formularies which shapes the

biopharmaceutical industry landscape mostly through regulatory policies by the Food and Drug Administration (FDA).

U.S. Food and Drug Administration

Before 1980 the FDA acted mostly as a protectionist regulatory entity in its approach to drug approvals and manufacturing inspections (Pazhayattil et al., 2019). Before 1980 the widespread AID pandemic made the FDA aggressive in response to public outcry for protection from the use of unsafe and contaminated clinical products by drug manufacturers (Chabner, 2011). Pazhayattil et al., noted that the U.S government through administrative orders and other legislations supported the FDA's protectionist approach however, after 1980 the FDA's senior leadership changed its position from protectionism to process quality regulation. The FDA through The Center for Biologics Evaluation and Research (CBER) began to protect the public through responsible safety, purity and potency regulations of biologics and other biopharmaceutical products (McLaughlin & Skoglund, 2015).

Center for Biologics Evaluation and Research

The FDA's Center for Biologics Evaluation and Research (CBER) is tasked with the responsibility of providing the US biopharmaceutical industry and the public with regulatory guidance to ensure the safety, purity, potency, and effectiveness of biological products such as blood and blood products, tissues, gene therapies, diagnosis, and the treatment of human diseases (FDA, 2018). Dorsey et al., (2009) noted that CBER research activities creates the FDA's regulatory requirements. For instance, through CBER annual guidance documents, the center provides guidance to biopharmaceutical

manufacturers on issues that relates to product quality design, production and manufacturing and testing of regulated products (FDA, 2018). In July 2020 the FDA through CBER issues guidance on *The Safe Importation Action Plan* which provides industry practitioners with the FDA's Food, Drug, and Cosmetic Act ("FD&C Act") section 804 to authorize demonstration projects to allow importation of drugs from Canada. Also, in January 2020, CBER issued *Human Gene Therapy for Hemophilia: Guide for Industry*. This document provides biopharmaceutical quality practitioners with specific guidance on how to attain FDA quality compliance requirements for the manufacture of Gene Therapy products used for the treatment of any bleeding disorders other than hemophilia A and B, because of the unique nature of those bleeding disorders (Peters, 2019). The FDA regulatory compliance regime also includes guidance from the Center for Drug Evaluation and Research (CDER). Drugs that are not biologics are under the administration of CDER.

Center for Drug Evaluation Research

The FDA's Center for Drug Evaluation Research (CDER) provides regulatory compliance requirement for the manufacture of most drugs as defined in the Food, Drug, and Cosmetic Act. Although, there are some biological products that are also legally considered drugs, these categories are covered by the Center for Biologics Evaluation and Research (FDA, 2018). The CDER, through the Office of Drug Security, Integrity, and Response (ODSIR) provides the biopharmaceutical industry with guidance on the global supply chain security and the minimization of consumer exposure to unsafe, ineffective and poor-quality drugs (FDA, 2018). Guidance from the CDER provides experts in the

field of drug manufacturing with clear approach to maintaining FDA quality requirements (Arab et al., 2017). Similarly, while discussing the role of the CDER in providing regulatory compliance guidance to industry, Conrad et al., (2017) noted that the CDER helped in providing industry with research breakthrough for therapy designation. Conrad et al., noted that the CDER provides quality compliance officers with drug certification process guidance and compliance strategies in the biopharmaceutical industry in conjunction with the FDA as well as leads the FDA's implementation of the Drug Supply Chain Security Act and its policies which ensures drug quality and risk information regarding product recalls.

Drug Quality and Security Act

The U.S Congress enacted the Drug Quality and Security Act of 2013 on November 27, 2013 with Title II of DQSA, the Drug Supply Chain Security Act (DSCSA) (Elliasen, 2020). Elliason pointed out that the FDA uses this Act to provide quality compliance managers with steps to build an electronic, interoperable systems to identify and trace quality component of prescription drugs in the United States. Manufacturers also use the Act to control quality because the Act highlights ways to remove counterfeit, stolen, contaminated, or otherwise harmful drugs from the manufacturer's supply chain. This is a regulatory framework to help manufacturers meet FDA's quality compliance requirement. According to Elona and Albert (2016), the Drug Supply Chain Act of 2013 will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

However, Haeyoung (2017) argued that the DSCSA had not been successful in providing compliance managers in solving product quality compliance issues as it compounds some compliance issues such as documentation processes. Likewise, Dinkelaker (2016) agreed and opined that the Act provides a false sense of safety to consumers but does very little to help quality compliance managers meet FDA quality requirements. Although the DSCSA may not answer all the compliance questions for quality compliance managers within the biotech industry, the Act provides a useful guidance. As Eliasen (2020) noted, the Act provides compliance managers with a useful start towards FDA regulatory compliance efforts. Under the DSCSA the FDA established a national licensure standard for wholesale distributors and third-party logistics providers, and requires these entities report licensure annually to the FDA. The FDA's quality regulatory regime remains a starting point for any quality compliance effort in the biotech industry (Eliasen, 2020). The FDA's quality regulatory regime forms the backbone of the biopharmaceutical quality compliance framework.

FDA's Quality Regulatory Policies

The FDA's drug regulatory policy provides guidance, structure, and regulates the pharmaceutical industry (Peters, 2019). However, some researchers opined that the FDA is still behind in developing a proper cadence of communication (Dorsey et al., 2009; Kweder & Dill, 2012; Ventola, 2015). This may be the case, but not always. As Elona and Albert (2016) opined that the FDA positively influenced healthcare policies in the United States and many other countries around the world. Further, Eliasen (2020) advised that drug manufacturers should seek more FDA intervention than less because the FDA

protect lives, improve drug quality, and prevent drug shortages in the United States. Eliasen further argued that the FDA protects the U.S healthcare system from nations with little or no quality regulations such as China and India. Kweder and Dill agreed and noted that the FDA has come a long way, and in the process developed more regulatory practices that has helped to strengthen the US biopharmaceutical quality compliance effort.

FDA's Current Good Manufacturing Practices Requirements

Product quality standards, in the biopharmaceutical industry, are set by the FDA using the guidelines as stipulated in the agency's cGMPs quality guidelines. The FDA using the cGMPs guidelines provides manufacturers with quality standards to meet product quality standards in the United States (Peters, 2019). Lincoln (2012) identifies the need for a quality management system as set forth by the Food and Drug Administration (FDA) within the Code of Federal Regulations. The current Good Manufacturing Practices (cGMP) is set forth in the Quality Systems (QS) regulation under sections 520 of the Food, Drug and Cosmetics (FD&C) Act of 1938. The FD&C Act of 1938 gave the FDA power to administer quality requirements for food, drugs and devices in the United States (FDA, 2018). The cGMPs are loosely written quality standards that allows each organization to set, develop and implement quality systems, write standard operating systems, and develop organizational forms for documenting compliance in accordance with the cGMPs guidelines (Peters, 2019). Wiggins et al. (2019) noted that, the cGMPs are meant to be easy to follow common sense guidelines that ensures safety and effectiveness of products delivered to members of the public as

product end users. Other researchers agreed the cGMPs standards are easy to follow, but noted that, it is the product manufacturer's responsibility to adopt the recommendations even when they appear to be cumbersome (Chabner, 2011; Schneppe, 2019). However, Pazhayattil et al. (2019) opined that some parts of the cGMPs are too rigid to adopt in certain manufacturing scenario.

Although many manufacturers consider the requirements of the FDA's cGMPs standards rigorous, Peters (2019) noted that other countries worldwide are beginning to emulate the quality management standards set forth by the FDA in the cGMP. The United States quality management requirements is a pace setter worldwide (Lincoln, 2012). The FDA's cGMPs provides biologics product manufacturers within the biotech industry with details of what a qualified quality management system should comprise (Wiggins et al., 2019). The cGMPs quality management guidelines provide manufacturers with a reference when designing their quality metrics, such as the proper documentation of processes associated with the product manufacturing procedure (Schnieppe, 2019). For example, if an organization fails to document a quality procedure in the manufacturing process, the FDA will conclude that the manufactured product is defective, adulterated and does not meet the FDA's quality requirement and thereby subject to product recall, and in some cases, closure of the manufacturing facility (Wiggins et al.,2019). In a less severe instance of cGMPs quality standard non-compliance, the FDA may issue an FDA Form 483 listing all observations, or may issue a warning letter (Peters, 2019).

An FDA form 483 is a report issued by the FDA to organizations in which the FDA documents concerns and observations for one of three reasons: (a) the organization

lacks proper procedures for regulated areas within the manufacturing facility, (b) organization has FDA approved procedures but fails to follow the procedures, or (c) organization lacks sufficient documentation evidencing proper implementation of procedure (Mirasol, 2020). Mirasol noted that he most common reason for FDA form 483 Observations and Warning Letters in the biotech industry is the lack of quality compliance procedure documentation. The lack of a culture of compliance accounts for other FDA form 483 Observation and Warning Letter issuance in the biopharmaceutical industry (Mirasol, 2020). The inability, by the quality compliance department to develop clear and concise written procedures in conjunction with other departments such as collaborations with quality assurance department, production department and information technology department also accounts for a reasonable number of FDA citations (Peters, 2020).

Poor laboratory procedure is the most common recurring theme in FDA warning letters (Wiggins & Albanese, 2019). Wiggins and Albanese further stated that, in many cases, either procedure is nonexistent, or the procedures are not properly documented. Other reasons for FDA 483 observation and warning letters includes equipment mismanagement issues such as lack of inspection and cleaning records, lack of maintenance documentation and improper handling of final products (FDA, 2018; Peters, 2020; Wiggins & Albanese, 2019). These research findings are relevant to this study because the current findings highlight the key issues faced by quality compliance managers in developing a strategy to attain FDA quality compliance regulatory

requirement within the U.S biotech industry. As noted by Wiggins et al. (2019) Quality assurance gives rise to a successful quality compliance in an organization.

FDA's Response to Biopharmaceutical Quality Compliance Failures

The FDA has developed detailed recommendation for product quality compliance for the U.S biopharmaceutical industry. Kweder and Dill (2012) discussed in their empirical study the FDA's response to biopharmaceutical quality issues and provides an analysis of the strategies adopted by the agency in developing and coordinating quality metrics as outlined in the revised cGMPs recommendations. The authors noted that, whereas the FDA has created rules developed and administered by CBER, the biotech industry is yet to gain all the benefits promised by the FDA. Quality failures in the biotech industry is cause by internal failures, not the FDA's inability to regulate the industry. Peters (2019) opined that FDA guidelines are to help the biopharmaceutical industry and not to hinder the industry. Accordingly, Kweder and Dill noted that since the agency's inception, it continued to work with drug manufacturers to avoid drug shortages that may result from quality failures by providing annual guidelines.

However, Wiggins et al. (2019) concluded the FDA's quality regulatory regime is beginning to look like the agency's pre-1980 approach as manufacturers within the biopharmaceutical industry are unable to meet the quality compliance standards set by the FDA through the applications of the cGMPs guidelines. In contrast, Peters (2019) noted that the FDA's cGMPs standards and recommendations are easy to follow whenever industry practitioners develop a metric for administering the requirements of the cGMPs. Quality compliance managers may efficiently adopt the cGMPs quality regulatory

guidelines when designing a working quality compliance metric that follows the FDA's annual cGMPs guidelines. As Peters pointed out, the FDA annually improves the quality compliance metrics for industry practitioners.

FDA's Quality Improvement Process Recommendations

The FDA quality improvement recommendations provides the biopharmaceutical industry with useful tools for addressing quality compliance issues such as quality compliance documentation processes. Quality compliance recommendation enunciated in the new FDA's cGMPs standards affords quality compliance officers across the industry with helpful tips and recommends that quality compliance officers in the biopharmaceutical industry can rely on to meet regulatory product quality requirements by the FDA (Peters, 2019). This is one way by which quality compliance officers may take a more vigilant and responsive role in responding to quality issues within the biopharmaceutical industry. Accordingly, Chabner (2011) discussed new efforts by the FDA to renew and improve response to the call for inspection of new manufacturing facilities. However, some researchers are of the view that the FDA's compliance requirement through the instrument of the cGMPs is not helpful. That is why Pazhayattil et al. (2019) argued that the FDA's current practices does very little to help in providing industry practitioners with helpful quality compliance guidelines that practitioners could consider as manufacturer friendly. It is important to note that, while Pazhayattil et al is not alone, authors who held this view were in the minority. The view that, the FDA's effort in providing regulatory guidelines that are design to help the biopharmaceutical industry with quality compliance requirements is in the majority. Hence Peters noted that

the FDA's effort is in the right direction as the agency's cGMPs are easy to follow and product manufacturers that are committed to quality compliance can effectively comply with the FDA's requirement for quality in the biopharmaceutical industry. For instance, the FDA continue to improve quality compliance requirements by providing updated cGMPs guidelines for practitioners to refer to and offer monthly and weekly updates for steps, processes, and strategies for compliance (FDA, 2018). Also, many researchers are of the view that the FDA's regulatory guidelines help manufacturers comply with quality standards and not to hinder manufacturing progress (Chabner, 2011; Kweder & Dill, 2012; Peters, 2019).

Quality Assurance Role in Product Quality Compliance in the Biotech Industry

Quality assurance when shared across departments creates a culture of compliance. Joghee (2019) explains the importance of Quality Assurance in the development and implementation of regulatory compliance strategies by discussing the methods for engaging quality engineering systems to leverage and optimize product quality assurance within the manufacturing process. Also, recent studies showed that, quality assurance role in the organization, when incorporated across all departments, and not left only with the quality assurance department, creates a significant improvement in product quality outcomes (Anwar et al., 2016; Kharub, 2019). For instance, Joghee opined that, to create a sustainable culture of quality, organizations must develop quality interactions that span all areas of the organization. In the same vein, another scholar noted that, management must foster an engaging relationship, centered around product

quality compliance, with all employees and departments and not left only in the hands of those who implement the quality requirements (Kharub, 2019).

To foster the inclusion of quality assurance into the quality compliance commitment, researchers argued that organizations who use technologies to integrate quality compliance requirements across departments improve product quality outcomes better than those who did not (Reid, Hultink, Marion, & Barczack, 2016). Organizations need technologies to implement data integration. Hence, Bajaj, Garg, Sethi, and Dey (2019) noted that, technology enhanced collaboration between quality assurance and quality compliance departments is inevitable to reduce quality failures. The efficient collaboration between departments reduce cost by avoiding duplication of quality compliance efforts within the organization (Baja et al., 2019). The use of technology to enhance collaboration between departments such as quality assurance department and quality compliance department is important in developing sustainable quality compliance strategies within the biotech industry (Vaidya, Ganapathy, & Kumar, 2019).

The degree to which quality assurance plays an important role in ensuring organizational quality compliance is determined by the tone set by upper management within the organization (Harold, Oh, Holtz, Han, & Giacalone, 2016; Vadaya et al., 2019). Harold et al. described environmental factors such as work cultures, work-life balance and the work team structures, and overall management commitment as some of the techniques used by management to instill a culture of quality assurance across all departments within an organization. Organizations create a culture of personnel motivation as a technique for encouraging employees to adopt a culture of quality

commitment within the organization. Rubin (2012) opined that, encouraging and motivating employees to incorporating product and process quality assurance requirement across the organization gives employees significant insight into the product being produced and the strategies employed. Motivating employees to embrace shared quality assurance strategies across organization improves overall quality compliance culture (Fida et al., 2015). In support of this view, Page et al., (2015) argued that organizations need employee commitment across departments to make quality compliance a shared responsibility across the organization. Further, when Quality Assurance operates without interrelations with other departments such as operations, production and quality compliance departments, product quality compliance risk increases (Fida et al., 2015). However, Rubin noted that, in some instances, Quality Assurance is sometimes viewed as an obstruction to production goal. Nevertheless, Page et al., (2015) noted that the requirement to make quality compliance a shared commitment within the organization is inevitable. Hence, according to Fida et al., (2015), management must set the organization commitment tone for quality compliance within the organization.

Government Policies and the Complexity of the Biopharmaceutical Delivery Systems

The complexity of the U.S biopharmaceutical delivery system impacts product quality compliance. McLaughlin and Skoglung (2015) noted that due to the delivery complexity of the U.S biopharmaceutical system, there is a lack of academic research and reservations within the product quality management systems as it relates to the

biopharmaceutical delivery systems. The limit in academic research in the biopharmaceutical quality management regime creates quality compliance issues which contributes to the delay in product development (McPhee, 2015). Munechika et al., (2016) argued that globalization and the popularity of biopharmaceuticals contributed to the complexity of the product manufacture and delivery systems. However, the FDA provides new guidelines with more research and to mitigate the complex product delivery system (FDA, 2018). However, management would develop individual practices to mitigate the complex delivery systems and attain full FDA product compliance requirements (Wang et al., 2016). The biopharmaceutical product delivery complexity accounts for many quality compliance failures within the industry (McPhee, 2015).

Accordingly, Marisol (2020) discussed how the globalization and popularity of biopharmaceuticals creates a degree of complexity for the FDA when designing compliance requirements. The authors observed the inherent complexities in the compliance requirement systems as it relates to communication between the FDA and industry practitioners when developing product quality compliance requirements. In contrast, Wang et al. argued that, beyond global process complexity, the FDA had not developed a compliance requirement good enough to effectively regulate biopharmaceutical product complex delivery systems. The FDA should not police manufacturers but should continue to offer simple and attainable guidelines that U.S biopharmaceutical manufacturers could rely on with certainty. According to the authors, the government can make compliance easy by creating a local platform for U.S manufacturers. The authors argued that by creating a local compliance platform without

focus on the global market, local compliance is made easy for local U.S manufacturers. Also, Janvier-James (2016) concluded that the solution to compliance in the biopharmaceutical industry rest with the individual organizations and not the FDA's regulatory regime. Wang et al. suggested using management strategies such as organizational changes and leadership training to implement FDA product quality requirements within the organization. Wu noted that, rather than using draconian regulatory strategies and creating increased violations and citations, the FDA could help improve quality compliance by utilizing a collaborative working relationship with the industry by developing a process of working collaboratively with the biopharmaceutical industry to attain and improve compliance within the United States. Though the product manufacture and delivery system are complex, Janvier-James concluded manufacturers are responsible for compliance through personnel planning and training.

From a quality management theory perspective, McPhee (2015) theorized quality management strategies as enunciated by Deming (1987) may provide industry practitioners with the needed approach to applying and implementing quality requirements in a very complex product delivery setting. Harold et al. (2016) agreed and stated that, FDA noncompliance citation hinders the growth of the biopharmaceutical industry. Other researchers had opined that, the application of quality management strategies that relies on organizational culture of quality management will improve compliance and reduce chaos resulting from lack of compliance (Harold et al, 2016) Deming's quality management theories applied in a complex manufacturing stetting may provide respite growth and reduce failures resulting from lack of quality compliance

(Deming, 1987). Additionally, as Janvier-James noted, organizations should train employees on specific government regulations and policies that impacts the organization's efforts towards quality compliance.

Government Policies and the Adverse Effects on Biotech Product Quality Outcomes

Government quality regulatory policies, in some instances, have adverse effects on product quality compliance efforts in the biotech industry. Some researchers agreed that cumbersome and hard to follow quality regulatory policies accounts for majority of the lack of compliance issues in the biotech industry (Giesecke, 2000). The contrasting roles of the U.S Government in the development of the biotechnology industry is undeniable (Deng, Hu, Pray, & Jin, 2019). Further, Harold et al. (2016) noted that, in some cases, the FDA creates new quality compliance problems while developing solutions to old quality compliance problems. Whereas Janvier-James (2016) argued that quality compliance rests solely with the individual organization, the implication of government policies such as the New Drug Application (NDA) processes and the Foreign Investment Risk Review Modernization Act (FIRRMA) of 2018 are examples of government policies that may have adverse effects on product quality compliance in the United States (Deng et al., 2019).

New Drug Application Policy

The new drug application (NDA) policy is under the auspices of the Food, Drug, and Cosmetics Act (FD&C) of 1938. The Act required pharmaceutical companies to include only information relating to a proposed new drug's safety. However, in 1962 the FD&C Act require pharmaceutical companies to include evidence on the new drug's

effectiveness for its intended use and confirm that the new drug's established benefits outweighed its known side effects. The rigorous NDA process may have a negative impact on drug quality compliance. Van and Pray (2019) argued that the NDA process as administered by the FDA's Center for Drug Evaluation and Research (CDER) is too lengthy and may have a few lessons to learn from the legalization of Marijuana process adopted by many states in the United States. The authors argued that the CDER's use of 10 months to review new drug applications as only one phase of multi-steps process that pharmaceutical companies must navigate in order to successfully bring a new drug to the market is problematic. As Harold et al. (2016) opined, FDA's policies such as the NDA process may negatively impact investor's commitment and interest in the biotech industry. Other policies such as the Foreign Investment Risk Review Modernization Act (FIRRMA) directly makes the biotech industry unattractive to foreign investors.

Foreign Investment Risk Review Modernization Act

In August 2018, Congress passed the Foreign Investment Risk Review Modernization Act (FIRRMA) as part of the Fiscal 2019 National Defense Authorization Act. FIRRMA may have a negative impact on product quality compliance by reducing foreign investment in the biotech industry. FIRRMA broadened the scope and oversight of the Committee on Foreign Investment in the United States (CFIUS) to include the review of foreign investments in companies involved in critical biotech technologies (Westbrook, 2019). Wakely and Indolf (2018) opined that the Act has an adverse effect on foreign investment. The U.S government directed the Act at curbing investment in the biotech industry from China, but the Act invariably has an adverse impact on venture

capital (VC) investment in biotech. Under the FIRRM regulatory regime, foreign investors are required to go through rigorous application reviews which required several months of review time and very expensive legal fees before investing in the biotech industry (Wakely & Indolf, 2018). According to Leiter, Caccia, Cruz, Hoffman, Gafni, and Gerkin (2019), FIRRM Act may push US investors to foreign markets and create shortage of essential drugs in the United States. The Council of State Bioscience Association (CSBA) noted that, the bill could lead to a reduction in drug manufacturers' revenues and may lead to a reduction of approximately eight to 15 new drugs coming to market (Wakely & Indorf, 2018). The Act may indirectly impact new product patents as biopharmaceutical patents are capital intensive projects.

America Invents Act of 2011

The America Invents Act (AIA) of 2011 provided the most extensive revision of U.S. patent law in the past 60 years and may undermine innovation (Miyagiwa, 2015). The Act is arguably one of the United States Patent and Trademark Office's (USPTO) most extensive guideline on Patents in the United States. According to Yelderman (2019), the Act has too many unintended and unknowable consequences for innovators who rely on the patent system to fund and protect their inventions. One significant impact of the AIA is that it allows a party to challenge the validity of an already issued patent before the USPTO. In discussing this aspect of the Act, Sipe (2019) argued that the Inter Partes Review (IPR) and the Post-Grant Review (PGR) of the AIA have the most significant negative impact for the biopharmaceutical industry.

In contrast, other researchers opined the AIA created viable and safe patent regime for the biopharmaceutical industry (Lingenfelter, 2015; Reis, 2012; Trilling, 2012). The AIA arguably protects SMEs patents from big pharmaceutical companies. Lingenfelter noted that, under the new guidelines, stolen patents are registrable with The USPTO before true owners could. Also, Sipe (2019) noted that, whereas the *first-to-invent* system to the *first-inventor-to-file* system is one positive aspect of the Act, the Act in reality creates confusion and delays in certain instances when the agency and the court fails to determine the true owner of a patent.

Transition

In Section 1, the chosen research method and design for this study is the qualitative case study. The research population is five biotech quality compliance managers in the West region of the U.S. These quality compliance professionals have 15 to 20 years of experience implementing FDA quality compliance requirements. The conceptual framework for this study is Deming's quality management theory. The statement of the problem and study purpose is consistent with how quality compliance managers perceive the challenges faced when responding to FDA quality regulatory compliance requirements.

In Section 2, I described: (a) the role of the researcher, (b) the population and sampling methods, (c) data collection and analysis techniques, (d) a description of the research participants, and (e) explanation of the ethical research process. Further, section 2 contains a description of the research reliability and validity. Section 3 contains a

detailed presentation of the research findings. In this section, I present recommendations for actions as well as suggestions for future research study.

Section 2: The Project

Purpose Statement

The purpose of this qualitative multiple case study was to explore the strategies that quality compliance managers in biotech companies use to integrate and apply FDA product quality compliance requirements into their products' quality compliance metrics. The target population consisted of five biotech quality compliance managers from three biotech companies in the West region of the United States who had successfully implemented strategies to integrate and apply FDA product quality compliance requirements into their products' quality compliance metrics. The findings of this study may contribute to social change by providing the U.S. population with more rapid access to urgently needed drugs and treatment. The findings from this study may also help to mitigate FDA citation compliance violation cost incurred by the biopharmaceutical industry, which is typically passed down to the public in the form of higher drug costs.

Role of the Researcher

In a qualitative research study, the researcher is responsible for the research design, data collection, and data analysis (Denzin & Lincoln, 2015). According to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), the researcher is also responsible for all ethical concerns that may arise in the research process. As noted in the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979), the researcher should always adhere to the core principles of respect for persons as research participants. Doody and Noonan (2016) emphasized the importance

of participants' voluntary participation and informed consent as core ethical research requirements. I obtained participants' signatures in the informed consent form. Also, the form contained a detailed explanation of the participants' rights to accept, reject, or withdraw consent at any time during the study.

Further, it is the researcher's responsibility to promote the research validity by ensuring and managing appropriate sample sizes and avoiding personal and participants' bias (Yin, 2017). Yin noted that the researcher is responsible for selecting the research design that fits the research purpose and accurately answers the research questions. I obtained Walden University's Institutional Review Board's (IRB) approval and guidance before contacting research participants. I encouraged the participants to explain their professional views freely and adequately without any suggestions or leading questions that may have caused personal bias to influence participants' answers. Researchers use qualitative research methods to gain deeper understanding of people's or groups' experience without the researcher's bias (Fusch & Ness, 2017). As Marshall and Rossman (2016) suggested, qualitative research questions may help the researcher identify and manage personal biases prior to the interview. Therefore, collected data will reflect the views of the participants and not the researcher's personal views, experiences, or expectations.

In this qualitative multiple case study, my role as the researcher was to explore strategies used by quality compliance managers in the biotech industry to apply FDA product quality compliance requirement in their products' quality metrics. Researchers use qualitative research methodology to gain deeper insight into the study topic (Yin,

2017). Researchers use interview protocols to seek deeper understanding of practices and scenarios (Jacob & Ferguson, 2015). In the current study, I used interview questions to understand the strategies used by quality compliance managers to apply FDA quality compliance requirements in their quality compliance metrics within their firms.

Participants

The eligibility criteria for the five quality compliance managers to participate in the study were as follows: (a) employed in a leadership position with a biopharmaceutical company in the West region of the U.S, (b) administration and development of supply chain management strategies for quality compliance, and (c) demonstrated implementation of successful quality compliance strategies in response to FDA quality compliance regulatory requirements. In this study, purposive sampling was used to select eligible participants working in the biotech industry. Purposive sampling provides the researcher with informed and knowledgeable study participants (Fusch & Ness, 2017). In the current study, quality compliance managers who had implemented quality compliance strategies to apply FDA quality requirements were selected as participants.

I established a working relationship with the research participants by sending emails and making phone calls when appropriate. I gained participants' trust by explaining the research overview and asking whether the participants were willing to participate in the study. I provided my email contact information and asked the participants to contact me at any time if they had any questions or needed clarifications at any time during the study. I provided the participants with a detailed study overview such as the problem statement, purpose, research questions, and interview questions.

Further, upon IRB approval from Walden University, I asked the study participants to review and return a formal letter of consent to me. This letter of consent returned by the participants signified their interest in participating in the study through their own free will. I also stated in the consent form that all participants were free to withdraw their consent at any time during the study. Although voluntary participation decreases participants' response rate, Marshall and Rossman (2016) argued that voluntary and willful participation decreases the pressure to fabricate responses. It is ethical to ensure participants participate willfully and truthfully.

The ethical requirement to protect participants' confidentiality is crucial to the study's reliability. As Yin (2017) opined, unethical data gathering undermines the study's reliability and validity. The measures to ensure ethical protection of participants' confidentiality include but are not limited to (a) use of confidentiality forms, (b) interview process approval by executive leadership, (c) a promise to respect participants' privacy and/or the company's confidential information, and (d) approval of the study from the IRB (Walden University, 2015).

Research Method and Design

A researcher selects a research method and design that are appropriate for the researcher's study goals (Morse, 2015). My goal for this study was to understand the strategies used by quality compliance managers in the biotech industry to integrate FDA quality compliance requirements into their products' quality metrics. To attain this goal, I selected a qualitative method and a multiple case study design.

Research Method

I selected qualitative methodology for this study to explore the strategies used by quality compliance managers to integrate FDA quality compliance requirement into their products' quality metrics. Researchers use the qualitative method to explore and analyze perceptions and experiences of people who are involved in an activity or process (Hoeber & Shaw, 2017). Through the effective use of qualitative methodology, researchers gain a deeper understanding of why study participants make decisions (Rosenthal, 2016). In the current study, the qualitative method was appropriate to provide a deeper insight into the strategies used by quality compliance managers in the biotech industry to integrate FDA quality compliance requirements into their products' quality metrics.

By contrast, researchers use quantitative method to analyze and examine relationships among variables using numerical data and hypotheses (Walsh, 2015). A quantitative method was not ideal for the current study because I did not test a hypothesis. Bernard (2013) argued that the researcher must carefully consider other alternative research methods before selecting an appropriate research method. Ritchie et al., (2016) stated that quantitative or mixed-methods approaches are not appropriate for studies that probe the study participants' underlying decision-making process. In the current study, I intended to probe the participants' underlying decision-making process: therefore, the quantitative or mixed-methods approach would have been inappropriate.

Research Design

The primary function of a research design is to ensure that the evidence gathered by the researcher can be used to effectively answer the research questions. Qualitative

researchers use the research design to ensure research reliability and validity (Noble & Smith, 2015). I selected a case study design for this study. Researchers use the case study design to gain a deeper understanding of the study subject (Fusch & Ness, 2015). Yin (2017) argued that researchers use the case study design to preserve the universal and evocative characteristics of a real-life event. I selected a case study design for this study because I intended to present the realities described by participants.

Other qualitative designs did not support the explorative nature of this study. The phenomenological design would have allowed the collection of interview data for this study, but the phenomenological design would not have allowed the collection of publicly available data from multiple sources; therefore, the phenomenological design was not appropriate for this study. Researchers use the ethnographic design when examining beliefs and behaviors of culture-sharing groups (Marshall & Rossman, 2016). I did not select the ethnographic design for this study because I did not examine cultures and behaviors. The ethnographic design was inappropriate to explore the strategies used by quality compliance managers to integrate FDA quality compliance requirements into their products' quality metrics.

Population and Sampling

Sampling addresses the number of participants, the number of contacts with each participant, and the length of time spent with each participant (Marshall & Rossman, 2016). Purposeful sampling is used to identify and select cases related to the research phenomenon in a qualitative study (Fusch & Ness, 2017). The sampling of research participants involves affirmation that each participant meets the selection criteria

(Marshall & Rossman, 2016). Purposive sampling is suitable in studies in which the researcher seeks participants with the best knowledge concerning the research topic (Yin, 2017). I used purposeful sampling in this study in the selection and engagement of the study participants.

I used Zoom interviews to collect data. Interviewees were the primary source of data for this study. As Yin (2017) noted, well-informed participants with the appropriate knowledge can add important and needed data to the study. Unlike in a quantitative study where researchers choose random sampling to obtain reliable inferential results, qualitative researchers use a nonprobabilistic approach to choose the sample. In the current study, I used purposeful nonrandom sampling to choose five study participants. Robinson (2014) referred to purposive sampling strategies as a nonrandom selection of participants as part of a final group based on the uniqueness of the knowledge that they possess. I used purposive sampling to select participants with proven experience and knowledge of FDA quality compliance requirements.

The researcher may not set an exact number of research participants; however, an initial range is necessary to establish effective research planning (Robinson, 2014). For instance, Marshall et al. (2013) interviewed 83 participants and concluded that the minimum number of cases in a multiple case study was two while the median was five. Further, Marshall et al. noted that the minimum number of interviews was 10 while the median was 39. In the current study, I interviewed five participants with knowledge and experience in addressing FDA quality compliance requirements. I collected data from five experienced quality compliance managers until data saturation was reached. Data

saturation occurs when exploring a problem under study offers no new or additional themes (Fusch & Ness, 2017). This selected population was enough to provide a robust understanding of the strategies used by biotech quality compliance managers to integrate and apply FDA quality compliance requirements into their products' quality metrics.

The specific population consisted of five quality compliance managers from two biotech companies in the West region of the United States who had experience applying and integrating FDA quality compliance requirements in their products' quality metrics. I conducted the interviews in a quiet and conducive environment. As Cahyadi and Prananto (2015) opined, an interview should take place in a quiet location free from distractions with little or no noise. Further, Cahyadi and Prananto suggested that a place suitable for audio recording is ideal for a study interview. Also, the researcher should ask the participants to choose the location and time of the interviews (Yin, 2017). Yin further noted that a good rapport before the interview is crucial to a successful interview because good rapport reduces the participant's discomfort, which can yield better answers to the interview questions. Based on these recommendations, I asked the participants to select an interview date, time, and location that was most suitable for them. I developed good rapport by asking about their day and other unrelated questions before the interview questions.

Ethical Research

Walden University's IRB procedures were used as a guide for this study. Walden University's IRB requires that each study participant receives an informed consent form that identifies the (a) purpose of the study, (b) researcher's responsibilities, (c) procedures

for ensuring confidentiality, and (d) participant's role (Walden University, 2015). Obtaining participants' informed consent is a core component of ethical research (Gaikwad, 2017). I obtained participants' consent to participate in this study by sending an informed consent form and a consent procedure letter via email to study participants. The procedure letter outlined the background and procedural information about the study. The procedure agreement included a clear and concise description of the study topic, sample interview questions, and participants' expectations regarding compensation or any other form of reward for participating. The consent form stated that the benefit of the study was to the public, and for participating participants would get a copy of the completed study if they chose to.

After I determined that participants had met the selection criteria, the research participants received an invitation to participate email from me. Upon returning the email communicating an interest to participate in the study, participants received another email with the consent form attached. The informed consent form contained information about the strict ethical compliance of the study, such as participants' ability to withdraw their consent at any time during their participation. Participants were free to withdraw their consent to participate by sending an email to me stating that they did not want to participate any longer. Participants did not need to provide reasons why they were withdrawing their consent to participate. The consent form, which the participants were required to return before participating, ensured participants that their privacy and the privacy of their organization would be a priority. This study was conducted using

Walden's ethical research procedures and the standard guidelines for qualitative research involving human subjects.

Strict adherence to ethical guidelines is an important aspect of qualitative research involving human subjects (Robinson, 2014). The research in this study is conducted in accordance with the recommendations in the Belmont report of 1979 which is the acceptable minimum standard for conducting research involving human research participants (U.S Department of Health and Human Services, 1979). I followed the recommendations contained in the Belmont report to ensure the adequate protection of this study participants. This research was conducted after approval and an approval number was received from Walden University's IRB. The approval number from the IRB for this study is 09-22-20-0660779. The study reports are protected using generic names. I did not use the actual names and location of any research participants and their organization. The research study data are stored on a password protected computer with codes and generic names. I stored all study related documents in a password protected thumb drive. I will store the password protected thumb drive in a locked safe for five years.

Data Collection Instruments

The researcher assumes the primary role of data collection and as such, the researcher is the primary data collection instrument in a case study (Gaikwad, 2017; Yin, 2017). The use of semistructured interviews and probes contribute to the validity and reliability of a qualitative study (Morse, 2016; Yin, 2017). In this qualitative case study, I collected data from review of public documents, news releases, website information, and

conducted face-to-face semistructured interviews. I interviewed individuals in biopharmaceutical quality compliance leadership positions in three biotech companies in West region of the United States. The study participants were responsible for the design, management and administration of supply chain management strategies used in their respective organizations to attain and apply FDA quality compliance requirements into their products' quality metrics. Marshall and Rossman (2016) opined that data triangulation of multiple sources is used to give credibility to a research outcome. Yin further noted that, case study researchers could use effective data triangulation by collecting pertinent information from multiple sources to corroborate the same phenomenon and ensure the overall study quality.

Data Collection Technique

I collected data via semistructured interviews, and the review of strategies used by quality compliance managers to integrate FDA product quality compliance requirements into their product quality metrics. In semistructured interviews, the researcher uses a set of open-ended questions combined with probes to explore participant responses (Rosenthal, 2016). Qualitative researchers should follow an interview protocol to conduct all interviews in a consistent manner and collect data from more than one source to achieve triangulation (Morse, 2016). In this study, I followed a semistructured interview protocol that would use open-ended questions combined with probes to explore the strategies used by quality compliance managers in the biotech industry to attain full FDA quality compliance requirements. I used interview protocols that contained steps for conducting a research interview, discussion of member checking, and explanation of

strategies. By following this semistructured interview and document review protocols, I was able to explore the strategies used by quality compliance managers in the biotech industry to integrate FDA quality compliance requirements into their products' quality metrics.

There are some disadvantages as well as advantages to collecting case study data in a semi structured interviews and in reviewing company data and documents. One of the advantages of collecting data through a semistructured interview is that the open-ended questions may prompt the study participants to answer questions as well as provide additional perspectives gained through experience (Rosenthal, 2017). Additionally, probing questions may be used to clarify information as well as create and explore a recurring theme (Gaikwad, 2017). The use of probing questions and review of company's data and documents may contribute to the research reliability and validity (Fusch & Ness, 2016). The advantage of these open-ended research questions listed in Section 1 and the review of relevant company documents will enable me to explore the strategies used by quality compliance managers in the biotech industry to attain full FDA quality compliance requirements.

One of the disadvantages of collecting data through a semistructured interview and the review of company data and documents is the amount of time involved in completing the process and analyzing the documents. Semistructured interviews and document reviews are time consuming and may create project creep in the research process (Rosenthal, 2017). As Gaikwad (2017) noted, the researcher should include an adequate time to complete these required steps: (a) scheduling and conducting interviews,

(b) document reviews, (c) transcription, and (d) member checking. To mitigate this disadvantage, I asked study participants to reserve an hour to review a summary of the interview for accuracy and to provide any additional information if needed. Therefore, time constraint would not impede the success of exploring the strategies used by quality compliance managers in the biotech industry to integrate FDA product quality compliance requirements into their product quality metrics.

Data Organization Technique

I organized the research data by creating and maintaining an electronic data logs on a password-protected computer. The researcher should categorize collected data and store the data in a safe and secure format with easy to retrieve capability (Baskarada, 2016). The entries in the log that I created included data information such as (a) the data type, (b) data identifier, (c) date of collection, (d) place of collection, and (e) corresponding research notes identifier. I recorded notes during the interviews. Microsoft Excel and NVivo are the standard tools used by qualitative researchers for data collection and organization, data analysis and data reporting (Bree & Gallagher, 2016; Robins & Eisen, 2017). I collected data such as the consent form, audio recording, or transcription. I used a secured easy to retrieve Microsoft Excel and Microsoft Word interface to organize and secure collected research data.

To keep collected data secure and organized, I created and labelled folders for each research participant. I used alphanumeric codes for each folder labels. I labelled audio recordings, consent forms and interview transcriptions with alphanumeric participants' code (e.g., P3 Consent Form) and stored it in the participant's folder. To

effectively analyze collected data such as interview transcriptions, I copied the transcribed interview data into an excel spreadsheet with appropriate headings (e.g., document code, participant code, question number, and responses).

I stored electronic data gathered for this study in a password protected laptop. I stored physical data in a locked safe. I stored all electronic data in a password protected thumb drive and delete all electronic data from my laptop after the study is completed. I will store the thumb drive and the physical data in a safe for 5 years. Afterwards, I will delete the electronic data from the thumb drive, and I will shred the physical data.

Data Analysis

In qualitative research studies, researchers analyze and gather data during interviews to identify emerging themes (St. Pierre & Jackson, 2017). In this study, I identified emerging themes through methodological data triangulation by (a) interviewed qualified and experienced quality compliance managers with more than 15 years of quality management experience within the biotech industry, (b) interviewed FDA regulatory compliance officers, and (c) reviewed quality compliance documents used to attain FDA quality compliance requirements by the biotech industry. The use of multiple data sources provides researchers with a comprehensive knowledge of a researched phenomenon while applying methodological data triangulation (Carter, Bryant-Lukosius, DiCenso, Blythe, & Neville, 2016; Joslin & Muller, 2017).

Qualitative researchers analyze data to discover themes that can answer their research question (Yin, 2017). In this study, the objective of the data analysis was to discover the strategies used by quality compliance managers in the biotech industry to

attain FDA quality compliance requirements. Defining the process and tools used for data analysis is an important step in the research planning phase in a case study (Rosenthal, 2017). As Hoeber and Shaw (2017) noted, methodological triangulation requires the use of more than one method to gather data. The documents review will include published FDA regulatory documents, organizations compliance documents and the responses to developed open-ended interview questions and other company documents such as FDA citation letters. Themes discovered during these data analysis provided the framework for addressing this study research question. I used more than one data sources such as coding and thematic data analysis.

Yin (2017) recommended five stages of data analysis: (a) compiling, (b) disassembling, (c) reassembling, (d) interpreting, and (e) drawing conclusions. Yin further noted that compiling data refers to the process of collecting and organizing data. Disassembling and reassembling include separating data and organizing data into groups and identifying data patterns and or themes. Interpreting data involves associating the emerging themes with existing research and the conceptual framework (Yin, 2017). I used Microsoft Word and Excel functions to gather data, disassemble, and reassemble interview data into meaningful themes. According to Ose (2016), the standard Microsoft Office program comes equipped with functionality ideal for organizing and coding qualitative research data. Whereas some researchers disregard Microsoft Excel as a viable means of organizing and coding qualitative research data (De Felice & Janesick, 2016), Moylan et al. (2016) opined Microsoft Office programs are the most viable, cheaper alternative to expensive data analysis programs for qualitative research.

Per Yin's (2017) data analysis methodology, the next step was to interpret the themes and their meaning. I compiled collected data from interviews and company documents and identified emerging themes through the interactive process of disassembly and reassembly. As I defined emerging themes, I related the themes to supply chain management strategies for attaining FDA product quality compliance information in the literature review, Deming's quality management theory, and newly published FDA rules and other related scholarly articles. Based on these data triangulation and interpretation, I drew and reported my research conclusions.

Reliability and Validity

Research reliability and validity refers to the research quality and result of the research outcome (Gaikwad, 2017). Research reliability and validity are related with the research dependability, transferability, and credibility (Morse, 2015). Fusch and Ness (2015) noted that, when conducting a qualitative research study, the researcher should adopt research techniques that contribute to the research reliability and validity. Qualitative researchers use four model criteria to ensure research data trustworthiness. The model's four aspects are: (a) credibility, (b) dependability, (c) confirmability, and (d) transferability (Cope, 2015; Morse 2015).

Reliability

Research reliability in a qualitative research study is analogous to the research's dependability (Gaikwad, 2017). Dependability refers to the reliability of the research data over time and in a different context (Cope, 2015; Morse, 2015). Qualitative researchers use different methods and strategies to attain dependability. Qualitative researchers use

member checking and case study protocols to solidify research findings (Cope, 2015). Fusch and Ness (2015) noted that, interview protocols and member checking increase the levels of data reliability obtained from research participants. Researchers engage study participants in the member checking process through semistructured interviews by which participants review data provided by the member for accuracy and authenticity in comparison to similar data from the same or other sources (Cope, 2015). Researchers link reliability and confirmability through similar means (Morse, 2015).

Confirmability refers to the objectivity of the research and the absence of personal bias in the study (Cope, 2015). According to Morse (2015), the study findings must be firmly rooted in participants' data without any part of the data invented by the researcher or influenced by personal bias. In this study, confirmability will occur through member checking, data interpretation and participants' interview summary reviews. In addition to member checking of data interpretation and transcript reviews, I will use reflective journals to create an audit trail of findings. Reflective journals represent a remarkable tool used by qualitative researchers to document research observations, analytical findings, and emerging themes (Young & MacPhail, 2016).

In this study, to ensure reliability, I utilized interview protocols, member checking, and reflective journaling. I conducted each interview using the same interview protocol (Appendix D) to ensure the same data collection method throughout the research data collection process. I used the same interview questions and the same interview protocols for all research participants. After each interview, I sent the same interview synthesis and interview summary to all the participants to validate my interpretation of

their given interviews and data. As Harvey (2016) noted, member checking gives the interviewee the opportunity to confirm the accuracy of the researcher's depiction of their experiences. I used a reflective journal to document all my observations throughout the interviews and data review in order to gain insights on emerging themes.

Validity

Qualitative research quality is dependent on the qualitative researcher's focus on key means of study validity (Marshall & Rossman, 2016). Accordingly, qualitative researchers ensure the validity of their research using credible procedures (Denzin & Lincoln, 2015; Marshall & Rossman, 2016). Qualitative researchers assess research trustworthiness by adopting the model by Lincoln and Guba which considers: (a) credibility, (b), dependability, (c) confirmability, and transferability (Cope, 2015; Morse, 2015). Qualitative researchers use data triangulation and member checking to gain research internal validity (Berger, 2016). Credibility refers to a qualitative research internal validity whereas transferability refers to external validity (Morse, 2015).

Transferability refers to the extent to which other researchers can replicate the study in a different context and would get the same results (Elo et al., 2016). Transferability describes the participants and data selection and gathering processes in a manner that, other researchers can replicate the processes in a different context and will get the same result (Morse, 2015). Confirmability is the degree of objectivity of the research and the absence of any personal bias on the part of the research participants (Cope, 2015). Research credibility refers to the truth, testability, and authenticity of the research data in a qualitative case study whereas dependability refers to the ability of

other scholars to rely on the research outcome (Morse, 2015). Data saturation ensures dependability and research validity (Cope, 2015).

Data saturation occurs at the point at which no further new information or theme is emerging (Fursh & Ness, 2017; Houghton et al., 2015). Researchers reach data saturation through data triangulation and member checking as well as participants' transcript reviews (Houghton et al., 2015) Abma and Stake (2016) identified member checking as a reliable mean to reach data saturation.

In this study, I attained data transferability by ensuring data validity and authenticity through member checking and multiple source reviews of collected data. I compared published FDA regulatory documents with data collected from participants to ensure currency and reusability by future scholars. I provided detailed descriptions of the study context so that future readers can determine for themselves the level of the applicability of the study in their future selected context. I ensured credibility through member checking, participants' transcript reviews and data triangulation. I interviewed only participants with 15 to 20 years of experiences attaining FDA quality compliance requirements in a nationally recognized biotechnology firm. I made participants review my synthetization of their documents and interview summary for accuracy and true depiction of their highlighted strategies use to integrate FDA quality compliance regulatory requirements into their product quality metrics. I addressed confirmability by member checking, participants' interview transcript reviews and data triangulation to ensure personal bias do not form part of the data synthesizing.

Data saturation is an important aspect of the qualitative research study (Fursch & Ness, 2017). According to Abma and Stake (2016), the researcher reaches data saturation when no new information or theme is emerging. I attained data saturation by a methodological data triangulation through giving interviewees the opportunity to provide additional and new information. This study data saturation was reached when no new information or theme is emerging from additional information and documents.

Transition and Summary

In section 1, the chosen research method and design for this study is the qualitative case study. The research population is five biotech quality compliance managers from biotech firms in the West region of the U.S. The participants have designed and implemented quality compliance strategies to attain FDA product quality compliance. The conceptual framework governing this research study is Deming's strategic models for developing and implementing quality (Deming, 1986). The statement of the problem and study purpose is consistent with how quality compliance managers perceive the challenges faced when responding to FDA quality regulatory compliance requirements.

In section 2, I described: (a) the role of the researcher, (b) the population and sampling methods, (c) data collection and analysis techniques, (d) a description of the research participants, and (e) explanation of the ethical research process. Further, section 2 contains a description of the research reliability and validity. Section 3 contains a detailed presentation of the research findings. In this section I present recommendations for actions as well as suggestions for future research study.

Section 3: Application to Professional Practice and Implications for Change

Introduction

This section includes the presentation of findings gathered from semistructured interviews with product quality compliance managers in the U.S. biotechnology industry with more than 15 years of FDA quality compliance implementation experiences within their selected organizations. This section also contains the application to professional practice, implications for social change, and recommendations for action. The section concludes with recommendations for further research, a reflection on my experience, and a summary of the study.

Presentation of the Findings

The purpose of this qualitative multiple case study is to explore the strategies used by quality compliance managers in the biotech industry to integrate FDA product quality compliance requirements into their products' quality metrics. Deming's (1986) management theory is the conceptual framework for this study. Using purposeful sampling and semistructured interviews, I interviewed five quality compliance managers with 15 or more years of experience implementing FDA product quality compliance requirements within the biotech industry in the West region of the U.S. The interviews were conducted via Zoom and were recorded, transcribed, and coded by using red text to identify themes. NVivo 12 software was used to establish significance, codes, and phrases among data sources. The analysis of the interview transcripts resulted in the identification of 42 codes and 300 meaningful quotes and phrases that supported the

identification of emerging themes. The emerging themes confirmed the study's underlying conceptual framework.

Three themes emerged from my analysis of the aggregation of the codes, phrases, and terms that summarized the strategies used by quality compliance managers to attain FDA product quality compliance requirements (see Table 1). The three themes were (a) product quality outcomes, (b) policies and procedures, and (c) collaborative partnerships. The three themes supported the conceptual framework of Deming (1986) and aligned with the research topic of the strategies used by quality compliance managers to attain FDA product quality compliance. The alignment of the emerging themes is seen in current peer-reviewed studies such as Anwar et al. (2016) and Mirza and Ahsan (2020) who noted that defining quality outcomes and determining required collaborative partnerships are key to product quality management.

Table 1

Cluster Related to the Three Emerging Themes

Participant	Partnership	Product quality outcome	Policies and procedures collaborative
P1	38	84	6
P2	60	123	24
P3	21	56	9
P4	27	37	13
P5	33	55	19
Total	179	155	71

Emergent Theme 1: Product Quality Outcomes

The first theme of the study indicated the strategic processes used by quality compliance professionals to define product quality outcomes that are used in the industry

to attain FDA product quality compliance. The participants identified the efficacy of clear, simple, and easy-to-follow product quality outcomes as a strategic requirement for attaining FDA product quality compliance. This theme was highlighted by all participants and was recorded in my notes. In creating a strategy for attaining expected quality outcomes, participants identified three strategic methods, practices, and rules adopted across the industry. Table 2 depicts the response frequencies for highly summarized strategies in Emerging Theme 1.

Table 2

Theme 1: Product Quality Outcomes

Theme	Number of participants	Number of documents	Number of references
Product quality	5	3	179

All five participants identified a clearly defined product quality outcome as one of the primary requirements for creating a product outcome that meets an FDA product quality requirement. P1 noted that “the organization must design a clearly defined product quality outcome that all employees involved in the quality process should understand and adhere to.” Further, in describing product quality outcome as a key theme, three subthemes emerged, as shown in Table 3.

Table 3

Subthemes Related to Emerging Theme 1 of Product Quality Outcomes

Subtheme	Participant	Number of documents	Number of references
Training	P3, P4, P5	4	25
Buy-in	P1, P2, P3, P4, P5, P6	5	60
Verifications	P1, P2, P3, P4, P5, P6	5	69

Employee training is required to attain intended product quality outcomes. As a corollary, Participant 4 stated that "employee training and commitment is the first port of call in the pursuit of product quality compliance requirements." Participant 2 stated that

> it should be emphasized that, only the employees who display understanding and mastery of the product quality outcome who should be allowed to be a part of the quality compliance team to develop a product that complies with FDA quality regulatory requirements.

Participants 3, 4, and 5 agreed. Participant 4 went further and stated that "regular quality compliance training and verification of understanding is required to earn expected product quality outcomes." Participant 3 also noted that "in any organization where employees involved in product quality compliance don't understand the product quality compliance requirements, FDA quality compliance citation increases in that organization." Anwar et al. (2016) opined that consistent verification of employee competencies is required to maintain product quality outcomes.

Employee and management buy-in emerged as a subtheme of Theme 1. Employee trainings and total buy-in are fundamental requirements in defining product quality

outcomes (Mirza & Ahsan, 2020). Participant 5 stated that “employees must sign some form of documents stating that they understood the product quality requirement and that they support the processes.” Jagsi et al. (2014) argued that training alone is not enough practice to earn total quality management credits within the organization. Jagsi et al. noted that confirmed employee buy-in is required at every level of the organizational quality compliance campaign. Participant 5 noted that buy-in gives the employees the opportunity to state their concerns should there be any. Discussing the effectiveness of employee buy-in, Participant 5 further stated that “it’s a continuous learning and relearning process.” Deming (1986) argued that quality management within an organization requires consistent management commitment to employee buy-in.

All participants further opined that, to create a quality product outcome, organizations should implement a step-by-step quality outcome measurement and verification process using confirmable technological systems. Participant 5 noted that, whereas employee training is required, management are expected to put in place “a system to verify full and total quality management systems requirement and adherence by employee.” Bajaj et al., (2019) noted that providing compliance and adherence incentives such as training and performance feedback could help employees follow a step-by-step compliance verification requirement within the product quality compliance department. According to Rijsbergen et al. (2016), though management trust employees to comply, the need to track, verify, and improve product quality compliance should be routine within the quality management department. Participant 5 noted that “the compliance documentation and verification requirement is a key requirement.” All study participants

noted that the creation of a well-defined product quality outcome is made possible by engaging in step-by-step recorded employee participation and adherence to the assigned product quality.

Product quality outcomes should be defined and clearly outlined. Deming (1986) noted that quality management theory recommends that quality outcomes are clearly defined as part of the product management processes in an organization. Also, Rijsbergent et al. (2016) opined that defining the quality outcome from the onset is an established product quality management technique. All current participants agreed. Participant 3 stated that "understanding of the quality outcomes is the first place to start, and management must ensure all quality management participants understand the product quality outcomes." Deming (1986) argued that organizations must define quality outcomes and help employees understand the outcomes by providing the guidance needed to attain outlined outcomes.

Emergent Theme 2: Policies and Procedures

The second theme that emerged was the importance of organizational product quality policies and procedures. All five participants identified organizational policies and procedures as an integral part of product quality compliance outcomes. Table 4 reflects Theme 2 that emerged from the analysis of the five participant transcripts and review of available practice documents.

Table 4

Theme 2: Policies and Procedures

Theme	Number of participants	Number of documents	Number of references
Policies and procedures	5	12	155

All participants noted that organizational policies set the tone for product quality compliance. Participants 3 and 4 noted that, beyond organizationally stated policies for compliance, defined compliance procedures are vital. Participant 1 stated that "the FDA has clearly defined compliance policies, but most of these policies are recommendations. The individual organization is expected to design their own internal policies to reflect and follow the FDA guidance and compliance policies." Participant 3 further noted that corporate policies and procedures form the basis of quality compliance: "every organization must signal a culture of compliance by establishing a clear quality compliance policy within the organization." Martyn et al. (2016) stated that policies and procures are organizations' strategies that create a culture within an organization. Organizations design and implement corporate strategies to implement intended corporate outcomes (Pinto & Winch, 2016). The implementation of corporate policies and procedures such as quality compliance procedures within an organization needs to be clearly defined (Alqahtani, 2016). In describing policies and procedures as a recurring theme, several subthemes emerged. Table 5 highlights the different subthemes mentioned by study participants.

Table 5

Subthemes Related to Emerging Theme 2 of Policies and Procedures

Subtheme	Participant	Number of documents	Number of references
Compliance tone	P1, P5	4	10
Accountability	P1, P2, P3, P4, P5	5	30
Policy clarity	P1, P2, P3, P4, P5	2	55
Strict adherence	P5, P4, P3	1	5

The core aspect of this theme aligned with the conceptual framework of this study, Deming's (1986) quality management theory. Deming argued that quality management in a production process accentuates an organization's competitiveness and sustainability, and organizations should make such quality notions part of their overall policies and procedures. In practice, the strategic use of policies and procedures to attain product quality and overall organizational effectiveness is an indispensable aspect of product quality implementation (Alqahtani, 2016).

Emergent Theme 3: Collaborative Partnerships

The third theme that emerged from this study was collaborative partnership. All participants identified collaborative partnership within and outside the organization as a key requirement for product quality compliance (see Table 6). Participant 1 noted that "organizations, in order to attain FDA product quality compliance requirements, must look beyond their own organization and look into processes by other partners."

Table 6

Theme 3: Collaborative Partnerships

Theme	Number of participants	Number of documents	Number of references
Collaborative partnerships	5	9	71

Participant 2 argued that the requirement to comply with regulatory quality compliance starts with management and frontline employees. Participant 2 argued that "management must understand frontline needs and requirement and put on a collaborative hat to fully attain FDA product quality requirement." Further, Participant 5 noted that "companies who want to attain compliance and avoid huge violation penalties must partner with external agents and experts to provide compliance training." Participant 1 noted that "every department within the organization must collaborate on the need to attain product quality compliance to attain full FDA product quality compliance." Further, Participant 4 stated that "collaborative partnership is required throughout the product life cycle." All participants agreed that FDA product quality compliance requires internal and external collaborative partnerships. Participant 3 noted that "quality compliance is an all-hands-on-deck requirement, from product conception to product end-users." Hernández-Carrión et al. (2017) noted that organizations thrive when they have a successful partnership within and outside their organizations. In identifying Emergent Theme 3, I observed several subthemes (see Table 7).

Table 7

Subthemes Related to Emerging Theme 3 of Collaborative Partnerships

Subtheme	Participants	Number of documents	Number of references
Internal collaboration	P1, P5	4	10
External partnerships	P1, P2, P3, P4, P5	5	30
Collaboration	P1, P2, P3, P4, P5	2	55

The improve-every-process aspect of Deming's (1986) quality management theory aligned with the collaborative partnerships theme of the current study. According to Deming, organizations must partner and collaborate with every process of the product or services for a single goal of product quality improvement. Participant 1 noted that "quality compliance managers must partner with external participants to attain product quality improvement." Also, Fawcett et al., (2016) suggested that better product improvement success rate occurs within the organization and desired quality outcome is attained through collaborative participation across all spectrums. Deming's product quality management theory was an appropriate framework for monitoring and engaging multiple participants within a product quality outcome effort. When engaging employees to attain product quality within an organization, leadership can use Deming's quality management theory to assist in this process.

Applications to Professional Practice

The result of this study provided strategies that quality compliance managers in the biotech industry can apply to obtain FDA product compliance requirements.

Compliance managers in the biotech industry are responsible for the implementation of FDA product quality compliance requirements. Still, many organizations within the biotech industry face product recalls for lack of quality compliance and are often fined for lack of compliance (Smith & Rupp, 2016). Current research indicates that many compliance managers are unable to integrate FDA product quality requirements into their quality metrics (Chellener, 2020).

The theme identified in this study are product quality outcomes, policies and procedures and collaborative partnerships. Each of these themes are product quality compliance strategies that different quality compliance managers throughout the Western region of the United State have identified as strategies used by experienced compliance managers to attain full FDA product quality compliance requirements.

Quality compliance managers can attain FDA product quality compliance through several ways. The themes in this study are significant and supports the professional practices in the region. The use of strategies such as Demings quality improvement strategies can help quality compliance managers attain FDA quality product requirements (Deng et al., 2019). Further, Harold et al. (2016) noted that, quality management strategies can be used to attain full quality improvement within the biotech industry.

Implications for Social Change

According to Haugh and Talwar (2016), positive social change is grounded in the elimination of restrictions that prevent or hinders the progress of an organization and, or community. Implications for social change for the biotech industry includes jobs and availability of much needed drugs for societies. Growth in the biotech industry would

improve the overall welfare and living conditions of the public. Also, the education and communication of new quality improvement strategies within the organization could improve employee morals. According to Oskooee (2017), positive change initiatives can increase employee commitment and reduce resistance. Therefore, the communication and implementation of quality compliance strategies within the industry can have positive effect on the success and growth of the industry resulting from a motivated workforce.

Recommendations for Action

Despite numerous quality compliance and good manufacturing publications by the FDA, many organizations within the biotech industry have failed to attain required FDA product quality compliance requirements. Consequently, more than 70% of businesses fail to attain the required quality compliance (Cândido & Santos, 2015). The findings of this study may assist current and future business leaders in managing the challenges associated with effectively implementing required product quality compliance within the biotech industry. Based on the research findings, from this study, the results are significant to organizational leaders and quality compliance managers because they may benefit from the participants' experience and the strategies revealed for the successful implementation of the strategies used to attain FDA product quality compliance requirements.

Additionally, other manufacturing organizations, besides those in the biotech industry could also benefit from implementing the quality implementation strategies enunciated in this study. Service organizations in the public and private sectors, profit and non-profit organizations may benefit from the findings in this study. The findings

from this study may be published as a resource to business leaders through journal articles and professional literature. Also, the findings of this study would be shared at conferences, seminars and in business courses that I teach.

Recommendations for Further Research

The purpose of this study was to help contribute to the gap of the lack of or ineffective strategies used by quality compliance managers in the biotech industry to attain FDA product quality compliance requirements. I recommend further research on this subject. The limitations of the study were the sample size of three biotech organizations in the Southern region of the United States not being a representation of all the biotech organizations in the United States. Although data saturation was reached in this study, extensive research with a broader group of participants is recommended. The other limitation of this study was that participants might not have provided honest answers to the interview questions that may have effectively represent the strategies used within their organization to attain full FDA product quality compliance requirements.

Reflections

The Doctor of Business Administration (DBA) program at Walden University was challenging, yet astonishingly rewarding. I did not anticipate the amount of time and energy required to complete the doctoral study, and as a result, I experienced a few setbacks. However, the knowledge obtained throughout this process was fulfilling. I took required actions to identify and limit my personal biases within the scope of this study. I followed an established interview protocol when conducting interviews with participants to mitigate bias. I also conducted member checking by having the participants review a

summary of my interpretations of the interview responses to ensure research validity. I am also very glad that, in the process of this study, I became familiar with FDA quality compliance regime and the strategies used by the biotech industry to attain product quality compliance.

Conclusion

To attain FDA product quality compliance requirements, organizations must create and adopt effective quality compliance strategies throughout all organizational product manufacturing processes (Mirza & Ahsan, 2020). Although organizations within the biotech industry thrive to attain product quality compliance, many of these organizations continuously gets cited for failure to adopt and implement product quality compliance requirements. Accordingly, Challener (2020) noted that, a culture of compliance is required within the organizations' manufacturing processes. In this study, I used open-ended, semistructured questions to interview five quality compliance managers in the Southern region of the United States. Data saturation occurred once information became repetitive. From these interviews, three major themes emerged from the collected data: product quality outcomes, policies and procedures, and collaborative partnerships. The themes which emerged from this study may form the basis upon which effective product quality regimes could be attained by product manufacturers in the biotech industry. Product quality compliance professionals may apply the findings from this study to attain full FDA product quality requirements.

References

Abma, T. A., & Stake, R. E. (2016). Science of the particular: An advocacy of naturalistic case study in health research. *Qualitative Health Research*, *24*, 1150–1161. https://doi.org/10.1177/1049732314543196

Alqahtani, S. (2016). King Saud University's strategic plan implementation (KSU2030). *Journal of Competitiveness Studies*, *24*, 1–15.

Anwar, J., Shah, S., & Hasnu, S. (2016). Business strategy and organizational performance. *Pakistan Economic and Social Review*, *54*(1), 97–122.

Arab, A. H., Bouchakour, S., Abdeladim, K., Amrouche, S. O., Semaoui, S., Taghezouit, B., & Yassaa, N. (2017). Connection of the CDER-Algiers photovoltaic system to low-voltage distribution grid. *Energy Procedia*, *136*, 145–150. https://doi.org/10.1016/j.egypro.2017.10.311

Bajaj, S., Garg, R., Sethi, M., & Dey, S. (2019). Classification and positioning of TQM practices for implementation in steel industries. *International Journal of Quality & Reliability Management*, *36*(9), 1556–1573. https://doi.org/10.1108/IJQRM-07-2018-0196

Bandura, A. (1978). Social learning theory of aggression. *Journal of Communication*, *28*(3), 12–29. https://doi.org/10.1111/j.1460-2466.1978.tb01621.x

Baškarada, S. (2016). Qualitative case study guidelines. *Qualitative Report*, *19*(24), 1–18.

Belschak, F. D., Den Hartog, D. N., & Kalshoven, K. (2016). Leading Machiavellians: How to translate Machiavellians selfishness into pro-organizational behavior. *Journal of Management*, *41*, 1934–1956.

https://doi.org/10.1177/0149206313484513

Berger, R. (2016). Now I see it, now I don't: Researcher's position and reflexivity in qualitative research. *Qualitative Research, 15,* 219–234. https://doi.org/10.1177/1468794112468475

Bernard, H. R. (2013). *Social research methods: Qualitative and quantitative approaches* (2nd ed.). SAGE Publications.

Bree, R., & Gallagher, G. (2016). Using Microsoft Excel to code and thematically analyse qualitative data: A simple, cost-effective approach. *AISHE-J: The All Ireland Journal of Teaching & Learning in Higher Education*, *8*, 2811–2819.

Brown, M. E., Treviño, L. K., & Harrison, D. A. (2005). Ethical leadership: A social learning perspective for construct development and testing. *Organizational Behavior and Human Decision Processes*, *97*, 117–134. https://doi.org/10.1016/j.obhdp.2005.03.002

Cahyadi, A., & Prananto, A. (2015). Reflecting design thinking: A case study of the process of designing dashboards. *Journal of Systems and Information Technology*, *17*, 286–306. doi:10.1108/JSIT-03-2015-0018

Cândido, C. J., & Santos, S. P. (2015). Strategy implementation: What is the failure rate? *Journal of Management & Organization*, *21*, 237–262. https://doi.org/10.1017/jmo.2014.77

Carter, N., Bryant-Lukosius, D., DiCenso, A., Blythe, J., & Neville, A. J. (2016). The use of triangulation in qualitative research. *Oncology Nursing Forum*, *41*, 545–547. https://doi.org/10.1188/14.ONF.545-547

Chabner, B. A. (2011). Drug shortages: A critical challenge for the generic-drug market. *New England Journal of Medicine*, *365*, 2147–2149. https://doi.org/10.1056/NEJMp1112633

Challener, C. A. (2020). Building data quality in generates quality data out: Ensuring the quality of data in process monitoring and control systems starts in process development phases. *BioPharm International*, *33*(3), 18–38.

Chen, C., Shih, Y., Hung, & Y-Ping, H. (2019). Beyond defense: Regulation of neuronal morphogenesis and brain functions via toll-like receptors. *Journal of Biomed Science*, *26*, 90–102. https://doi.org/10.1186/s12929-019-0584-z

Conrad, R., Bertha, A., Harrington, A., Kish, A., Stark, G., Taylor, K., &, Raggio, M. (2017). Breakthrough therapy designation: CDER analysis of requests 4 years into the program. *Therapeutic Innovation & Regulatory Science*, *51*(4), 509. https://doi.org/10.1177/2168479017696284

Cope, D. G. (2014). Methods and meanings: Credibility and trustworthiness of qualitative research. *Oncology Nursing Forum*, *41*, 89–91. https://doi.org/10.1188/14.ONF.89-91

Cygler, J., & Dębkowska, K. (2015). Coopetition effect determinants: Competitor's size, geographical scope, market and technological positions. *Organizacija, 48*, 219–231 . doi:10.1515/orga-2015-0019

De Felice, D., & Janesick, V. J. (2016). Understanding the marriage of technology and phenomenological research: From design to analysis. *The Qualitative Report, 20*, 1576–1593. https://doi.org/10.46743/2160-3715/2015.2326

Deming, W. E. (1986). *Out of crisis.* Cambridge.

Deng, H., Hu, R., Pray, C., & Jin, Y. (2019). Impact of government policies on private R&D investment in agricultural biotechnology: Evidence from chemical and pesticide firms in China. *Technological Forecasting & Social Change, 147,* 208–215. https://doi-org.ezp.waldenulibrary.org/10.1016/j.techfore.2019.07.011

Denzin, N. K. (2012). Triangulation 2.0. *Journal of Mixed Methods Research, 6,* 80–88. doi:10.1177/1558689812437186

Denzin, N. K., & Lincoln, Y. S. (2015). *Introduction: The discipline and practice of qualitative research. In N. K. Denzin & Y. S. Lincoln (Eds.), The Sage handbook of qualitative research (4th ed.)* Sage Publications.

Dinkelaker, T. (2016). A false sense of safety: How the drug quality and security act fails to protect patients from harm. *Saint Louis University Journal of Health Law & Policy*, *2*, 329. https://doi.org/10.46743/2160-3715/2015.2326

Dittes, S., Urbach, N., Ahlemann, F., Smolnik, S., & Müller, T. (2016). Why don't you stick to them? Understanding factors influencing and countermeasures to combat deviant behavior towards organizational IT standards. *Wirtschaftsinformatik*, 615-629.

Doody, O., & Noonan, M. (2016). Nursing research ethics, guidance and application in practice. *British Journal of Nursing*, *25*, 803–807. doi:10.12968/bjon.2016.25.14.803

Dorsey, E. R., Thompson, J. P., Dayoub, E. J., George, B., Saubermann, L. A., &

Holloway, R.G. (2009). Selegiline shortage: Causes and costs of a generic drug shortage. *Neurology; 73*, 213–217. doi:10.1212/WNL.0b013e3181ae7b04

Eliasen, Logan J. 2020. “The drug quality and security act: Providing Quality, but Not Security, for Patients.” Iowa Law Review 103 (3): 124–175.

Elo, S., Kääriäinen, M., Kanste, O., Polkki, T., Utriainen, K., & Kyngas, H. (2016). Qualitative content analysis: A focus on trustworthiness. *SAGE Open*, *4*, 1–10. doi:10.1177/2158244014522633

Elona, G., & Albert, W. (2016). Review of drug quality and security act of 2013: The drug supply chain security act. *Innovation in Pharmacy, 3*, 7–11. doi:10.24926/iip.v7i3.462

Escoffery, C., Kenzig, M., & Hyden, C. (2018). Getting the most out of professional associations. *Health Promotion Practice, 16*(3), 309–312. doi:10.1177/1524839914566654

Fawcett, S. E., Ellram, L., & Ogden, J. A. (2016). *Supply chain management: From vision to implementation. An integrative approach*. Pearson Higher Ed.

Food and Drug Administration (2018). *U.S. Food and Drug Administration.* https://www.fda.gov/about-fda/fda-organization/center-drug-evaluation-and-research-cder

Ferreira, A. I. (2017). Leader and peer ethical behavior influences on job embeddedness. *Journal of Leadership & Organizational Studies*. Advanced online publication. doi:10.1177/1548051817702095

Fida, R., Paciello, M., Tramontano, C., Barbaranelli, C., & Farnese, M. L. (2016). Yes, I

can: The protective role of personal self-efficacy in hindering counterproductive work behavior under stressful conditions. Anxiety, Stress, & Coping, 28, 479–499. doi:10.1080/10615806.2014.969718

Fox, E. R., Sweet, B. V., & Jensen, V. (2017). Drug shortages: A complex care crisis. *Mayo Clinic Proceedings, 89,* 361–373. doi:10.1016/j.mayocp.2013.11.014

Fusch, P. L., & Ness, L. R. (2017). Are we there yet? Data saturation in qualitative research. *The Qualitative Report, 20,* 1408–1416. https://doi.org/10.46743/2160-3715/2017.2580

Gaikwad, P. (2017). Including rigor and artistry in case study as a strategic qualitative methodology. *The Qualitative Report, 22,* 3431–3446. https://doi.org/10.46743/2160-3715/2017.3436

Giesecke, S. (2000). The contrasting roles of government in the development of biotechnology industry in the US and Germany. *Research Policy*, *29*(2), 205–223. https://doi.org/10.46743/2160-3715/2000.3436

Giri, B. C., & Sarker, B. R. (2017). Improving performance by coordinating a supply chain with third party logistics outsourcing under production disruption. *Computers & Industrial Engineering, 103,*168–177. doi:10.1016/j.cie.2016.11.022

Green, K. W., Zelbst, P. J., Meacham, J., & Bhadauria, V. S. (2012). Green supply chain management practices: Impact on performance. *Supply Chain Management: An International Journal, 17,* 290–305. doi:10.1108/13598541211227126

Goedhuys, M., & Sleuwaegen, L. (2016). International standards certification,

institutional voids, and exports from developing country firms. *International Business Review, 25*, 1344–1355. doi:10.1016/j.ibusrev.2016.04.006

Golparvar, M. (2016). Unconventional functions of deviant behaviors in the relationship between job stress and emotional exhaustion: Three study findings. *Current Psychology, 35*, 269–284. doi:10.1007/s12144-014-9292-8

Gunia, B. C., & Kim, S. Y. (2016). The behavioral benefits of other people's deviance. *Group Processes & Intergroup Relations, 19*, 653–675. doi: 10.1177/1368430216638532

Hackman, W. J., & Wageman, R. (1995). Total quality management: Empirical, conceptual, and practical issues. *Administrative Science Quarterly, 40*(2), 309–343. doi:10.4236/jssm.2015.81004

Hadjul, M., & Kolinska, K. (2016). Supply chain management risks based on logistic and statistical indicators. *Logforum, 10*(1),15–27. doi: 10.17270/J.LOG.2016.1.2

Haeyoung, K. (2017). The drug quality and security act of 2013: Compounding consistently. *Journal of Health Care Law & Policy*, *19*(2), 299–335. https://doi.org/10.4135/9781452240121.n308

Halldorsson, A., Hsuan, J., & Kotzab, H. (2015). Complementary theories to supply chain management revisited – From borrowing theories to theorizing. *Supply chain management, 20*, 574–586. doi:10.1108/scm-06-2015-0228

Harold, C. M., Oh, I. S., Holtz, B. C., Han, S., & Giacalone, R. A. (2016). Fit and frustration as drivers of targeted counterproductive work behaviors: A multifoci perspective. *Journal of Applied Psychology, 101*, 1513–1535

.doi:10.1037/apl0000150

Hartmann, A., & Dorée, A. (2015). Learning between projects: More than sending messages in bottles. *International Journal of Project Management, 33*, 341–351. doi:10.1016/j.ijproman.2014.07.006

Harvey, L. (2016). Beyond member-checking: A dialogic approach to the research interview. *International Journal of Research & Method in Education, 3*8, 23–38. doi:10.1080/1743727X.2014.914487

Haugh, H. M., & Talwar, A. (2016). Linking social entrepreneurship and social change: The mediating role of empowerment. Journal of Business Ethics, 133, 643–658. doi:10.1007/s10551-014-2449-4

Hernández-Carrión, C., Camarero-Izquierdo, C., & Gutiérrez-Cillán, J. (2017). Entrepreneurs' social capital and the economic performance of small businesses: The moderating role of competitive intensity and entrepreneurs' experience. *Strategic Entrepreneurship Journal*, *11*(1), 61–89. doi:10.1002/sej.1228

Hoeber, L., & Shaw, S. (2017). Contemporary qualitative research methods in sport management. *Sport Management Review*, *20*, 4–7. doi:10.1016/j.smr.2016.11.005

Horsburgh, J., & Ippolito, K. (2018). A skill to be worked at: Using social learning theory to explore the process of learning from role models in clinical settings. *BMC Medical Education*, 18, 1–8. doi:10.1186/s12909-018-1251-x

Houghton, C., Murphy, K., Shaw, D., & Casey, D. (2015). Qualitative case study data analysis: An example from practice. *Nurse Researcher, 22(5)*, 8–12. doi:10.7748/nr.22.5.8.e1307

Huang, L., Chao, S. & Hu, C. (2020). Clinical trials of new drugs for Alzheimer disease. *Biomed Science **27, 18***. doi.org/10.1186/s12929-019-0609-7

Jacob, S. A., & Furgerson, S. P. (2015). Writing interview protocols and conducting interviews: Tips for students new to the field of qualitative research. *Qualitative Report*, 17, 1–10. https://doi.org/10.4135/9781452240121.n308

Jacobs, et al. (2015). Determining the predictors of innovation implementation in healthcare: A quantitative analysis of implementation effectiveness. *BMC Health Services Research, 15 (6),* 1–13. doi:10.1186/s12913-014-0657-3

Jagsi, R., Spence, R., Rathmell, W. K., Bradbury, A., Peppercorn, J., Grubbs, S., & Moy, (2014). Ethical considerations for the clinical oncologist in an era of oncology drug shortages. The Oncologist, 19(2), 186–192. doi:10.1634/theoncologist.2013-0301

Janvier-James, A. M. (2012). A new introduction to supply chains and supply chain management: Definitions and theories perspective. *International Business Research, 5*, 194–207. doi.10.5539/ibr.v5n1p194

Joghee, R. (2019). Six sigma metrics based on lognormal distribution for life tests. *The International Journal of Quality & Reliability Management, 36*(9), 1477–1489. doi:10.1108/IJQRM-05-2018-0135

Joslin, R., & Müller, R. (2016). Identifying interesting project phenomena using philosophical and methodological triangulation. *International Journal of Project Management, 34*. 1043–1056. doi:10.1016/j.ijproman.2016.05.005

Juran, J. M., & Gryna, F. M. (1988). *Juran's Quality Control Handbook* (4th ed.).

McGraw Hill.

Katamesh, A. B., Alafnan, A., & Alshammari, R. F. (2019). An oncoinformatics study to predict the inhibitory potential of recent FDA-approved anti-cancer drugs against human Polo-like kinase 1 enzyme: A step towards dual-target cancer medication. *3 Biotech, 9*, 70–84. doi:10.1007/s13205-019-1594-

Kalshoven, K., van Dijk, H., & Boon, C. (2016). Why and when does ethical leadership evoke unethical follower behavior? *Journal of Managerial Psychology, 31*, 500 - 515. doi:10.1108/JMP-10-2014-0314

Kharub, M. (2019). Critical factors of effective implementation of IT-enabled ISO-9000 QMS. *The International Journal of Quality & Reliability Management, 36*(9), 1600–1619. doi:10.1108/IJQRM-09-2018-0253

Kirkwood, A., & Price, L. (2017). Examining some assumptions and limitations of research on the effects of emerging technologies for teaching and learning in higher education. *British Journal of Educational Technology, 44*, 536–543. doi:10.1111/bjet.12049

Kirovska, Z., Josifovska, A., & Kiselicki, M. (2016). Efficient management of supply chain in achieving a significant competitive advantage in the market. *Journal of Sustainable Development, 5*(14), 5–22.

Knight, K., Worrall, L., & Rose, T. (2015). The provision of health information to stroke patients within an acute hospital setting: what happens and how do patients feel about it? *Topics in Stroke Rehabilitation, 22*, 78–97. doi:10.1310/FC6M-P7L0-W3XD-4WAE

Koc, T., & Bozdag, E. (2017). Decision support: Measuring the degree of novelty of innovation based on Porter's value chain approach. *European Journal of Operational Research, 257,* 559–567. doi:10.1016/j.ejor.2016.07.049

Kweder, S. L., & Dill, S. (2012). Drug shortages: The cycle of quantity and quality. *Clinical Pharmacology Therapeutics, 93*, 245–251. doi:10.1038/clpt.2012.235

Leiter, M., Caccia, J., Cruz, H., Hoffman, M., Schnell, J., Schlager, I., Vieira, D., Gafni, J., & Gerkin, D. (2019). Governance implications of CFIUS reform for US investment funds with foreign investors. *Journal of Investment Compliance (Emerald Group), 20*(1), 36–39. https://doi-org10.1108/JOIC-01-2019-0010

Lincoln, J. E. (2012). Overview of the US FDA GMPs: Good Manufacturing Practice (GMP)/Quality System (QS) Regulation (21 CFR Part 820). *Journal of Validation Technology*, *18*(3), 17

Lingenfelter, J. A. (2015). Putting the "public" back in "public use": interpreting the 2011 Leahy-Smith America Invents Act. *Georgia State University Law Review*, *4*, 867.

Lichtman, M. (2017). *Qualitative research for the social sciences.* Sage Publications, Inc.

Marshall, C., & Rossman, G. B. (2016). *Designing qualitative research* (6th ed.). Sage Publication.

Marshall, B., Cardon, P., Poddar, A., & Fontenot, R. (2013). Does sample size matter in qualitative research? A review of qualitative interviews in IS research. Journal of *Computer Information Systems*, *54*(1), 11–22. doi:10.1080/08874417.2013.11645667

Martyn, P., Sweeney, B., & Curtis, E. (2016). Strategy and control: 25 years of empirical use of Simons' levers of control framework. *Journal of Accounting & Organizational Change, 12*, 281–324. doi:10.1108/JAOC-03-2015-0027

McLaughlin, M. M., & Skoglund, E.W. (2015). Drug shortages and patient safety. *Journal of Infusion Nursing*, *38*(3), 205–208. doi:10.1097/NAN.0000000000000101

McPhee, W. (2015). A new sustainability model: Engaging the entire firm. *Journal of Business Strategy*, *35*(2), 4–12. doi:10.1108/JBS-11-2013-0106

Mirasol, F. (2020). Navigating GMPs for gene therapies. *BioPharm International*, *33*(3), 29–32.

Mirza, S. S., & Ahsan, T. (2020). Corporates' strategic responses to economic policy uncertainty in China. Business Strategy and the Environment, 29(2), 375–389. doi:10.1002/bse.2370

Miyagiwa, K. (2015). The 2011 America Invents Act: Does it undermine innovation? *Journal of Economics & Management Strategy*, *24*(2), 211–227. https://doi-org./10.1111/jems.12092

Morse, J. M. (2015). Critical analysis of strategies for determining rigor in qualitative inquiry. *Qualitative Health Research, 25*, 1212–1222. doi:10.1177/1049732315588501

Moylan, C. A., Derr, A. S., & Lindhorst, T. (2016). Increasingly mobile: How new technologies can enhance qualitative research. *Qualitative Social Work, 14*,36–47. doi:10.1177/1473325013516988

Munechika, M., Sano, M., Jin, H., & Kajihara, C. (2016). Quality management system for health care and its effectiveness. *Total Quality Management & Business Excellence, 25*, 889–896. doi:10.1080/14783363.2014.906112

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*.

Noble, H., & Smith, J. (2015). Issues of validity and reliability in qualitative research. *Evidence-Based Nursing, 18*(2), 34–35. doi:10.1136/eb-2015-102054

Ose, S. O. (2016). Using excel and word to structure qualitative data. *Journal of Applied Social Science, 10.* 147–162. doi:10.1177/1936724416664948

Oskooee, H. A. (2017). Key factors in strategy implementation. Kidmore End: Academic Conference International Limited. *Journal of International Business Disciplines*, *14*(1), 21–52

Page, R. A., Cyr, D. M., & Richardson, A. S. (2015). Sustainability and stratified noncompliance in the pharmaceutical industry. *Journal of International Business Disciplines*, *10*(1), 18–40.

Pazhayattil, A. B., Ingram, M., & Sayeed, N. (2019). Lessons from FDA 483s and cGMP Inspection Data: Production and process controls, organization and personnel were the top problems found, while packaging and labelling citations increased in 2017 and 2018. *Pharmaceutical Technology Europe, 10*, 38.

Peters, R. (2019). Warning Letters Signal Steps to Compliance: Warning letters tell the tale of missteps by drug companies and offer a path to compliance for quality

teams that monitor these enforcement actions. *BioPharm International*, *33*(3), 3–4.

Porter, M. (1985). *Competitive advantage: Creating and sustaining superior performance.* The Free Press.

Pinto, J. K., & Winch, G. (2016). The unsettling of "settled science: The past and future of the management of projects. *International Journal of Project Management, 34*, 237–245. doi:10.1016/j.ijproman.2015.07.011

Prajogo, D., Oke, A., & Olhager, J. (2016). Supply chain processes. *International Journal of Operations & Production Management*, *36*, 220-238. doi:10.1108/IJOPM-03-2014–0129

Quality Council of Indiana. (2007). *Certified Six Sigma Black Belt Primer*. West Terre Haute, IN: Quality Council of Indiana

Reid, M., Hultink, E. J., Marion, T., & Barczak, G. (2016). The impact of the frequency of usage of IT artifacts on predevelopment performance in the NPD process. *Information & Management, 53*(4), 422. doi.org/10.1016/j.im.2015.10.008

Reis, R. I. (2012). Smoke and mirrors: America Invent Act 2011: A chill in the air. *Akron Intellectual Property Journal*, *2*, 301. doi.org/10.1016/j.im.2015.10.008

Ritchie, J., Lewis, J., Nicholls, C. M., & Ormston, R. (Eds.). (2016*). Qualitative research practice: A guide for social science students and researchers*. Sage.

Rijsbergen, B. A., Elbers, W., Ruben, R., & Njuguna, S. N. (2016). The ambivalent impact of coffee certification on farmers' welfare: A matched panel approach for cooperatives in central Kenya. World Development, 77, 277–292.

doi:10.1016/j.worlddev.2015.08.021

Robins, C. S., & Eisen, K. (2017). Strategies for the effective use of NVivo in a largescale study: Qualitative analysis and the repeal of Don't Ask, Don't Tell. *Qualitative Inquiry*, *23*, 768–778. doi:10.1177/1077800417731089

Robinson, O. (2014). Sampling in interview-based qualitative research: A theoretical and practical guide. *Qualitative Research in Psychology*, *11*(1), 25–41. doi:10.1080/14780887.2013.801543

Rosenthal, M. (2017). Qualitative research methods: Why, when, and how to conduct interviews and focus groups in pharmacy research. *Currents in Pharmacy Teaching and Learning*, *8*, 509-516. doi:10.1016/j.cptl.2016.03.021

Rubin, E. N., (2012). A partnered approach to QA increases efficiency through early problem detection. *Global Business & Organizational Excellence*, *31*(4), 28–37. 10.1002/joe.21431

Schniepp, S. J. (2019). Quality risk management plans create effective quality systems. *Pharmaceutical Technology*, *43*(8), 50–49.

Sharma, L. L., Teret, S. P., & Brownell, K. D. (2010). The food industry and self-regulation: Standards to promote success and to avoid public health failures. *American Journal of Public Health*, 100, 240–246. doi:10.2105/AJPH.2009.160960

Simons, R. A. (1995), *Levers of Control*, Boston, MA: Harvard Business School Press.

Sipe, M. G. (2019). Experts, generalists, laypeople, and the federal circuit. *Harvard Journal of Law & Technology*, *2*, 575

Small, W., Maher, L., & Kerr, T. (2014). Institutional ethical review and ethnographic research involving injection drug users: A case study. *Social Science & Medicine, 104*, 157–162. doi:10.1016/j.socscimed.2013.12.010

Smith, A. D., & Rupp, W. T. (2016). Supply chain integration and innovation in a global environment: Case studies of best business practices. *International Journal of Logistics Systems and Management, 22*(3), 1–15. doi:10.1504/IJLSM.2015.072284

Standing, O., Standing, S., & Kordt, E. (2016). Explaining attribution in information technology projects. *Journal of Systems and Information Technology, 18*, 216–227. doi:10.1108/JSIT-01-2016-0002

St. Pierre, E. A., & Jackson, A. Y. (2014). Qualitative data analysis after coding. *Qualitative Inquiry, 20*, 715–719. doi:10.1177/1077800414532435

Stoica, R., & Brouse, P. (2017). An adaptive and preemptive theory for improving systemic IT project failure trends ("AdaPIT" theory). *Procedia Computer Science, 28*, 247–256. doi:10.1016/j.procs.2014.03.031

Strauss, L. M., & Borenstein, D. (2015). A system dynamics model for long-term planning of the undergraduate education in Brazil. *Higher Education, 68*, 375-397. doi:10.1007/s10734-014-9781-6

Trilling, D. W. (2012). Recognizing a Need for Reform: The Leahy-Smith America Invents Act of 2011. *Journal of Law, Technology & Policy, 2012*(1), 239.

U.S. Census Bureau News. (2017). *Manufacturing and trade inventories and sales.*

United States Department of Health and Human Services: Office for Human Research

Protections. (1979). The Belmont Report. https://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-belmont-report-1979

Vaidya, O. S., Ganapathy, L., & Kumar, S. (2019). A cost minimization model for system reliability allocation. *The International Journal of Quality & Reliability Management, 36*(9), 1620–1643. doi:10.1108/IJQRM-07-2018-0199

Vale, J., Branco, M. C., & Ribeiro, J. (2017). Individual intellectual capital versus collective intellectual capital in a meta-organization. *Journal of Intellectual Capital, 17*, 279–297. doi:10.1108/JIC-06-2015-0058

Van Dusen, V., & Pray, W. S. (2019). Teaching non-FDA approved nonprescription products: Educating students about potential risks and liability. *Currents in Pharmacy Teaching and Learning*, *11*(7), 655–657. doi-10.1016/j.cptl.2019.03.002

Vellema, W., Casanova, A. B., Gonzalez, C., & Haese, M. (2016). The effect of specialty coffee certification on household livelihood strategies and specialization. *Food Policy, 57,* 13–25. doi:10.1016/j.foodpol.2015.07.003

Ventola, C. V. (2015). The drug shortage crisis in the United States: Causes, impact, and management strategies. *Pharmacy and Therapeutics, 36,* 740–757

Wakely, J., & Indorf, A. (2018). Managing national security risk in an open economy: Reforming the committee on foreign investment in the United States. *Harvard National Security Journal*, *9*(2), 1–50.

Walsh, I. (2015). Using quantitative data in mixed-design grounded theory studies: An enhanced path to formal grounded theory in information systems. *European*

Journal of Information Systems, 24, 531–557. doi:10.1057/ejis.2014.23

Wang, L., Zheng, H., Ren, X., & Sun, H. (2016). Trend analysis of FDA warning letters issued to medical products about violations to current good manufacturing practices (cGMP) between 2007 and 2014. *Therapeutic Innovation & Regulatory Science, 50*, 312–318. doi:10.1177/2168479015619201

Westbrook, A. D. (2019). Securing the nation or entrenching the board? The evolution of cfius review of corporate acquisitions. *Marquette Law Review, 102*(3), 643–699.

Wiggins, J. M., & Albanese, J. A. (2019). Revision Process for Global/National Pharmacopoeias: This article describes the revision process and the resulting publication of proposed and official updates for pharmacopoeias around the world. *BioPharm International,33*(3) 14–24

Woodcock, J., & Wosinska, M. (2013). Economic and technological drivers of generic sterile injectable drug shortages. *Clinical Pharmacology &. Therapeutics, 93*(1), 170–176. doi:10.1038/clpt.2012.220

Wu, Y. C. (2017). Mechanisms linking ethical leadership to ethical sales behavior. *Psychological Reports, 120*, 537-560. doi:10.1177/0033294117693594

Yelderman, S. (2019). Prior art in inter partes review. *Iowa Law Review, 5*, 2705.

Yin, R. K. (2017). *Case study research and applications: Design and methods* (6th ed.). Sage.

Young, A. M., & MacPhail, A. (2016). ‘Standing on the periphery’: Cooperating teachers’ perceptions and responses to the role of supervision. *European Physical Education Review, 21*, 222–237. doi:10.1177/1356336X14557582

Appendix: Case Study Interview Protocol Checklist

Pre-Interview	
Interview date:	Interview time:
Interview location:	Interview duration estimate:
Participant pseudonym:	Participant code:

Interview documentation and materials	
Receipt of Informed Consent (Yes or No):	Eligibility criteria met (Yes or No):
Receipt of Permission to Record and Transcribe (Yes or No):	Test Primary and back-up recording device (Yes or No):

Conduct of interview	
Introductions (Yes or No):	Overview of research topic (Yes or No):
Discuss purpose	Questions from participant (Yes or No):
Discuss risk	Questions from participant (Yes or No):

Discuss confidentiality	Questions from participant (Yes or No):
Discuss right to withdraw	Questions from participant (Yes or No):
Discuss benefits	Questions from participant (Yes or No):
Discuss data security	Questions from participant (Yes or No):

Interview	
My observations and actions: a. Body language b. Non-verbal cues c. Paraphrasing	a) What leadership strategies do you use to embed a culture of quality and compliance within your company
d. Probing questions e. Follow-questions	b) How does your management team formulate and adopt product quality compliance techniques?

		c) How does your organization integrate quality compliance strategies into your internal and, or external quality compliance metric systems?
		d) What total quality management processes and tool does your organization use to implement your quality management strategies?
		e) How does your organization identify the key opportunities for quality improvement within your quality and compliance processes to assure FDA quality compliance requirements are met?

	f) What, if any, supply chain management technologies do your organization use to address key barriers to integrating FDA product quality requirements into your product quality metrics?
	g) What other information can you provide about the strategies used by your organization to apply and integrate FDA's quality compliance requirements into your products' quality metrics?

Post-interview follow-up	
Thank participant for contribution	Actual interview duration:
Discuss next steps:	Questions from participant (Yes or No):
a. Completion of transcript b. Concept of member checking c. Set up a date for member checking follow-up d. Notification of findings e. Duration of data security	Questions from participant (Yes or No):

<table>
<tr><td colspan="2">Member checking follow-up</td></tr>
<tr><td>Follow-up date:</td><td>Provide copy of synthesis for each question</td></tr>
<tr><td>Introduce member checking process</td><td>Questions from participant (Yes or No):</td></tr>
<tr><td rowspan="6">My observations and actions:
• Additional probing questions
• Affirm synthesis for each question
• Ask for further interpretation or additional information
• Ask what was missed in the initial interview</td><td>a) Synthesis of 1st question</td></tr>
<tr><td>b) Synthesis of 2nd question</td></tr>
<tr><td>c) Synthesis of 3rd question</td></tr>
<tr><td>d) Synthesis of 4th question</td></tr>
<tr><td>e) Synthesis of 5th question</td></tr>
<tr><td>f) Synthesis of 6th question</td></tr>
</table>