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Strategies to Influence a Quality and Compliance Culture

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This is to certify that the doctoral study by

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Abstract

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MBA, Walden University, 2010

BS, The Pennsylvania State University, 1979

Doctoral Study Submitted in Partial Fulfillment

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Abstract

In drug, medical, and consumer products businesses, leaders should establish strategies that ensure production of quality products and drive profitability. Sales of defective or substandard products carry a potential risk of unintended effects on the consumer. The purpose of this single case study was to explore the strategies used by leaders to influence a culture of quality and compliance, leading to production of saleable products, and business profitability. The conceptual framework of the theory of constraints served to guide the scope and data analysis for this study. Participants included ten individuals with a minimum of 5 years of experience at the study company, based in the northeast region of the U.S., in director, manager, and technical leader roles who participated in individual, telephone-based interviews. Additional data sources for methodological triangulation included observations during a tour of the headquarters site, and analysis of policies, procedures, annual reports, and publically available information. Data analysis included coding of the data and analysis to identify themes and patterns that identify the strategies leaders use to embed a culture of quality. The emergent themes in this study included: leadership, culture and habits, communications, and management systems and data analysis. The findings of this study may contribute to positive social change and improved business practice by providing tools and skills needed by business leaders to ensure product quality and business success. By consistently delivering quality products to the market, the organization builds a sustainable business where the community can benefit from a stable supply of jobs and the consumer from a reliable supply of products that safely meet customer needs.

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Dedication

I would like to dedicate this study to my parents, brothers, husband, and sons for

their support, patience, and encouragement as I worked to achieve this goal.

Acknowledgments

I would like to thank my family, including my "younger sister", and colleagues and friends for their support as I completed this journey. I would also like to thank the Walden University faculty and staff who have supported me during the DBA process. In particular, I would like to thank my chair, Dr. Anne Davis, for her patience and critical feedback driving me to deliver the best work possible. I would also like to thank my committee, Dr. R. Dwyer and Dr. J. Savard; and Dr. Doron Zilbershtein and Dr. Ann L. Claesson, both of whom mentored me at critical points early in my DBA journey.

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Section 1: Foundation of the Study

In 2013, the U.S. Department of Justice (DOJ) issued over $450 million in fines to major pharmaceutical companies for health care violations (DOJ, 2014) covering product and manufacturing process related issues. Fines from regulatory agencies increase business costs but ensure that the products sold meet customer expectations (Liu & Xiong, 2015; Roman, 2014). The use of a quality management system (QMS) improves product quality providing clear guidance to employees on work performance (Hongyan & Yanan, 2014). In addition, a QMS unites the culture by embedding quality and compliance principles, ensures that products meet specifications and comply with applicable regulations, and drives production of marketable products that meet customer demand and secure business profitability (Doyle, McGovern, & McCarthy, 2014; Tzavara & Heritier, 2012; Weingarten, Fynes, Cheng, & Chavez, 2013; Zehir, Ertosun, Zehir, & Müceldilli, 2012).

Hofmann and Oldehaver (2015) noted the need for a high commitment to product quality. Without this commitment, an enterprise may produce substandard products, driving higher business risks, and in drug, medical, and consumer healthcare products, increasing the possibility of unintended side effects and health affects (Hofmann & Oldehaver, 2015). Schmiedel, vom Brocke, and Recker (2013) posited that four core values of customer orientation, excellence, responsibility, and teamwork guide the development of a culture. These core values create the link between a quality culture and effective business process management (Schmiedel, vom Brocke, & Recker, 2012). An effective organizational culture integrates three characteristics, including: consistency

across cultural indicators, a consensus among organizational members, and a focus on leaders as culture creators (Green, 2012). While Schmiedel et al. and Green chose different words to describe the key factors, they both emphasized the need for an effective organizational culture to incorporate similar behaviors where excellence aligns to consistency, responsibility aligns to leadership, and organizational consensus aligns to teamwork. To embed a culture of quality, leaders need to establish work routines and habits linking quality to organizational performance (Polites & Karahanna, 2013), ensuring that employees utilize internal procedures and adhere to quality processes. Neal, Wood, Labrecque, and Lally (2012) posited that there is a positive behavioral association in relation to goals and actual habit performance, and a nonlinear relationship between the influences of goals on habit performance.

Background of the Problem

A quality product needs to meet consumer expectations, product specifications, and health authority regulations (Doyle et al., 2014; Tzavara & Heritier, 2012; Weingarten et al., 2013; Zehir et al., 2012). When a product does not meet specifications, it will not meet customer expectations or health authority regulations, potentially resulting in regulatory citations, fines, and product recalls (Doyle et al., 2014; Tzavara & Heritier, 2012). Citations, fines, and recalls increase the cost of doing business, potentially influencing the overall success of the enterprise. Ensuring product quality and compliance requires that manufacturers invest in processes that ensure products sold meet customer expectations (Liu & Xiong, 2015; Roman, 2014). These same processes must encourage employees to adopt the habits and behaviors that embed

a culture of quality and compliance. A sustainable enterprise meets customer demand by delivering products that meet quality specifications and deliver expected results (Liu & Xiong, 2015; Roman, 2014).

To ensure a culture of quality, leaders and employees require an understanding of the behaviors and habits that embed a culture of quality into the organization (Rashid & Aslam, 2012). Rashid and Aslam (2012) identified the need to reward employees who identify opportunities for product and process improvement as a means to institute a culture focused on continuous improvement. Business leaders also need information on how to ensure compliance by integrating health authority regulations and standards into the organizational culture while maintaining a high level of employee performance and manufacturing productivity (Valmohammadi & Roshanzamir, 2015). The ability of an enterprise to deliver quality consumer healthcare, pharmaceutical, and medical products that meet compliance obligations may enable sustained market performance by meeting customer requirements and needs.

Problem Statement

Businesses unable to meet quality and compliance requirements produce fewer saleable products, resulting in decreased sales and profit (Kober, Subraamanniam, & Watson, 2012). In 2013, the U.S. DOJ acted on behalf of the Food and Drug Administration (FDA), issuing over $450 million in fines to healthcare products manufacturing companies for violations of the regulations that ensure the safety of consumers by requiring that the products sold meet specifications (DOJ, 2014). The general business problem is that the availability of marketable products, negatively

affected by the quality and compliance culture, results in product shortages, an inability

to meet customer demand, and loss of business profitability. The specific business

problem is that some healthcare manufacturing leaders of consumer healthcare,

pharmaceutical, and medical device companies lack the strategies to embed a culture of

quality and compliance within their organizations to assure sufficient production of

marketable products that meet customer demand.

Purpose Statement

The purpose of this qualitative case study was to explore the strategies healthcare

manufacturing leaders use to embed a culture of quality and compliance within their

organization in order to assure sufficient production of marketable products to meet

customer demand and be profitable. The targeted population consisted of leaders in a

healthcare products company located in the northeast region of the United States where

the products include chemical intermediates for use in consumer healthcare, medical, and

pharmaceutical products. The findings from my study may contribute to positive social

change and improved business practice by providing tools and skills needed by business

leaders to ensure product quality.

Nature of the Study

I used the qualitative research method, using a single case study design, for this

study. Cronin (2014) and Yin (2014) discussed that the choice of a qualitative method

enables the use of interviews, documentation, and secondary sources for data collection.

Percy, Kostere, and Kostere (2015) discussed the use of *what* and *how* questions in

qualitative research to explore the experiences of individuals and groups, and how those

experiences influence actions and decisions. Researchers following the quantitative method use data and statistical analysis to identify and support study findings (Norris, Plonsky, Ross, & Schoonen, 2015), allowing the researcher to test theory, examine variations and connections between variables, and analyze numerical data (Bettany-Saltikov & Whittaker, 2013; Macur, 2013).

Researchers use the quantitative method to test hypotheses (Jacobs et al., 2015). In this study, I did not test a hypothesis; therefore, the quantitative method was not appropriate. Mixed methods researchers combine the use of qualitative and quantitative methods into one study. The decision to engage in mixed methods research depends on the research question, purpose, and setting (Venkatesh, Brown, & Bala, 2013). I felt that it was not necessary to use the additional complexity of the mixed methods approach for this study at this time. Use of the qualitative method provided a good starting point to explore the strategies used by the study company to influence a culture of quality and compliance. Further study using the mixed methods approach may be appropriate at a future date. The qualitative method suited my study, using *what* and *how* questions to explore the strategies used to influence a culture of quality and compliance.

The single case study design enables a thorough investigation of a single management situation (Mariotto, Zanni, & de Moraes, 2014). I applied the single case study design to explore strategies to influence a quality and compliance culture within one organization across different geographical locations. Other research designs I considered included phenomenology, grounded theory, narrative, and ethnography. Phenomenology enables researchers to study the learned behaviors of a study population

across multiple businesses and does not allow for in-depth exploration of the phenomenon and rich description within one enterprise (Moustakas, 1994; Yin, 2014). A researcher using the grounded theory design uses an inductive approach to answer research questions exploring the relationships between people (Redman-MacLaren & Mills, 2015). The inductive research approach of the grounded theory means that a researcher moves from the specific to the general to explain the phenomenon under study (Foley & Timonen, 2015). The grounded theory process requires the researcher to stay open to whatever the data says, developing a concept and theory after data collection and analysis (Foley & Timonen, 2015; Redman-MacLaren & Mills, 2015) and was not suited to this study.

A researcher using a narrative design systematically explores the stories of a particular study group (Robert & Shenhav, 2014; Souto-Manning, 2014). Analysis of the stories potentially enables researchers to develop new theories and identify connections between the emotional and symbolic aspects of an enterprise (Garcia & Gluesing, 2013) and was not suitable for this study. A researcher using an ethnographic design looks into the daily lives, community processes, and activities of a study population looking at the behaviors of a particular culture (Small, Maher, & Kerr, 2014). The ethnographic design would not allow me access to a diverse study population located in different geographic locations. I chose to use a single case study design allowing me to explore the strategies used to influence a culture of quality and compliance. Businesses unable to meet quality and compliance requirements manufacture fewer saleable products resulting in decreased sales and profit (Kober et al., 2012). The reduction of saleable products can create drug

shortages affecting the range and variety of treatments available to consumers (Roman, 2014).

Research Question

The experiences of business leaders in an enterprise in embedding a culture of quality and compliance formed the basis for the interview questions for this study. The central research question for my study was: *what strategies influence quality and compliance in an organization assuring production of marketable products and meeting customer demand?* The following eight interview questions enabled an understanding of the experiences of business leaders and guided the interviews for my study.

Interview Questions

1. What leadership strategies do you use to embed a culture of quality and compliance within your company to assure production of marketable products?

2. What habits does your organization identify as critical to sustaining a culture of quality and compliance?

3. How did you determine where there are opportunities for improvement of your quality and compliance culture?

4. How do you choose programs to address and correct internal and/or external failures assuring production of marketable products and achievement of business profitability goals?

5. Which appraisal programs do you find effective in reinforcing a culture of quality and compliance and why?

6. What prevention programs do you find effective as part of your leadership strategies and why?

7. How do you shift your culture, when needed, to maintain a culture of quality and compliance, and assure production of marketable products?

8. What other information could you provide on quality culture that might be helpful in completing this study?

Conceptual Framework

Goldratt (1992) introduced the theory of constraints (TOC) to business professionals as a five-step process (Naor, Bernardes, & Coman, 2013; Pacheco, 2014; Sadat, Carter, & Golden, 2012). When applying the TOC, the business professional asks: *What must be changed? What is the change goal? How does one implement this change?* (Ying-Chyi, Ching-Hua, & Ya-Yun, 2012, p. 4688). Goldratt's five steps help professionals estimate whether a constraint could arise in a specific place within a process, and then identify opportunities to manage and/or eliminate the constraint(s) (Naor et al., 2013). Ronen and Spector (1992) enhanced the TOC methodology by adding two additional steps to Goldratt's five-step process (Goldratt, 1992; Spector, 2011). Goldratt's five steps included:

1. Identify the system's constraint.

2. Decide how to exploit the system's constraints.

3. Subordinate everything else to the above decision.

4. Elevate the system's constraint(s).

5. If in the previous steps a constraint has been broken, go back to step 1, but do

not allow inertia to cause a system's constraint. (Goldratt, 1992, p. 307)
Ronen and Spector added the following two preliminary steps to use in advance of
Goldratt's first step:

(1a) Define the system's goal.

(1b) Determine global performance measures. (Spector, 2011, p. 3389).

In the early 2000s, Naor et al. (2013) refined the application of the TOC to the healthcare
industry. Literature exists about the TOC principles describing the application to
production analysis in various industries, project management, knowledge management,
product analysis, and the healthcare industry (Naor et al., 2013).

I utilized the TOC as my conceptual framework because business leaders have
utilized this framework to identify problems and then identify strategies to solve the
problem (Ying-Chyi et al., 2012). When organizations apply the TOC, leaders define the
framework for analysis from the perspective of the company as a system. The system
reflects the relationship of the different parts of an organization, and how the different
parts or subsystems fit together (Spector, 2011). When applying the TOC, leaders define
goals within the system, relying on a series of subsystems with the potential to have one
or more constraints (Pacheco, 2014; Spector, 2011).

Part of my TOC analysis includes measuring performance within the subsystems
against business goals to identify the constraints (Goldratt, 1992; Gupta, Gurjeet, &
Chahal, 2013; Naor et al., 2013; Pesic, Andelkowic, & Dasic, 2013). Constraints
interfere with the functioning of the system or subsystems resulting in poor production
performance and impacting product quality and compliance (Goldratt, 1992). By using

the TOC, leaders can identify the constraints that affect product quality and compliance at

the origin and eliminate the constraint (Librelato, Lacerda, Rodrigues, & Veit, 2014).

Definition of Terms

Compliance: Compliance assures that safe and effective products are available to

consumers that meet government regulations preventing the sale of unsafe, ineffective,

and poor quality products (CPSC, 2012; FDA, 2015).

Healthcare, pharmaceutical, and medical device intermediate: The U.S. FDA

defines an intermediate as a material produced during steps to manufacture a product that

must undergo additional molecular change or processing to become the end product

(FDA, 2015).

Leader: De Hann (2015) defined a leader as an individual who assists a team to

perform better, and increases their productivity and influence. Changing stakeholder

expectations broadens the aspects of a leader to go beyond economic responsibility and to

include legal requirements, institutional norms, philanthropy, and social issues (Pless,

Moak, & Waldman, 2012).

Organizational culture: An organizational culture includes the beliefs, values, or

social norms used in decision making within an organization or institution that evolve

based on relative costs and benefits (Nunn, 2012).

Quality: The ability of a manufacturer to produce products or provide services to

satisfy stated or implied needs and expectations of the user (ASQ, n.d.; Macur, 2013).

Assumptions, Limitations, and Delimitations

Assumptions

In the qualitative research method, key assumptions establish how to begin the study (Yin, 2014). McCusker and Gunaydin (2015) discussed the perception that the goals and procedures of qualitative research may be imprecise when compared to quantitative research, due to a focus on understanding the experiences and perceptions of the target population. The subjective nature of qualitative research may produce results of questionable validity (Trafimow, 2014). I assumed that the participants in the interviews would present honest answers and experiences that formed the basis of their understanding and process for embedding a culture of quality and compliance. I also assumed that the experiences of the study company participants related to embedding a culture of quality would describe the phenomenon under exploration.

Limitations

Limitations in research are constraints on the transferability of the findings (Yin, 2014) and can include method biases where participants offer less than optimal responses due to confusion in regard to questions, faulty memory, or lack of motivation (Podsakoff, MacKenzie, & Podsakoff, 2012). Method bias may influence the reliability and validity of a study and a researcher must know of ways to control method biases that may exist in their study (Podsakoff et al., 2012). One limitation of this study was the decision to use one site. This limitation encompassed the limited number of participants from one enterprise. Although the sample size was sufficient for a qualitative case study, capturing

the lived experiences of one enterprise may not be sufficient to ensure transferability across other sites and industries.

Delimitations

Simon and Goes (2013) stated that delimitations define the boundaries reflecting the conscious exclusion and inclusion of elements during development of the study plan. Directors, managers, and technical leaders participated in my study in which I explored how one organization embeds a culture of quality and compliance. I did not focus specifically on Total Quality Management (TQM) tools, methods, or related quality certification processes. Participants had at least 5 years of experience in quality, compliance, corporate governance, and operations roles.

Significance of the Study

To establish the significance of the study, I discussed the value of embedding a culture of quality and compliance to achieve business success. By identifying strategies that deliver success in the case study company, other business leaders may adapt the findings and implement strategies that enable their companies to deliver products that meet quality and compliance requirements. In this way, business leaders may add value and drive the potential for social change.

Contribution to Business Practice

The findings from my study may add value to businesses regulated by the U.S. FDA and other country-specific regulatory agencies by identifying the factors needed to embed an employee culture of quality. Rashid and Aslam (2012) explored the strategies needed to create and sustain a culture of quality, identifying the need to allow employees

to engage in a process of continuous, bottom up improvement across their supply chain. Roman (2014) noted that drug shortages resulting from a reduction of saleable products could create drug shortages affecting the range and variety of treatments available to consumers. Aligning management employees to a culture of quality and compliance may minimize fines and penalties incurred by organizations, increase profitability, eliminate possible drug shortages, and ensure production of products that meet consumer expectations.

Implications for Social Change

Findings from this study may contribute to positive social change by providing tools and skills needed by business leaders to ensure product quality and compliance, deliver safe products to customers, and drive sustainable enterprises. Such tools and skills enhance the ability of leaders to develop and implement strategies for manufacturing employees that embed a culture of quality. These chemical intermediates will meet customer expectations, ensuring a consistent presence on the market for delivering products that safely meet customer needs and ensure the success of the business. This success may drive business stability and growth by providing employment opportunities to the local community. By consistently delivering quality products to the market, the organization builds trust within the customer base that the products sold deliver the features promised by the company.

<div style="text-align:center">A Review of the Professional and Academic Literature</div>

In this qualitative case study, I explored the strategies leaders use to embed a culture of quality and compliance within their organization by removing constraints to the

production of marketable products. Businesses with product quality and compliance constraints produce fewer saleable products, resulting in decreased sales and profit (Kober et al., 2012). The sources for the literature review included peer-reviewed scholarly studies obtained from the Walden University library, the Pennsylvania State University library, and professional organizations including the Clute Institute for Applied Business Research, and the American Society for Quality. I structured the literature review integrating scholarly studies under the following major categories: *History*, *Organizational Culture and Habit*, *Quality Management and Compliance Systems, Product Quality*, and *Information Technology and Knowledge Management*. The authors of all of these articles provided background information and findings linking product quality and compliance to business success factors such as culture, employee behavior, government requirements, and organizational knowledge.

The sources for the literature review included peer-reviewed scholarly studies obtained from the following databases and professional organizations: ABI/Inform Complete, Business Source Complete, ProQuest LLC, Gale Virtual Reference Library, LegalTrac, LexisNexis, Academic, ProQuest Central, SAGE Premier, SAGE Research Methods Online, Science Direct, Science Journals, Springer ebooks, and the Social Science Research Network (SSRN). I investigated the concepts of product quality and total quality management in relation to supply chain and manufacturing productivity, organizational and employee behavior, and technologies and processes used for information and knowledge management. One hundred and eighty eight references

supported the findings of the literature review and this study, with 170 studies from peer-reviewed journals, and 88% with publication dates between 2012 and 2016.

History

Issues with product quality and product risk may result in negative impacts to business reputation. When recalled from the market, defective products result in lost revenue, potentially increased product liabilities, and decreased customer satisfaction (Garstenauer, Blackburn, & Olsen, 2014; Hofmann & Oldehaver, 2015; Rosencrance & Wu, 2015). These product quality issues affect brand equity and long-term market share, and may influence business survival due to lost sales (Nagaich & Sadhna, 2015; Rosencrance & Wu, 2015). Globalization has increased awareness of product quality issues, and increases the vulnerability of businesses (Nagaich & Sadhna, 2015; Rosencrance & Wu, 2015). This increased awareness among global customers necessitates that businesses remain competitive on product price and quality while delivering compliant products to the market (Nagaich & Sadhna, 2015; Rosencrance & Wu, 2015).

Blome, Schoenherr, and Rexhausen (2013) described the different aspects of the supply chain including suppliers, producers, and customers where there is an interrelationship between operational competence, agility, and organizational performance. To enhance competitiveness, businesses should focus on improving agility across the supply chain without influencing product quality and compliance (Blome et al., 2013). The quality of raw materials may affect downstream product quality, influencing the ability of business leaders to deliver marketable products.

Product quality and product safety influence the global supply chain and affect the components and materials businesses purchase from suppliers to manufacture products (Abdallah, 2013). Quality, an important factor in a company management system, drives competitive advantage (Garstenauer et al., 2014) and requires alignment of values, attitude, and behavior within an organization, which leads to the creation of an employee culture of quality and compliance (Doval & Bondrea, 2011).

Health authorities issue regulations to ensure that drug, medical, and consumer products meet quality and safety requirements to ensure a supply of marketable products that meet customer expectations. In the United States, the FDA and the Consumer Product Safety Commission (CPSC) establish product safety requirements, and monitor the production processes and products made and sold in the United States. When these products do not meet quality and compliance requirements, companies face the challenges of fines, lost sales, an inability to meet customer demand, and decreased profit (Liu & Xiong, 2015; Roman, 2014). The FDA requirements apply to all food, drug, medical device, and cosmetic manufacturers regardless of size (FDA, 2015). The organizational cultures of FDA-regulated businesses and the aspects of those cultures that allow organizations to embed a culture of quality was the focus of my study.

Doval and Bondrea (2011) defined employee culture as the notion of quality as a joint obligation with common worth. In addition to focusing on the employee culture, integration of a business strategy to include customers, manufacturers, and suppliers provides a basis to control product quality across the supply chain (Doval & Bondrea, 2011). Battini, Faccio, Persona, and Sgarbossa (2012) examined the cost of quality in

production operations, focusing on product inspection and defect identification. Strategically placed inspection stations may assist manufacturers with early identification of product defects (Battini et al., 2012). Early identification of defects allows manufacturers to implement corrective action to eliminate product defects and the costs associated with product rework and recalls (Battini et al., 2012). Das (2011) explored the value of strategic planning across the global supply chain to drive product quality, emphasizing that traditional business decisions allowing trade-offs between product quality, safety, and price no longer met customer expectations. When the products sold by enterprises no longer meet customer expectations, the company reputation may be impacted.

Company reputation prior to a recall potentially influenced the magnitude of the overall business impact of loss of market share and reputation (Grunwald & Hempelman, 2011). Companies with high prerecall reputations faced high consumer expectations that may affect their success in returning the product to market (Grunwald & Hempelman, 2011). When products failed to meet customer expectations, or were not fit for use, companies incurred additional costs to recall and dispose of defective products (Pang, Xue, Zhou, & Li, 2012).

Theory of Constraints

The TOC model enables employees in manufacturing operations to analyze process constraints and identify process improvement opportunities (Naor et al., 2013). When businesses have product quality and compliance issues, they produce fewer saleable products, resulting in decreased sales and profit (Kober et al., 2012). Improving

performance by eliminating the constraints affecting product quality allows manufacturing employees to produce products that meet quality and compliance requirements, which satisfies market demands and achieves the ultimate goal of making money (Gupta et al., 2013; Pacheco, 2014).

Goldratt's (1992) TOC process sought to answer three questions: *What to change? What to change to? How to cause the change?* Goldratt's five steps to follow in order to answer these three questions include:

1. Identify the system's constraint.

2. Decide how to exploit the system's constraints.

3. Subordinate everything else to the above decision.

4. Elevate the system's constraint(s).

5. If in the previous steps a constraint has been broken, go back to step 1, but do not allow inertia to cause a system's constraint. (p. 307)

By applying Goldratt's five steps, employees can facilitate a process of analysis that drives process improvement through elimination of system constraints and eliminating the need for redesign of an entire process or system. Sale and Sale (2013) suggested a broader application of the TOC principles going beyond the manufacturing environment and applying the TOC to eliminate business, government, and nonprofit sector operational constraints.

Cox, Robinson, and Maxwell (2014) posited that every system, including organizations, has at least one constraint that prevents leaders from achieving optimum performance. Using the TOC to identify and eliminate constraints may increase output.

Ryan et al. (2013) applied the TOC to improve organizational throughput using

Goldratt's (1992) five steps to identify constraints that influence performance. By

applying the TOC to the identified five critical constraints in a patient management

process, Ryan et al. prioritized the constraints to eliminate the most restrictive constraint

first. This resulted in improved patient management. Similarly, when enterprises use the

TOC to identify constraints, they also need to eliminate the most restricting constraint

first.

Product Quality

Health authorities and the pharmaceutical industry define a quality product as one

that is defect free and delivers the appropriate treatment (Mesut, Özsoy, & Aksu, 2015).

In this way, businesses produce and deliver marketable products, meeting customer

demand, and generating profit (Liu & Xiong, 2015; Roman, 2014). Toivonen (2012)

followed the quantitative exploratory case study method to examine the link between

consumer perceptions of product quality and price in the wood products category. When

considered holistically, a product contains tangible and intangible factors that influence

customer perceptions of product quality with research indicating a positive link between

the two factors (Toivonen, 2012). Toivonen defined tangible product attributes to include

physical factors that the consumer can see and feel, and intangible factors including

services, producer features, and environmental and supplier characteristics (Toivonen,

2012). Trentin, Perin, and Forza (2012) examined the link between product quality and

product configuration to develop a tool to use across business sectors, expanding upon

Toivonen's research. Product configuration includes the tangible and intangible factors

that translate customer needs into product features. The importance of the different

tangible and intangible factors changed depending on the product and type of customer,

resulting in conclusions generalizable across business sectors (Trentin et al., 2012).

Trentin et al.'s configurator tool enabled business professionals to integrate

analysis for variety and customization in product development. This helped professionals

to identify the best features to meet customer needs and provide the details needed to

align on price, materials, production process, and other supply chain elements. This

reflected the core principles and techniques that compose an effective quality

management system. Trentin et al. found a positive link between the use of a

configurator tool and product quality, which enabled business leaders to identify the best

strategies to ensure production of a compliant, quality product. Lukas, Whitwell, and

Heide (2013) defined product capabilities as being aligned to the customer's belief that

the product will perform as advertised. To manufacture products that consistently deliver

the designed features and meet customer expectations, an organization should share

values and beliefs that drive product quality and compliance to specifications and

regulations. Leadership strategies that are used to embed a culture of quality should

ensure that the business can deliver products meeting customer expectations (Lukas et al.,

2013).

Leadership strategies driving product quality link to other business strategies that

maximize profit, including the strategic interaction between firms and strategic

performance incentives for managers (Veldman & Gaalman, 2014). Veldman and

Gallman (2014) examined the link between product pricing and product quality to

develop a theoretical model for product quality and process improvement. The

researchers used data collected from two different firms: one in which the firm offered

incentives to managers to maximize profit, and the other in which the firm offered other

incentives. The central research questions of their research evaluated the link between

performance rewards and behaviors centered on improving business processes, enhancing

product quality, and driving profitability. Veldman and Gaalman associated how

customers preferred that features integrate into the product developed for sale, identifying

the potential impact of leadership decisions on product quality. Veldman and Gaalman

concluded that there was a positive link between managerial incentives rewarding

product quality and process improvement and lower pricing. Their conclusion is similar

to the positive links established by Toivonen (2012) and Trentin et al. (2012) between

product quality, intangible and tangible product features, and customer expectations. The

Veldman and Gaalman research was theoretical in nature, requiring additional, empirical

research to enhance the credibility and transferability of their tool.

Expanding on the link between profit and product quality, Abowd, Kramarz, and

Moreau (1995) examined the economic link between product price, product quality, and

worker quality. Abowd et al. equated product quality with market price and worker

quality with product price using a measure of wage rates with data from the French

Producer Index survey for the period 1978 to 1988. The theoretical model developed by

Abowd et al. related differences in worker quality to differences in detailed product price

in an early exploration between organizational culture and product quality. Abowd et al.

found a weak, generally positive link between worker quality and product quality identifying the need for further research.

Organizational Culture and Habit

Organizational culture is a social factor that includes shared norms and perceptions influencing the behavior of individual employees, groups of employees, and the company (Valmohammadi & Roshanzamir, 2015). As an element of organizational culture, a quality culture should align to business processes and overall customer satisfaction (Schmiedel et al., 2013). To establish a quality culture requires integration of organizational norms and values that drive business processes and strategy (Alotaibi, Yusoff, & Islam, 2013). In competing for a share of the market, a business should remain focused on product quality, in addition to product cost, to meet customer expectations (Schmiedel et al., 2013).

Customer trust in product quality and value should play a role in business survival (Maurer, 2013). While price influenced customer purchase decisions, price also influenced customer perception of quality (Lalwani & Shavitt, 2013). Employee ideas to improve the product and reduce cost complemented a business strategy ensuring success (Choi, Lee, & Yoo, 2010). In addition, product innovation should not negatively affect product quality. Business leaders should create a culture integrating the values and norms for both product quality and employee innovation (Wagner et al., 2014). Barriers to successful implementation of a quality culture included a perception of a lack of value, a lack of time and financial resources, insufficient leadership commitment, and ineffective training across the employee population (Davis et al., 2014).

Culture. Product quality and compliance should integrate elements of an organization's culture, governmental regulations that ensure products meet performance and customer requirements, employee knowledge, and equipment performance (Edwards, Hugman, Tobin, & Whalen, 2012; Yang, 2012; Zhang, Linderman, & Schroeder, 2012). Green (2012) examined how cultivating an employee culture with behaviors that supported compliance to standard operating procedures, process requirements, product inspections, error elimination, and regulatory compliance required leadership strategies to integrate behaviors aligned to these requirements, and behaviors that constructively managed deviations. In achieving a culture of quality and compliance, an organization's culture included shared values, beliefs, and expectations that should express a commitment to quality and compliance (Green, 2012; Lukas et al., 2013). In this way, the products manufactured and sold on the market should meet customer expectations (Lukas et al, 2013). Cristea, Paran, and Delhomme (2013) examined how beliefs influenced actual behavior, the influence of other individuals on behavior, the individual's willingness to engage in risky versus planned behaviors, the influence of past behavior as a predictor of intention and behavior, relative judgments regarding risk, sensation seeking, and the influence of anger and emotion in adopting a risky behavior. Perceived control, social pressure, and perceived difficulty in complying with requirements potentially influenced decisions to deviate from required procedures (Cristea et al., 2013).

Pharmaceutical and medical device products that do not meet quality and compliance requirements may inadvertently harm customers (Madadi, Kurz, Mason, &

Taaffe, 2014). Product quality issues potentially occur at points across the supply chain, increasing risks to the business (Madadi et al., 2014). Leaders at the enterprise should establish clear processes that heighten employee awareness of quality and compliance requirements, and align individual efforts to achieve quality and compliance (Kleijnen, Dolmans, Willems, & van Hout, 2014). Lukas et al. (2013) identified a positive link between culture and the values that drive product and management attributes that negatively influence the customer. These negative impacts included mismatches between product capabilities and customer needs. Lukas et al. expanded upon existing research by Zhang, Linderman, and Schroeder (2012) on product quality using three factors to examine the relationship between culture, customer needs, and product quality. Lukas et al. proposed four hypotheses that identified a positive relationship between the three factors; however, the findings indicated the potential for a negative relationship invalidating the hypotheses. Moreover, Lukas et al. concluded that product capabilities link to organizational culture and identified the potential for negative outcomes. The Lukas et al. study was unique in examining how culture could drive a company to offer products for sale that do not meet customer needs. In comparison, Wagner et al. (2014) explored the link between organizational culture, organizational management structure, and quality management in hospitals in a cross-sectional, observational study. Wagner et al. concluded that the type of organizational culture did not positively link to the development of quality management in hospitals, and found that factors other than culture influenced the development of quality management including establishing formal work protocols and management support for innovation.

In exploring the relationship between quality management and manufacturing performance, Zhang et al. (2012) identified four factors that included customer need, market demand, manufacturing plant performance, and competition that may influence quality performance. Zhang et al. used the quantitative method to explore the relationship between product quality, culture, and manufacturing plant performance using survey data from 238 manufacturing plants in the automotive, manufacturing, and electronics sectors. Zhang et al. identified the need to expand their research to include the entire supply chain to improve the credibility and transferability of the findings. Chen, Zhang, and Delaurentis (2014) examined the link between product quality and the manufacturing supply chain in a study examining the 2008 Chinese adulterated milk incident using factors that included raw material quality and profit, in addition to manufacturing, and expanding upon the research of Zhang et al. Chen et al. examined the incident using information available in the public record before, during, and after the incident to study cost and revenue for the supplier and the retailer as key factors influencing product quality in centralized and decentralized food businesses. Chen et al. found that the type of quality sampling methods used in a supply chain could, distort product quality (Chen et al., 2014). Based on Chen et al.'s case study, implementation of poor vertical product quality control strategies within a supply chain have the potential to ensure product quality prior to market release. Chen et al. expanded the research of Zhang et al. by adding additional factors including the influence that culture has on product quality and the affect that business partners have on the quality of products sold to consumers.

The product quality control strategies discussed by Chen et al. (2014) identified business processes that influenced the quality of work delivered by quality and compliance professionals and supply chain employees. Public health researchers established a positive link between infant consumption of melamine contaminated milk and an increase in infant death and kidney damage (Cheng, Li, & Luo, 2014; Ortega, Wang, Olynk, Wu, & Bai, 2012). The contaminated product did not meet industry standards and government regulations for milk products reinforcing the findings of Green (2012) on the need to integrate leadership strategies that embed a quality of culture in an organization to ensure product quality. To embed a culture of quality into business processes, Schmiedel et al. (2013) identified the necessity of four core values to include customer orientation, excellence, responsibility, and teamwork. The attributes for customer orientation and excellence enable employees to focus on the need to provide products that meet specifications in order to meet customer expectations. To cultivate a culture where employees take responsibility for ensuring that products meet customer expectations requires leadership strategies that minimize the inclination for employees to engage in risky behaviors (Hirschauer, Bavorova, & Martino, 2012).

Business success in the pharmaceutical and medical products sector requires the distribution of compliant, quality products to the customer to minimize risks to public health (Madadi et al., 2014). In assuring the need to produce quality products, enterprises should consider the potential impact of employee engagement in risky behaviors. Short cuts around standard operating procedures to achieve production quotas may produce products that do not meet quality and compliance requirements (Hirschauer et al., 2012).

Hirschauer et al. (2012) examined the link between human misconduct and individualism in an analysis of behavioral risk in business enterprises, multiple, conflicting goals, and unprincipled behavior. Using a literature review for data gathering, Hirschauer et al. identified that the factors leading to behaviors that influence noncompliance to production standards and regulations, and cause product quality issues, included risk aversion, social norms and values, and emotions. In addition to exploring the behaviors linked to human misconduct, leaders should understand the influence of professional background, experience, and practices in supporting quality and compliance. Rosen, Parker, and Nielsen (2012) followed the quantitative method examining the link between the professional backgrounds of the persons in charge of compliance; how they analyze costs, benefits, and risks of noncompliance; and compliance structure and practice. Rosen et al. concluded that the profession of the person responsible for compliance does not make a difference to the firm's perception of the risks of noncompliance, and that intrafirm processes effectively manage the different values and norms of individuals in compliance roles. Rosen et al. concluded that compliance structures while more formal, tended to be primarily symbolic.

Noël (2014) examined the link between consumer perceptions and a consumer driven quality program using the quantitative method to develop a theory and test in a case study. Noël identified a lack of a clear methodology to use in applying benchmarking to determine consumer perceptions of total quality that differs from measurement of consumer preferences for product attributes versus measurement of the more intangible aspects of product. The research by Toivonen (2012) linked product

quality to tangible and intangible qualities, and to consumer perception, and provided an initial basis that Noël's research expands. Noël identified that marketing related measures for consumer perceptions of product quality rely on standard statistical analysis and ignore subjective measures that determine how overall product features satisfy stated or implied customer needs. Business leaders may use the model proposed by Noël to benchmark specific product features with regard to customer-perceived product quality attributes enabling the opportunity for customer feedback prior to launching a new product to the market.

   Habit. With the digital technologies, networks, and social media available there is the opportunity to influence habits through messages received by individuals anytime and anywhere (Giraudo & Hugo, 2014). Baldwin (2014) posited the use of a structured path to the desired choice as a way to influence development of new habits. Through this approach, Baldwin identified the opportunity for development of intervention strategies to influence choice and behavior. In examining the link between mechanisms that trigger habits and habits in daily life, Neal et al. (2012) concluded that behavior frequency and context might influence habit strength. Leaders who developed strategies to embed a culture of quality needed to consider the strength of the habits desired in the organization. Specific cues within the organization triggered habits and an associated behavior establishing a potential link to behaviors influencing organizational routines and culture (Neal et al., 2012). Winter (2013) followed the qualitative method to study organizational routines and capabilities exploring the link between habit, deliberation, and action addressing a perceived gap in organizational research. Winter concluded that

the contribution of the individual becomes lost in organizational research focusing on structure, routines, capabilities, culture, institutions and other systems and concepts that focus first on the organization. Greaves, Zibarras, and Stride (2013) examined the link between environmental behavioral intentions of individuals and the workplace using the theory of planned behavior. Greaves et al. identified a positive link between three behavioral themes including attitude, subjective norms, and perceived behavioral control identifying a second positive link between the specificity of the goal behavior and the type of behavioral result.

Leaders may need to consider the degree of specificity of quality and compliance goals versus the types of behaviors they wish to embed in a quality culture (Greaves et al., 2013). Winter (2013) linked the routines and capabilities in an enterprise to organizational culture to explore how the treatment of individuals links to organizational routines and capabilities, and how to maximize an individual's capability to make a rational choice and to contribute. Winter emphasized that each individual contributes knowledge that, if removed from the whole, would disrupt the continuity of the routine of the organization. The interrelationships identified by Winter between these factors explained how individuals make decisions in an organization. When leaders identify the need to change habits in an organization, employees should forget old habits and replace them with new habits (Winter, 2013). Dreisbach and Bäuml (2014) examined the link between daily routines and habits. Through experiments on directed forgetting, Dreisbach and Bäuml found that an individual's memory for habits linked to cues associated with the context. Similarly, Dreisbach and Bäuml identified that the forget

cue potentially interfered with an individual's ability to access the original context cue.

Dreisbach and Bäuml identified a positive correlation between the forget instruction and

the influence of previously delivered instructions concluding that directed forgetting

reduces the influence of newly established habits. The findings of Winter regarding the

importance of individual contributions to the organization considered that leaders

implementing a strategy to drive change within the organization may need to exercise

caution in the selection of the behaviors and habits targeted for change in order to achieve

the desired results.

In addition to understanding the factors that influence behavior and habit,

business leaders should understand the factors influencing how employees freely and

consciously follow operating procedures designed to deliver quality and compliant

products. Shepherd (2012) conducted three related studies examining the link between

free will and consciousness. Shepherd's definition of consciousness included awareness

of the world and us, and free will as involving the abilities of the individual for

controlling behavior, making choices, and responding to goals. A leader should set

strategies to ensure that employees become conscious of the requirements to deliver

quality and compliant products, and should be willing to implement those requirements in

achieving business goals and producing marketable product.

In contrast, Glod (2015) explored the link between influencing individual choice

and altering behavior into predictable patterns. By structuring choices to follow a

specific path, enterprises can guide employees on standards implementation and

procedures influencing production quality and efficiency (Baldwin, 2014; Giraudo &

Hugo, 2014; Glod, 2015). Giraudo and Hugo (2014) explored the conflict between

informing consumers of product attributes and consumer understanding of those

attributes. At times, the consumer perception of the benefits and features of the product

may not match the true benefits and features (Giraudo & Hugo, 2014). Similarly,

employee training to communicate the manufacturing standards and procedures that

deliver compliant and quality products may be misinterpreted resulting in employee

mistakes (Polites & Karahanna, 2013). Leaders can apply the findings of Baldwin, Glod,

and Giraudo and Hugo, to design a strategy that links structured goals to new behaviors

and **provides** employees with a path that guides them toward the correct decisions.

The intuitive connections between consciousness and free will influence

individual perceptions regarding these two factors (Shepherd, 2012). Shepherd (2012)

concluded that in the first of three studies 83% of participants agreed that they could have

free will because they have consciousness. In the second study, Shepherd found that 91%

of study participants agreed with the same statement recording a difference of almost

10% in participant responses. Shepherd determined that while the results to the third

study correlated similarly to the first and second studies, the study group did not include

enough participants to provide useful data concerning free will. Shepherd provided a

framework to explain how leaders could set strategies that influence individual decisions

by linking employee consciousness to decisions of free will. The strategies leaders

select, supported by employee training, could embed a culture of quality and compliance.

Baldwin (2015) and Glod (2015) posited a structured decision path may influence an

individual's decisions, while a subliminal message did not necessarily influence choice

when a strong habit existed. This finding identified in the studies conducted by Baldwin and Glod provided additional insight on how to influence organizational culture. When leaders deliberately or inadvertently send subliminal messages, they may enhance or derail the intended changes.

Trust linked habits and repeat behaviors in research conducted by Chiu, Hsu, Lai, and Change (2012) that modeled familiarity, perceived value, and satisfaction in online shopping behavior. Chiu et al. concluded trust served as a mechanism that reduced uncertainty and the impact of trust decreases as conscious uncertainty decreases. When a strong habit exists, the individual's intention to take action connects to past behavior instead of attitude (Chiu, Hsu, Lai, & Change, 2012). Just as retailers look for a repeat habit of shopping at their store, leaders in pharmaceutical and medical device manufacturers look for a repeat habit of following established procedures and regulations (Al-Bourini, Al-Abdallah, & Abou-Moghli, 2013; Chiu et al., 2012). Polites and Karahanna (2013) concluded that some behaviors performed in a work environment become habits. These habits became automatic behaviors where context and context stability influenced the strength and triggering of habits (Polites & Karahanna, 2013).

Habit may play a positive and a negative role providing an opportunity for leaders to establish strategies reinforcing the positive habits necessary to produce marketable products. Liu-Thompkins and Tam (2013) examined the link between attitudinal loyalty and habit with regard to repeat behaviors. Leaders should establish and reinforce the repetitive behaviors needed to embed a culture of quality and compliance. Liu-Thompkins and Tam also explored the factors that could disrupt repeat behaviors

concluding that   habit-driven consumers value the opportunity to adapt and optimize

their routines more than their conscious goals. Leaders should establish strategies that

reinforce positive, repetitive behaviors while valuing employee needs to adapt and

optimize their daily routines.

Polites and Karahanna (2013) extended the research of Chiu et al. (2012),

Shepherd (2012), Liu-Thompkins and Tam (2013), Baldwin (2014), and Glod (2015) to

the enterprise to explore the link between habits and work routines with a goal to

understand work-related habits. Leaders setting strategies to embed a culture of quality

and compliance should identify the work-related habits required to ensure production of

marketable products. Polites and Karahanna studied how employee habits enabled, or

disabled, behavior and the positive and negative impact on work routines in information

sciences (IS) departments. Polites and Karahanna focused on work-level routines and

task sequences in IS using four factors including time, location, social, and task to

explore habit acceptance and formation, general versus specific habits, and habits as a

habitual choice that embeds into work routines. Polites and Karahanna explored the link

between a time-related trigger and IS related work tasks. A time trigger for work tasks

generalizes to other disciplines and departments in manufacturing where production

quotas and customer orders require performance to a schedule in order to meet customer

demand (Polites & Karahanna, 2013). Since turning off an old system and forcing

employees to use a new system is not always feasible, Polities and Karahanna explored

other factors and frameworks. The factors and frameworks explored by Polities and

Karahanna included action slips (when an employee, after receiving training, makes a

mistake), training in context, goal management, interference, and distraction. Similarly, when product specifications or production process requirements change, employees need to respond and retain the new instructions to ensure compliance and production of quality products. Polites and Karahanna concluded that habits could facilitate the practice of routine behaviors increasing mental and behavioral efficiency. Habits may potentially prevent adoption of new systems and inhibit exploration of opportunities for continuous improvement (Polites & Karahanna, 2013).

Enterprise leaders that implement information systems (IS) knowledge management (KM) systems offer enterprises the potential to improve organizational performance   Implementation of IS and KM systems reinforce habits embedding quality and compliance into work routines and daily tasks (Polites & Karahanna, 2013). In seeking to embed a culture of quality through information and knowledge management systems, the culture changes should take place across the enterprise.

Total Quality Management and ISO 9000

Mehmood, Qadeer, and Ahmad (2014) defined total quality management (TQM) as a process used to maintain organizational performance and drive continuous improvement helping organizations to manufacture quality products, reduce costs, and increase employee and customer fulfillment. Leaders provide tools that help employees identify opportunities for improvement through implementation of TQM (Mehmood et al., 2014). These improvements may include improved product quality and compliance, or sustained product quality and compliance while reducing operating costs.

Iyer, Saranga, and Seshadri (2013) examined the link between quality initiatives on output productivity in the Indian auto components industry using data for 1993 to 2006 to study quality and learning, and productivity. In addition to production data, Iyer et al. used publicly available information to collect quality certification and award information for each firm. Iyer et al. concluded that implementation of TQM initiatives resulted in an 11% increase in productivity after implementation reinforcing the findings of Mehmood et al. (2014).

Mehmood et al. (2014) concluded that factors driving potential failure in implementation of TQM included setting vague goals and lack of development of a quality culture. Green (2012) determined that implementation of TQM processes required that individuals take responsibility for performing roles to align the values of employees and leaders with respect to the company. In addition, Al-Bourini, Al-Abdallah, and Abou-Moghli (2013) identified a positive relationship between the values embedded in the organizational culture and TQM. Green identified disagreement in the literature concerning the necessity for cultural change to achieve total quality, versus whether successful TQM implementation used the existing culture to embed a culture of quality. Culture functioned as an integrating mechanism with three characteristics that included consistency across cultural manifestations, consensus among cultural members, and a focus on leaders as culture creators (Al-Bourini, Al-Abdallah, & Abou-Moghli, 2013).

Hongyan and Yanan (2014) examined options for analysis of enterprise quality management system operational effectiveness following the quantitative design. The

factors identified as affecting an enterprise wide, quality management system included

quality policy objectives, product quality stability, quality improvement and innovation,

and resource management. The International Standards Organization (ISO) used the ISO

9000 series of global standards to establish a product quality framework for the design

and governance of quality management systems (Ollila, 2012; Vilkas & Vaitkevicius,

2013). Tkachenko (2013) examined the link between an industrial enterprise and the

quality product approach of ISO 9000. Using a series of mathematical relationships

positioning elements of a quality management system as functions of key factors

grounded on process theory and systems theory, Tkachenko (2013) proposed a quality

management model based on the ISO 9000 methodology. The model monitors different

factors of a quality management system including employee behavior (Tkachenko, 2013).

To create a culture of quality, behaviors need to align to quality and compliance

requirements and become integrated habits within the organization (Polites & Karahanna,

2013). The model developed by Tkachenko integrated different aspects of factors studied

by other researchers including Polites and Karahanna (2013), Greaves et al. (2013),

Shepherd (2012), and Veldman and Gallman (2014) linking employee behaviors and

habits to strategies necessary for embedding a culture of quality. Tkachenko began the

research needed to explore the link between employee behavior, product quality, and

compliance with a theoretical model that requires testing and application to real-world

cases.

　　　　Kluijnen, Dolmans, Willems, and van Hout (2014) explored the links between the

conceptions and perceptions of quality, quality management, and organizational values

using the competing values framework. Kluijnen et al. used semistructured interviews, to

explore how employee conceptions of quality values influence day-to-day activities, and

influence decisions and behaviors in departments representing the three most effective

and the three least effective within 53 universities located in the Netherlands. While the

conceptions of quality were similar between the six departments studied, the practices

between the high and low performing departments differed. Employees in higher

performing departments had structured quality practices aligning closely to day-to-day

activities ensuring ease of implementation and driving continuous improvement

(Kluijnen et al., 2014). Similarly, Polites and Karahanna (2013) identified how habits

influenced work routines, and the need for factors like training and goal management to

reinforce desired or new habits. Although Kluijnen et al. focused on academic

department effectiveness in establishing a quality culture, the findings align to the needs

of manufacturers of pharmaceutical and medical device products where the influence of

organizational values, internal standards, and government regulations ensure that the

products sold meet customer expectations (Abowd, Kramarz, & Moreau, 1995; Agus &

Hassan, 2011; Zhang et al., 2012).

Agus and Hassan (2011) examined the TQM framework and the link to

production and customer centered performance at Malaysian-based manufacturers linking

to the research of Hirschauer et al. (2012) and Lukas et al. (2013). The research by Agus

and Hassan connected customer needs and expectations to performance, quality, and

compliance requirements. Agus and Hassan identified four TQM elements including

supplier relations, benchmarking, quality measurement, and continuous process

improvement proposing a model. The new model proposed by Agus and Hassan related TQM, production performance, and customer-centered performance to four factors of an enterprise. The four quality culture factors used by Agus and Hassan in the new model included customer value, customer responsiveness, manufacturing effectiveness, and efficiency. Agus and Hassan concluded that TQM offered a framework to establish an organizational culture focused on product, production, and quality improvement to enhance an enterprise's ability to deliver value added products.

Organizational Effectiveness

Taylor and Taylor (2014) studied the connection between organization size and performance based on six success factors including organizational learning and quality management culture. An analysis by Taylor and Taylor of data obtained through a questionnaire sent to 1,117 manufacturing organizations located in the United Kingdom reinforced the criticality of firm leadership on quality management, regardless of size. Zelnik, Maletic, Maletic, and Gomiscek (2012) examined the link between quality management systems, management, and employees. Zelnik et al. identified a positive link between top management attitudes toward the QMS and employee general satisfaction. By applying the findings of Zelnik et al., leaders could identify options to improve employee understanding of why a QMS added value and for leadership behaviors. Zelnik et al. identified that implementation of the QMS depended upon management support for the QMS and involvement in driving employee satisfaction, motivation, and communication.

Valmohammadi and Roshanzamir (2015) studied the connection between organizational culture, TQM, and organizational effectiveness, which complements the research by Rai (2011) on organizational culture and knowledge management and the factors driving improvement. Valmohammadi and Roshanzamir identified culture as a shared collective structure and a characteristic of the work unit where a positive link existed between culture, TQM, and organizational performance. The model developed by Valmohammadi and Roshanzamir enabled measurement and analysis of culture, TQM, and performance in an organization. In their model, Valmohammadi and Roshanzamir established an empirical basis for leaders to identify strategies to improve quality management and organizational performance.

Knowledge Management

Organizational knowledge is unique and difficult to reproduce adding value to the distinctiveness of a business (Biotto, De Toni, & Nonino, 2012) and fitting into Porter's (2008) five forces business strategy. If effectively harnessed, the interactions and innovations derived from this knowledge may offer an enterprise a competitive advantage. Information systems may enhance knowledge sharing and provide a point of alignment from which to embed a culture of quality (Biotto et al., 2012) with the interactions between both employees and business partners creating explicit and tacit knowledge (Schoenherr, Griffith, & Chandra, 2014). The common memory established through explicit and tacit knowledge within an enterprise can differ in terms of understanding and consistency in application across organization (Goujon, Didierjean, & Poulet, 2013). The need to ensure uniformity in understanding and application of

standardized procedures that ensure compliance is a challenge for leaders. Leaders need

to eliminate barriers to knowledge sharing to enhance enterprise culture, reduce

duplication, and stimulating innovation within and between organizations (Qureshi &

Evans, 2015). Qureshi and Evans (2015) identified the need to differentiate the two

categories of shared knowledge including the more easily shared explicit knowledge, and

the harder to share tacit knowledge.

In studying the performance of teams and organizations, Choi, Lee, and Yoo

(2010) observed that team norms and behaviors integrated into daily work practices.

Choi et al. concluded that investment in information systems enhanced explicit and tacit

knowledge sharing and application, resulting in improved team performance and

compliance. Leaders may create a positive relationship between quality and culture from

the perspective of organizational learning and innovation (Long, Abdul Aziz, Kowang, &

Ismail, 2015). Choi et al. concluded that to create a competitive advantage and sustain

compliance, the shared knowledge should identify opportunities for continuous process

improvement and product innovation.

Knowledge management systems such as communities of practice, knowledge

repositories, document management systems, bulletin boards, and integrated search

engines enhance team performance (Choi et al., 2010). Iyer et al. (2013) concluded that

the implementation of TQM includes seminars and training that enhance employee

knowledge and understanding such that organizational barriers are broken and the culture

shifts to integrate quality. These electronic information systems enhanced compliance

through knowledge application within an organization expanding beyond small teams to

encompass larger groups within, and outside of, the organization (Nevo, Benbasat, & Wand, 2012). The value added may streamline and improve research and development, manufacturing, and business processes by embedding a culture of compliance and continuous improvement (Nevo et al., 2012). An employee culture develops that drives down operating costs, decreases time to market, ensures compliance, and enhances competitive advantage (Delic´, Radlovačkia, Kamberovic´, Vulanovic´, & Hadžistevic, 2014).

Implementation of information technology to enhance knowledge management and embed a culture of compliance, the organization should exploit the transactive systems that develop in small teams, broadening them across the organization and key partners (Nevo et al., 2012). The transactive systems that small groups develop identify individual expertise, and the knowledge repository process the group will use (Nevo et al., 2012) reinforcing the knowledge required for compliance including standard operating procedures, internal standards, and regulatory requirements. In implementing information systems to broaden transactive systems, the organization should remember that context plays a role in how memory and learning trigger for each individual (Nevo et al., 2012) aligning to the research by Neal et al. (2012) on contextual triggers for habit development and change.

Rai (2011) followed the qualitative method to explore the link between organizational culture and knowledge management (KM) in organizations based on the belief that a critical link exists between organizational culture and KM in organizations. Rai established a goal to propose a new framework to model and explain the nature of

organizational effectiveness, linking organizational culture to knowledge management.

Rai built on the research of Valmohammadi and Roshanzamir (2015) identifying the need

for further research to explain the relationship between organizational culture and

organizational effectiveness. Rai's research also complements the findings of Choi et al.

(2010) who concluded that knowledge sharing and application improved team

performance. Leadership strategies that drive consistent delivery of marketable products

need to consider how to influence organizational effectiveness and team performance.

The new framework developed by Rai provided a way to understand how organizational

culture drives improvement and organizational effectiveness. To continue to improve,

the organization should learn from mistakes, taking action and analysis to eliminate the

cause of the mistake (Rai, 2011). Leveson (2011) explored the link between

investigation of events, organizational learning, and human error. Using the factors of

reliability, retrospective versus prospective analysis, and human error, Leveson

concluded that the limitations used to learn from events link to two aspects of an

enterprise. These aspects included the inadequacy of organizational learning and the

ability of an enterprise to prevent a repeat of the same or a similar event. Leveson

concluded that the application of systems theory to event investigation improved the

analysis and recommended further study.

Organizational learning occurs during the transfer and integrations of individual

knowledge into the employee community (Schmitz, Rebeloa, Graciac, & Tomás, 2014).

Garstenauer et al. (2014) posited that when integrating knowledge management and

quality management processes, leaders and employees benefit through the creation of

operational efficiencies and timely knowledge sharing. A similar link was evident in Rai's (2011) study that identified a positive link between organizational culture, process improvement, and organizational effectiveness.

Loke, Downe, Sambasivan, and Khalid (2012) studied the relationship between TQM and KM to create a framework that unifies factors associated with TQM and KM, including culture. Loke et al. concluded that enterprise success linked directly to the ability of enterprise employees to learn and apply knowledge better and faster than the competition. Similarly, Garstenauer et al. (2014) explored the relationship between knowledge management and quality management processes positing that sharing knowledge faster contributed to improvement in organizational effectiveness.

Other findings by Loke et al. (2012), Taylor and Taylor (2014), and Zelnik et al. (2012) identified leadership as a key factor in establishing a quality improvement culture, strategic planning as necessary to ensure appropriate allocation of resources to quality, and leadership support for solving problems, and making decisions to assist the enterprise in embedding a culture of quality. Malik and Blumenfeld (2012) examined the association between commitment to quality and information sharing, continuous improvement, and team working, and identified a positive connection between the integration of quality management practices, including quality culture, and organizational learning. Moreover, Malik and Blumenfeld concluded that a surface-level commitment to quality management practices will not allow these programs to realize their full potential unless there is a leadership commitment to learning, open-mindedness, and shared learning.

Lotfi, Sahran, and Mukhtar (2013) used a mixed methods approach to investigate the connection between supply chain integration and aspects of quality performance from the perspective of internal integration, customer integration, and supplier integration impacts on alignment to quality in the manufacturing sector. Lotfi et al. developed a proposed model incorporating supply chain integration and quality performance into a single business model. The new model provided business leaders with a tool to use in to evaluate the impact of manufacturing factors on product quality and the delivery of input to use in developing effective strategies for quality and compliance.

Long et al. (2015) examined the relationship between innovation performance and TQM. Long et al. recognized that the effectiveness of information analysis within a TQM program has a positive impact on innovation and organizational performance. The results of Long et al.'s quantitative study established a positive link between TQM and personnel administration, a customer centric philosophy, and process management. Long et al. established that, with a customer centric focus, employees in the organization more frequently engaged in product innovation allowing them to meet customer needs. The findings of Long et al. align to the findings of Lotfi et al. (2013) which noted the importance of customer integration as a success factor to ensuring business profitability.

Davis et al. (2014) explored the implementation of quality improvement initiatives at ten public health agencies. Case study participants included health directors, quality improvement team leaders, and team members using individual and group interviews for collection of data. Davis et al. concluded that leadership support was a key element in creating a mature and integrated quality culture. Davis et al. found that when

the agencies formally engaged in quality improvement initiatives, quality culture

initiatives had leadership support. These findings aligned to the findings of Malik and

Blumenfeld (2012), which also identified the need for leadership support to ensure the

success of quality management processes. The agencies studied by Davis et al.

participated in national quality improvement initiatives, and management provided

formal training for staff in quality improvement principles. Davis et al. found that for

agencies informally engaged in quality improvement, the event that initiated the desire to

create a quality culture was a decision to seek a quality category accreditation like ISO

9000 certification. Davis et al. concluded the role of accreditation to drive quality

improvement diminished over time as the agency built a sustainable quality culture. The

findings may apply to other businesses and business leaders in developing strategies to

implement quality improvement initiatives and to develop a sustainable quality culture.

The literature review provided an understanding of the importance of ensuring

quality and compliance in the manufacture of pharmaceutical and medical device

products. Rosen et al. (2012) and Hirschauer et al. (2012) identified and discussed the

risks to an enterprise that cannot meet product quality and compliance requirements to

include fines and loss of sales. Madadi et al. (2014) discussed the risks to public health

from products that do not meet quality and compliance requirements including drug

shortages and negative health impacts. For example, Ortega et al. (2012) reinforced the

risks to public health of tainted products through their research on the effects of

consumption of melamine contaminated milk products. Lotfi et al. (2013) and Chen et al.

(2013) explored the impact of quality and compliance across the supply chain taking into

consideration the relationship between suppliers, manufacturers, and consumers. Lotfi et al. and Chen et al. emphasized that quality and compliance issues with suppliers and raw materials influenced a manufacturer's ability to produce marketable product. Lotfi et al., Chen et al., Ortega et al., Madadi et al., Hirschauer et al., and Rosen et al. explored the relationship between product quality, compliance, business success, and the public health reinforcing that leaders should set strategies that embed a culture of quality and compliance within their organizations in order to produce marketable products. Employee behaviors and habits may play a role in influencing learning and employee ability to retain and follow procedures potentially influencing product quality and compliance. Key quality systems such as ISO 9000 and TQM provide frameworks to influence employee behavior and may improve product quality and compliance.

Transition and Summary

In Section 1, the discussion focused on understanding the underlying influences driving success when trying to embed a culture of quality and compliance. Results from my analysis of data derived from interviews of the study participants identified strategies leaders could use to embed a culture of quality and compliance. The discussion included an introduction to the study, problem and purpose statements, and the nature of the study. A discussion on the research question, conceptual framework, assumptions, limitations, and delimitations further defined my approach to the study.

Section 2 includes an overview of the project restating the purpose statement and describing the research methodology. When I established the role of the researcher, I framed how I would interact with interviewees to gather data, including the ethical

treatment of the study subjects. The remainder of the section covers the research method and design, population and sampling method, data collection and organization.

In Section 3, I have presented the findings of my research study restating the research question and presenting a detailed analysis and discussion of the findings. The findings include a presentation of the themes, an analysis against other peer-reviewed studies, and a discussion regarding the link between the findings and the conceptual framework. In addition, I discuss the potential application of the findings to the professional practice of business, and the implications for social change. The final elements of Section 3 include recommendations for action and further research, personal reflections, and conclusions.

Section 2: The Project

In this research project, I used a qualitative case study to explore the strategies leaders use to embed a culture of quality and compliance in an organization. I used the literature review to identify the range and scope of current research on this topic. Because of my research, I identified the impact product quality has on business performance and some strategies used to ensure quality and compliance to form a basis for the questions used for the study interviews. The ten interviews I conducted were done with purposefully selected directors, managers, and technical leaders based on their roles in the organization. This study group provided me with the opportunity to develop a detailed understanding of the leadership strategies employed to embed a culture of quality and compliance.

I used several confirmatory procedures including member checking and triangulation to ensure consistency, validity, and reliability of the study. I also tracked the progress of the results to ensure data saturation. A failure to reach saturation affects study quality and hinders validity (Fusch & Ness, 2015). Saturation is indicated when no new information is introduced and no new coding themes are created (Fusch & Ness, 2015). I anticipated reaching saturation after the third interview and found that I reached saturation after five interviews. I continued to collect data from the reminder of the participants, maintaining a study population of 10 participants.

Purpose Statement

The purpose of this qualitative case study was to explore the strategies healthcare manufacturing leaders use to embed a culture of quality and compliance within their

organization to assure sufficient production of marketable products to meet customer

demand and be profitable. The targeted population consisted of leaders in a healthcare

products company located in the northeast region of the United States, where the products

include chemical intermediates for use in healthcare, medical, and pharmaceutical

products. I conducted semistructured interviews with 10 purposefully selected directors,

managers, and technical leaders to gain an understanding of how leaders embed the

required regulations and standards into the organizational culture of their business. The

study findings may contribute to positive social change and improved business practice

by providing tools and skills needed by business leaders to ensure product quality.

Customers should receive products that meet quality specifications, therefore reducing

the potential risks from using substandard products (Liu & Xiong, 2015; Roman, 2014).

Role of the Researcher

I was the primary research instrument and I collected data through telephone

interviews using an interview protocol. Prior to the interviews, participants completed a

participant consent form confirming their willingness to participate in the study. I

recorded and transcribed each interview for data analysis.

Data collection through one-on-one telephone interviews allows for increased

flexibility during the research process, giving the participant an opportunity to respond to

what and how questions (Abutalibov & Guliyev, 2013; Yin, 2014). Use of telephone

interviews with open-ended interview questions may offer the researcher the potential to

obtain honest responses from participants (Trier-Bieniek, 2012). O'Cathain et al. (2014)

noted that telephone interviews were more efficient and suitable for interviewing

business professionals that are in different geographic locations. In addition, Deakin and

Wakefield (2013) noted that face-to-face interviews with participants that are

geographically diverse could be problematic due to time, logistical, and cost elements.

I conducted one-on-one telephone interviews for data collection with 10 directors,

managers, and technical leaders of a single enterprise. The purpose of these interviews

was to understand the strategies used to embed a culture of quality and compliance within

the study organization. Based on the research of Baškarada (2014), Griffith (2013), and

Hyett, Kenny, and Dickson-Swift (2014), I used a purposefully selected sample

population and chose a relatively small, but targeted group for the study.

Baškarada (2014) emphasized the need to manage bias introduced by the

investigator's personal beliefs and expectations. Two sources of researcher bias were

identified by Morse (2015), including the tendency for the researcher to see what they

want to see in the data, and the use of a nonrandom sample population. Morse and Yin

(2014) recommended a cyclical process of review, checking data and patterns during the

interview process, followed by consideration for contrary evidence. I managed personal

bias and set aside judgments, approaching the one-on-one interviews in an open and

receptive manner. Basing my approach on the work of Morse and Yin, I reviewed data

from the interviews in a continuous cycle and checked for contrary evidence and

adjusting the interview questions if needed.

I have direct experience with the challenges of integrating a culture of quality into

an organization and understand the impacts failures in quality can have on a business. As

a quality, compliance, and supply chain professional for over 30 years, I have examined

organizations for compliance with regulations and conformance with organizational standards. The organization I focused on in this case study is a supplier to the corporation I work for; however, it has no direct link to my role in the organization. I am professionally acquainted with some of the participants in the study, but they did not have a direct association with me in my role at my current company. The study company supplies healthcare, pharmaceutical, and medical device intermediates, and several participants indicated that the study organization may have a relationship as a materials supplier with my current employer.

My study required interaction with human study subjects and required conformance to the requirements of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Commission). The conduct of biomedical and behavioral research using human study subjects requires conformance to the National Research Act: Public Law 93-348 (the Act) (U.S. Department of Health and Human Services [HHS], 1974). Leaders at the HHS created the Commission to enforce ethical guidelines established in the Act. The members of the Commission wrote the Belmont Report (HHS, 1979), which established ethical principles and guidelines for studies involving human subjects. I conducted my research study in compliance with the requirements of the Belmont Report (HHS, 1979). The research study review and approval process implemented by the Walden University Institutional Review Board (IRB) ensures that the study complies with the requirements of the Belmont Report. The IRB research study approval number for this study is 12-09-15-0225280B.

When researchers conduct semistructured interviews using open-ended questions, a pilot study is optional (Yin, 2014). I did not conduct a pilot study. Alternatively, in a pilot test of the interview questions, the researcher reviews the interview questions for bias and tests for participant clarity and understanding (Block & Erskine, 2012; Jacob & Fergerson, 2012). I conducted a pilot test of the interview questions using quality and compliance professionals identified through preexisting business relationships. Using a telephone interview format similar to the format for the study, I used the pilot test to verify that the interview questions were clear and easily understood. An interview protocol guided the interview process and enabled collection of similar types of data from study participants. I developed a case study protocol (Appendix B) and an interview protocol (Appendix D), to guide the research process.

During the initial portion of the interview, Broadhurst (2015) and Snyder (2012) recommended that the researcher seek to build trust and engage the interview participant. The interview process provided participants with an opportunity to get to know me prior to the interview, as a way of building trust. Irvine, Drew, and Sainsbury (2012) recommended use of a journal to capture personal reflections regarding verbal cues such as pauses, questions, umm's, ahh's etc. during the data collection process to capture participant reactions to the questions and manage bias (Baškarada, 2014; Houghton, Casey, Shaw, & Murphy, 2013). Darawsheh (2014) recommended implementing a process of continuous self-reflection to increase an awareness of the researcher's reactions and insights. As I listened to the study participants, I wrote down my personal reflections and recorded things I noticed and perceived during the interviews into the

interview protocol. To minimize researcher bias, Baškarada (2014) and Snyder (2012) advocated having the participants answer the same interview questions. I minimized the introduction of researcher bias and used the case study protocol (Appendix B) to ensure consistency in my approach to the research study. I also used an interview protocol (Appendix D) to assure that each study participant answered the same interview questions. During the first interview, several key words required clarification. I incorporated these clarifications into the interview protocol to ensure consistency throughout the interview process.

Participants

I explored the participants' experiences using a single case study with homogeneous purposive sampling. The participant pool consisted of quality and compliance directors, managers, and technical leaders. Palinkas et al. (2013) posited that use of homogeneous sampling reduces variation. I reduced variation through the selection of participants from a targeted division of the study company with roles in quality, compliance, operations, and corporate governance. Using homogeneous purposive sampling for selection of participants from one enterprise allows the researcher to use a smaller sample population to engage in an in-depth exploration of the phenomena under study (Baškarada, 2014; Griffith, 2013; Hyett et al., 2014). Daniel (2012) identified that purposive sampling allowed the researcher to manage selection bias by eliminating random selection of replacement participants. In this study, 10 directors, managers, and technical leaders with a manufacturer of pharmaceutical and medical device intermediates participated in semistructured, telephone interviews. The director of

compliance at the study company acted as the study sponsor and provided assistance in identifying and arranging for access to participants by providing phone numbers and email addresses. The 10 study participants included directors, managers, and technical leaders from the compliance, quality, operations, and corporate governance departments. Four participants representing compliance and two representing quality participated, and two participants each were from the operations and corporate governance departments. A sample of this size and composition allowed me to gather a variety of perspectives, information, and processes associated with the leadership strategies used to embed a culture of quality and compliance. The study participants worked in different geographic locations across the U.S., which necessitated the use of a telephone interview format.

Purposive selection of the participants allows a researcher to invite participation of individuals who have experience with the phenomenon under study (Erlingsson & Brysiewicz, 2013; Snyder, 2012). In this study, participants had a minimum of 5 years of experience in quality and compliance at the study company in director, manager, and technical leader roles that require implementation of strategies and leadership decisions about product quality and compliance. After final confirmation to conduct the study with company management, contact proceeded by phone and email with potential participants for participation in the study. During the initial contact, I provided each participant with a clear explanation of the purpose of the study; a formal invitation to participate, and the need to review, sign, and send the informed consent form. At the request of the director of compliance at the study company, I used email as the primary method of communication and agreed to provide each participant with the interview questions prior

to the formal interview. In my initial contact with the study participants, I provided a

clear explanation regarding the purpose and scope of the study, a copy of the invitation to

participate and informed consent form, and an estimate of the time commitment needed

to complete the interview. In a follow-up contact via email, I confirmed the appointment

for the interview. At that time, I responded to questions regarding the purpose of the

study, reviewed participant confidentiality, discussed potential conflicts of interest, and

provided the interview questions. During the planning phase for the study, I worked with

the director of compliance at the study company to identify potential substitute

participants to use as replacements for employees who elected not to participate or

nonrespondents.

To ensure ethical protection of the participants, I followed legal and academic

requirements. The early phases of research ethics focused on discussing moral concerns

and providing advice to researchers (Johnsson, Eriksson, Helgesson, & Hansson, 2014).

These expansions to the scope of research ethics included research boards, researcher

guidelines, and formal procedures such as the informed consent process in order to

protect study participants from harm (Johnsson et al., 2014). Moreover, both

governmental and nongovernmental organizations, such as the U.S. HHS, and the World

Medical Association, became involved in establishing new standards (Johnsson et al.,

2014).

To ensure ethical protection of participants, I followed the IRB requirements to

secure written consent to participate from every participant, reinforcing the voluntary

nature of their participation. McComas (2012) noted that conflicts of interest may

influence the direction followed for the research study and may bias the results. Effective

management of potential conflicts of interest includes disclosure during the research

process and use of a peer review process (McComas, 2012). I discussed potential

professional or business conflicts of interest in the research study report in order to ensure

clear disclosure of potential bias that may have influenced the study and findings.

By maintaining the confidentiality of study participants and their identifying

information, a researcher maintains public confidence that private information will

remain protected (Beskow et al., 2012; Yin, 2014). I safeguarded confidentiality of the

names of the director of compliance who is the study sponsor, the study participants, and

the name of the study company by replacing names and identifying characteristics with

codes. Hard copy data and interview recordings will remain in a locked filing cabinet in

a secure, limited access location, and retained for 5 years. The hardcopy and digital

materials will go to secure disposal after the fifth year.

Research Method and Design

I used the qualitative research method with the case study design to explore the

strategies used by leaders to embed a culture of quality and compliance within their

organization. The ability of a manufacturer to produce product that meets quality and

compliance requirements ensures their ability to meet customer demand and be profitable

(Mesut et al., 2014). Manufacturers starting out in business identify the parameters that

define a salable product, and seek to define the culture, materials and components, and

manufacturing processes that consistently produce salable products (Korkofingas & Ang,

2011). These product parameters define the quality of the products offered to consumers and establish the basis for managing compliance (Korkofingas & Ang, 2011).

Research Method

The qualitative methodology emerged as early as 1925 as a tool for researchers interested in exploring and understanding human behavior (Bailey, 2014). Use of the qualitative research method applies when the researcher focuses on the *how*, *who* and *why* of organizational processes (Percy et al., 2015; Yin, 2013). To understand the dynamics of the workplace and the factors that influenced product quality, I needed to interact with the study subjects. To understand the social and professional interactions of the work place, the researcher needs to pay attention to employee opinions and experiences (Cronin, 2014). The qualitative, single case study method suited this type of research that explored the strategies leaders need to use to embed a culture of quality ensuring production of marketable products, meeting customer demand, and being profitable.

The qualitative methodology used for this study allowed me to understand *how* leaders select the strategy they use to make quality products, *who* in the organization influences production of quality products, and *why* production of quality products influences business survival (Baškarada, 2014; Yin, 2014). Quantitative and mixed methods methodologies were not suitable for this. The quantitative method focuses on data analysis and the relationship between research variables (Norris et al., 2015) and did not support the study problem statement. A mixed methods study combines qualitative and quantitative design elements into one study (Boeije, van Wesel, & Slagt, 2014).

While the mixed methods approach allows the study of a social or business phenomenon, the level of complexity goes beyond the purpose of the study and integrates quantitative methodology. In this study, I explored an unknown business phenomenon. This topic suited the use of the qualitative method to understand the meaning of a phenomenon based on the experiences of the study participants (Polkinghorne, 2005).

Research Design

I followed the qualitative method using a single case study design. Applying the single case study research design to business research provides the researcher with the opportunity to study a single unit in depth over a specific point in time (Abutalibov & Guliyev, 2013; Baškarada, 2014; Mariotto et al., 2014; Yin, 2014). Yin (2014) defined the case study method as useful to explore a particular problem or topic where the researcher focuses on the meaning of the human experience seeking to identify qualitative elements of behavior. The single case study method allowed me to engage in a detailed exploration of the strategies leaders use to embed a culture of quality and compliance, to assure production of marketable products, meeting customer demand, and ensuring profitability. A researcher interested in focusing on a specific situation to analyze a single phenomenon in the workplace will follow the case study approach (Cronin, 2014; Mariotto et al., 2014; Yin, 2014). I used the case study approach to study the influence of leadership behaviors on a quality culture in establishing strategies that assure production of marketable products, meet customer demand, and be profitable.

As a study design, the case study supports research into individual cases to make use of naturally occurring sources of knowledge (Hyett et al., 2014). Other research

designs I considered included phenomenology, grounded theory, narrative, and

ethnography. Phenomenology enables researchers to study the lived experiences of a

study population across multiple businesses and does not allow for in-depth exploration

of the phenomenon within one enterprise (Moustakas, 1994; Yin, 2014). A researcher

uses the grounded theory design staying open to the patterns and trends that develop

during data collection, and developing a concept and theory after data collection and

analysis (Foley & Timonen, 2015; Redman-MacLaren & Mills, 2015). A researcher

using a narrative design systematically explores the stories of a particular study group

(Robert & Shenhav, 2014; Souto-Manning, 2014). Analysis and interpretation of the

stories enables researchers to develop an understanding of how the study participants

view their world. Joyce (2015) described the application of the narrative method as a

process to identify connections and develop original ideas (Joyce, 2015). I determined

that the narrative design was not suitable for this study. A researcher using an

ethnographic design investigates the daily lives and activities of a study population to

look at the behaviors of a particular culture (Small et al., 2014). The ethnographic design

did not allow me access to a diverse study population located in different geographic

locations. I chose to use a single case study design to study how one organization

embeds a culture of quality and compliance and assures production of marketable

products, meeting customer demand, and being profitable.

Population and Sampling

After identification of a phenomenon to study, a case study design defines the

framework for the research study. A critical next step includes planning to define and

select the study population (Baškarda, 2014; Onwuegbuzie et al., 2012; Snyder, 2012; Yin, 2014). The participants in this study hold leadership roles making decisions on strategies that ensure quality and compliance, and producing marketable products that meet customer demand and ensure profitability.

When researchers use purposeful sampling in qualitative research, they engage information-rich individuals to participate in the study (Palinkas et al., 2013). When using purposeful sampling, Elo (2014) and Snyder (2012) posited that the researcher needs to determine who should be selected to participate, and should define the type of sampling to be used which include purposive, snowball, and intensity (Ingham-Broomfield, 2015). I used purposeful sampling for this study. A study population of 10 participants conforms to trends in current case study theory and practice. Daniel (2012) and Yin (2014) recommended a study population of 10 participants for a single case study. Daniel described homogeneous and nonhomogeneous sample populations recommending a smaller sample population for homogeneous study groups, and a larger sample population for nonhomogeneous study groups. I expected to have a homogeneous sample population, purposefully selected from quality and compliance leaders with a minimum of 5 years of experience from four departments within a single enterprise. Daniel (2012) recommended a study population of 6 to 10 for a case study when using a nonprobability sample design. Yin (2014) recommended 12 or more possible study candidates for a case study. Rapley (2014) recommended 10 to 15 participants.

Onwuegbuzie and Leech (2005) defended use of a sample size of 6 to 10 based on the nature of the study, versus Mason (2010) who recommended a sample size of 20 as the best way to ensure sufficient representation of the sector under study. Baškarda (2014) reinforced that no ideal number exists and depends on the nature of the research question, the resources available, the study timeframe, and the availability of participants. In my study, the participants represented quality and compliance, operations, and governance professionals who hold accountability for development, implementation, and governance assurance for quality and compliance. In a review of 20 qualitative, single case studies that were identified using the search terms *single case study* and *qualitative* in the ABI Inform database, and published between 2012 and 2016, I determined the following: (a) six studies included zero to three interviews for data collection, (b) five studies included four to seven interviews, (c) five studies included 9 to 15 interviews, and (d) four studies included more than 15 interviews. The average number of interviews used for data collection in the 20 studies was 9.6, the median was 6.5, and the mode was 0. Based on my analysis, I used a study population with 10 interview participants conforming to recent trends for selection of effective case study interview populations.

For this study, a homogeneous purposeful sample of 10 study participants ensured an adequate pool of interview data. I achieved saturation after five interviews. Fusch and Ness (2015) defined data saturation as the point when sufficient data exists to replicate the study, when the data collected does not provide new information, and when no additional coding is needed. To determine when saturation occurs, a continuous cycle of data generation, coding, and analysis occurred (Baškarada, 2014; Finfgeld-Connett,

2014). Initial code development took place at the beginning, and during the course of

data collection to identify themes and patterns. This analysis occurred continuously

during the data collection process to allow for evaluation of the development of repeat

themes and patterns. By following a process of continuous analysis, I identified the point

where saturation occurred at five interviews and continued to interview the 10 study

participants to collect data from the entire pool of participants.

Participants eligible to participate in the study included employees in leadership

roles with more than 5 years of experience that represented a cross section of departments

at the study company. The purposefully selected participants represented operations,

corporate governance, quality, and compliance. Consistent with the recommendation of

Daniel (2012), the purposefully selected employee participants had an intimate

knowledge of the quality and compliance requirements for the study company ensuring

their ability to respond to the study questions. Two attributes of quality and compliance

include proactive actions to ensure product quality and regulatory compliance, and

reactive actions in response to product and compliance nonconformance issues (Foster,

1998; Lin, Chu-hua, & Kang-Wei, 2013) that ensure production of marketable products,

meeting customer demand, and being profitable. The responsibilities of study

participants reflected these two attributes of quality and compliance. One source of data

for this study came from the participant interviews. Additional data came from

documentation including the 2014 Annual Report, the Supplier Code of Conduct

document, the Product Stewardship training requirements document, an organization

chart for the Global Industrial & Supply Chain Department, the Corporate Social

Responsibility training curriculum, and the Product Safety Code strategy document. I

also reviewed publicly available compliance information including the 2014 Health,

Safety, Environment, and Quality Policy, the 2013 Sustainable Development Report, the

2016 Product Responsibility Statement, the 2016 Responsible Care® Statement, and the

2016 [branded program] Statement. Yin (2014) posited that using a pilot test of the

interview questions provided the researcher with an opportunity to clarify and refine the

questions. A pilot of the interview questions enhances the credibility and trustworthiness

of the data collection instrument (Baškarada, 2014; Elo et al., 2014; Ingham-Broomfield,

2015; Noor, 2008; Yin, 2014). I conducted a pilot test of the interview questions and

revised some of the interview questions after the pilot test to clarify the terms habit,

appraisal, and prevention.

Ethical Research

Each participant for this qualitative single case study received a letter of invitation

for voluntary participation offering no material or financial incentives (Appendix A), and

the informed consent form. The request for participation detailed participant expectations

and rights, and planned procedures for gathering, displaying, evaluating, disseminating,

and storing the data (Ingham-Broomfield, 2015). Once the interviewee communicated an

initial expression of interest in participating to me, I used a follow up email to send a

second copy of the informed consent form and the interview questions. The informed

consent form provided detailed information about the research study so that the

participants could familiarize themselves with the planned line of questioning during the

interview (Snyder, 2012). I answered any questions or concerns posed by participants

before, during, and after the study. By signing the informed consent agreement, the

participant acknowledged their understanding and agreement for participation in this

research study. Data collection for the study began after receipt of the informed consent

form from each participant with one exception. One interview required rescheduling

when circumstances prevented successful receipt of the consent form at the time of the

first interview.

The procedures outlined in the informed consent form support a process that

minimizes bias, provides transparent communications with study participants, and

minimizes the potential for post interview misunderstandings in regard to use of the

interview data. I used alphanumeric coding to assist in the confidentiality of the study

site and participant identifies. Alpha codes described the participant role in the

organization and sequential numbers tracked the number of participants in each group,

including: Q for quality, R for regulatory, O for operations, and G for governance. I also

used the codes D for director, M for manager, and T for technical leader. The addition of

a sequential number to the code tracked how many participants were in each group. This

approach allowed me to maintain the confidentiality of participant and organization

identities. I am storing the codes in a secure location accessible only by me as the

researcher. By maintaining the confidentiality of study participant identifying

information, a researcher maintains public confidence that private information will

remain protected (Beskow et al., 2012). Personal email addresses and other identifiable

information for participants have remained confidential. I provided a teleconference

number to ensure the confidentiality of individual telephone numbers for the interviews,

follow-up conversations, and member checking. Participants had the right not to participate, to withdraw from the study, or not to answer any question at any time during the research study. After the interview, all of the participants received the top three themes identified from a review of their interview transcript. The study data, including the alphanumeric code sheet, hard copy files, and digital and audio data will remain in a secure location accessible only by me, the researcher, for a period of 5 years. Data destruction will occur after 5 years using a confidential document disposal service.

Different organizations, such as, the World Medical Association, and the U.S. HHS, expanded human research requirements to include formal procedures such as the informed consent process to protect study participants from harm (Johnsson et al., 2014). The expansion was, in part, due to past unethical practices (Johnsson et al., 2014). The study approval process included an ethics review by the IRB at Walden University with approval granted to proceed with the study (Research Study IRB #: 12-09-15-0225280B). This review indicated that the study met IRB requirements. The study population included consenting adults over 18 years old who volunteered to participate.

Data Collection

After obtaining IRB approval, data collection began with final confirmation of interviewee participation via email and execution of the informed consent form. The initial email conversation with each interviewee covered the scope of the case study interviews, the informed consent process and necessary sign-off, and the measures established to ensure confidentiality of participant identity, company identity, and study data. Snyder (2012) recommended sending interview questions to the participants a few

days in advance as a reminder of the interview, but timed to prevent over analysis prior to the interview. Interviewees received a copy of the interview questions within 3 days of the interview to relieve anxiety about the questions, and to serve as a reminder of the interview time and date. Telephone-based participant interviews provide an effective approach and consistent interview format across the study group (Baškarda, 2014; Vogl, 2013), which included interviewees from different geographic locations.

Data Collection Instrument

As the primary data collection instrument, I used open-ended questions for the interviews. The one-on-one telephone based, semistructured interviews typically lasted 40 minutes per participant with some lasting 60 minutes. The interviews occurred at a time and location convenient for the participant. I conducted the pilot test of the interview questions to refine the questions, and the semistructured study interview process, from the privacy of my home office. The informed consent form verified permission of the study participant to record the interview to capture verbatim comments. During and after the study, the interview recordings and transcriptions will remain in a locked filing cabinet in a secure office location in Pennsylvania for 5 years. Additional data sources enhance credibility and trustworthiness of the findings (Elo et al., 2014; Onwuegbuzie et al., 2012; Morse, 2015; Yin, 2014). I asked the company sponsor to share additional data from documentation including the 2014 Annual Report, the Supplier Code of Conduct document, Product Stewardship training requirements document, combined organization chart for the Global Industrial & Supply Chain Department, Corporate Social Responsibility training curriculum, and the Product Safety Code

strategy document. I also reviewed publically available compliance information including the 2014 Health, Safety, Environment, and Quality Policy, the 2013 Sustainable Development Report, the 2016 Product Responsibility Statement, the 2016 Responsible Care® Statement, and the 2016 [branded program] Statement. When the researcher uses a pilot test of the interview questions there is the opportunity to test and refine the questions enhancing credibility and trustworthiness (Baškarada, 2014; Elo et al., 2014; Ingham-Broomfield, 2015; Noor, 2008; Yin, 2014). I used a pilot test of the interview questions, a case study protocol (Appendix B) and an interview protocol (Appendix D) to ensure consistency in my research and data collection process.

The data collection process used for this study included one-on-one telephone interviews using open-ended questions and consistent with the design of a qualitative, case study (Ingham-Broomfield, 2015; Isaacs, 2014; Onwuegbuzie et al., 2012; Yin, 2014). The telephone interviews captured the lived experiences of employee culture and habits that embedded a culture of quality at the study enterprise. Baškarada (2014) and Houghton et al. (2013) discussed the value of taking notes, and recording personal observations during the interview. During the call I listened, took notes directly on the interview protocol, and digitally recorded the interview to capture the responses and verbal cues such as the words hmmm, ahh, can you clarify, ummm, and prolonged silence to identify data that replaces visual cues.

Snyder (2012) recommended providing study participants with the questions a few days in advance as a reminder of the upcoming interview. Study participants initially received a letter of introduction to the study and the informed consent form, followed by

an interview confirmation appointment and a copy of the interview questions in advance.

Yin (2014) discussed the use of a pilot test of the interview questions to test and refine

the interview questions. Using a preliminary review, or pilot test, of the interview

questions ensures the wording is clear and understandable with the target participants

(Baškarada, 2014; Elo et al., 2014; Ingham-Broomfield, 2015; Noor, 2008; Yin, 2014).

Prior to conducting the interviews, I conducted a pilot test the interview questions with a

group of quality and compliance professionals based on the East coast to assure clarity

and understanding with the participants. Doody and Noonan (2013) compared structured,

unstructured, and semistructured interview approaches noting that a semistructured

interview process utilized a script using open-ended questions, and allowed the researcher

the flexibility to adapt wording as needed, and to explore issues and concepts that arose

during the interview. During the interviews the terms habits, appraisal, and prevention

typically needed clarification. By initially establishing an interview protocol (Appendix

D) with a script of the interview questions, the participants responded to the same

questions, however, these open-ended questions allowed me to seek clarification and

explore issues that arose during the interview.

Data Collection Technique

Data collection occurred through telephone conversations to ensure uniformity in

the interview approach (Baškarada, 2014; Houghton et al., 2013). Although different

from traditional in-person interviews, researchers have indicated that telephone

interviews provide an equivalent level of data collection quality (Baškarada, 2014;

Houghton et al., 2013; Vogl, 2013). I used a telephone interview format to facilitate the

participant interviews using a standard format to ensure consistency in the data collection process. The telephone based interviews allowed participants at different geographic locations to participate letting participants to come from a wider pool of study candidates. The telephone format does not allow for visual observations, a perceived disadvantage of the data collection process (Baškarada, 2014; Houghton et al., 2013). A telephone interview provides the study candidates with greater flexibility to schedule the interview at a convenient time and location, and reduces logistics issues (Baškarada, 2014; Houghton et al., 2013). In this case, I managed the interview schedule around the year-end holiday, business trips, and the planned relocation of the headquarters offices to a nearby building. While using telephone interviews differs from traditional in-person interviews, data collection through telephone interviews provides valid results (Baškarada, 2014; Houghton et al., 2013; Vogl, 2013).

Prior to the interview, the study candidates received a letter of introduction to the study and a copy of the interview questions to familiarize themselves with type and scope of the questions (Baškarada, 2014; Houghton et al., 2013). Chikweche and Fletcher (2012) and Snyder (2012) discussed how sharing questions in advance could build trust between the researcher and the participant. By sharing the questions in advance, I built participant trust by allowing the participants an opportunity to prepare and become comfortable with the process. I found that each participant valued the opportunity to review the questions in advance and had the list open for reference during the interview with notes they had prepared.

Nottingham and Henning (2014) discussed the value of member checks as a process to improve the credibility of qualitative data. In addition, Baškarda (2014) and Snyder (2012) discussed the use of member checking to verify the accuracy of researcher interpretations of participant comments. The member check process allows the researcher to check understanding, and for participants the opportunity to verify researcher interpretations (Li, Westbrook, Callen, Georgiou, & Braithwaite, 2013; Morse, 2015; Nottingham & Henning, 2014). Li et al. (2013) and Morse (2015) both posited that member checking enhances credibility. The options for member checks include incorporating it into the research process during the interview, at the conclusion, or both (Harper & Cole, 2012; Li et al., 2013; Morse, 2015). I chose to conduct member checking after each interview. Morse noted the value in establishing guidelines for the use of semistructured interviews. To facilitate uniformity of my approach to each interview and the member check process, I created an interview protocol (Appendix D). Nottingham and Henning proposed a format for member checks where the researcher identified the three key points from each interview and provided the study participant with the researcher's interpretation for review after their interview. After each interview, I presented the participant with the three prominent themes from their interview, based on my interpretation, through a follow up email. I allowed the participant the option to respond to me via a phone call or email, and to provide edits or identify any additional ideas they had that might benefit the study.

The one-on-one telephone interviews occurred at a time and location convenient for study participants. Recording of the interviews proceeded after reconfirming the

permission of the study participants to assist me in capturing interview details and nuances. After the interview, I transcribed the recordings, conducted further analysis, and stored the transcriptions and recordings in a secure location. Additional data sources included field notes, recording of verbal cues, observations made during a tour of the headquarters building, and archival documents.

Sources of data in qualitative research can include interviews, personal journal notes, observations, archival documents, and physical artifacts (Baškarda, 2014; Hanson et al., 2011; Snyder, 2012; Yin, 2014). Additional sources that offered relevant data included observations during a site tour of the headquarters site, and different types of archival sources including public records and documents (Baškarda, 2014; Percy et al., 2015; Snyder, 2012; Yin, 2014). During the data collection process, I requested the following from the director of compliance at the study company: (a) a tour of the headquarters site, (b) access to internal archival records, and (c) reference copies of those archival documents which may include posted policies and procedures used to guide the quality and compliance process. I reviewed the following documentation provided by the organizational sponsor: (a) the 2014 Annual Report, (b) the Supplier Code of Conduct document, (c) Product Stewardship training requirements document, (d) the organization chart for the Global Industrial & Supply Chain Department, (e) Corporate Social Responsibility training curriculum, and (f) the Product Safety Code strategy document. I also reviewed publically available information including (a) the 2014 Health, Safety, Environment, and Quality Policy, (b) the 2013 Sustainable Development Report, (c) the

2016 Product Responsibility Statement, (d) the 2016 Responsible Care® Statement, and

(e) the 2016 [branded program] Statement.

Data Organization Techniques

Data storage occurred in a password-coded and encrypted laptop computer in

electronic files sorted by data source. I used an interview format to gather data, which

allowed interviewees to share stories about their experiences in implementing strategies

to embed a culture of quality and compliance, and assuring production of marketable

products to meet customer demand and be profitable. To enhance credibility and

trustworthiness of the data, I standardized my approach to data collection (Baškarda,

2014; Elo et al., 2014). Snyder (2012) noted the value of taking journal notes

recommending using a fixed format to ensure consistency. Snyder (2012) reinforced the

value of an interview protocol to ensure consistency during the different interviews. I

used the interview protocol (Appendix D) as the standard format to record notes during

the interview and for reflexive journal notes. Similarly, the recorded interview transcripts

followed a standardized format capturing the verbatim conversation directly from the

recording, with storage in a secure location for duration of 5 years.

<div align="center">Data Analysis Technique</div>

Per the recommendation of Baškarda (2014), Ingham-Broomfield (2015), and

Snyder (2012), data analysis occurred in parallel with data collection allowing for

adjustments to the coding that enhanced the research process. Based on

recommendations posited by Baškarda, Ingham-Broomfield, and Snyder, I created an

initial list of codes at the start of the data gathering process based on the literature review.

I used a continuous cycle of data generation, coding, and analysis, as posited by

Baškarada (2014), and Finfgeld-Connett (2014), updating the lists of codes to reflect

emerging patterns and outlying variations. I stored the coded interview transcript in a

secure and encrypted electronic file set up specifically for the coded data.

Methodological triangulation improves data credibility by showing concurrence

between interview data and at least two other sources of data (Baškarda, 2014; Ingham-

Broomfield, 2015; Snyder, 2012; Yin, 2014). The primary source of data came from the

interviews and personal journal notes (Baškarda, 2014; Snyder, 2012; Yin, 2014). I used

additional sources for methodological triangulation that offered relevant data to include

observations during a tour of the headquarters site, policies, procedures, annual reports,

and publically available compliance information.

After reading the transcripts several times to identify repeat themes, further

analysis occurred using the Wordij (http://wordij.net/) software tool for text analysis. I

used Wordij to analyze how the language used by interviewees in the transcripts, and the

text documents collected, can express meanings. By using Wordij, I showed the

relationships pictorially as a visual network. Garcia and Gluesing (2013) noted that by

using the tool, researchers could organize the words and phrases to show biword

connections. My analysis of the different word based relationships identified during data

analysis identified links between the data, the literature review, and conceptual

framework showing strategies used to overcome constraints and identifying ongoing

constraints requiring resolution.

Reliability and Validity

Researchers have the choice to follow either a quantitative or qualitative research

design. I chose the qualitative design for this study. When using the quantitative design,

a researcher looks to determine a source of truth while controlling for variables and

minimizing variation, while also maintaining an objective point of view (Erlingsson &

Brysiewicz, 2013). The terms credibility and trustworthiness relate to the methodological

rigor followed to ensure the quality of the data and findings for a qualitative study. The

researcher who uses the qualitative design explores a phenomenon in a natural context

using multiple sources of data (Baxter & Jack, 2008; Houghton et al., 2013). Lincoln and

Guba (1985) proposed using the criteria of credibility, dependability, confirmability, and

transferability to establish the credibility and reliability and validity of qualitative

research. These terms address reliability through the dependability and confirmability of

the data and findings; and validity through the credibility, transferability, and

confirmability of the research process, data accuracy, and findings (Houghton et al.,

2013). Houghton et al. discussed approaches for demonstrating rigor to include

triangulation and member checking to demonstrate credibility, and an audit trail to

demonstrate dependability and confirmability, and detailed descriptions to enhance

transferability.

Reliability

I developed a case study protocol (Appendix B) based on guidance on approach

and format from Cronin (2014) and Yin (2014). The case study protocol allowed me to

define the data collection process and interview questions ensuring consistency of the

interviews and dependability of the data. A pilot test of the interview questions provides

an opportunity to refine the questions and assure that the data collected during interviews

is dependable (Elo et al., 2014; Yin, 2014). I conducted a pilot test of the interview

questions, to test and refine the interview questions and interview process, using a

telephone interview format with quality and compliance professionals identified through

preexisting business relationships. Sandelowski (1993) and Houghton et al. (2013)

promoted the use of the member checking process where participants have the

opportunity to confirm the accuracy of their interview feedback to enrich the credibility

and trustworthiness of the research. I utilized the process of member checking by

summarizing my interpretations of the three prominent interview responses for each

interviewee. Study participants received a copy of the three interpretations by email and

have had an opportunity to confirm my interpretation.

Validity

For qualitative research, two of the means for establishing the believability and

trustworthiness of the data and research include credibility and transferability (Houghton

et al., 2013). Processes a researcher may use to enhance credibility include an interview

guide to ensure consistency, member checking of data obtained from the interviews, and

a pilot test of the interview questions (Baškarada, 2014; Elo et al., 2014; Houghton et al.,

2013; Vogl, 2013; Yin, 2014). Houghton et al. indicated that confirmability includes

establishing an audit trail by recording decisions made during the research process to

enhance the trustworthiness of the research. I included journal notes in the coded

transcript using the MS Word Review New Comment feature to record interpretations,

reflections, and decisions made during the research process. Making a record of detailed descriptions of the findings enhances the transferability of the research allowing the reader to identify opportunities where the research applies to their particular situation (Erlingsson & Brysiewicz, 2013; Houghton et al., 2013; Lincoln & Guba, 1985). I have enabled the reader to draw their own conclusions and determine how to apply my findings to their own circumstances with detailed descriptions. Triangulation of the data, based on observations and documentation obtained through the data collection process, enhances the credibility and transferability of the study results (Baškarda, 2014; Houghton et al., 2013; Ingham-Broomfield, 2015; Snyder, 2012; Yin, 2014). I triangulated the data derived from the interviews with observations made at the headquarters sites and documentation obtained from the organizational sponsor and from publically available sources.

Elo et al. (2014) discussed the importance of selecting an appropriate sample size to ensure the credibility of data content analysis. For qualitative studies, the optimum sample size depends on the nature of the study, and data saturation indicates achievement of the optimal sample size (Elo et al., 2014). By collecting and analyzing data in a cyclical fashion throughout the research process, the researcher may monitor data saturation by observing replication of themes, patterns, and categories (Baškarada, 2014; Elo et al., 2014; Goffin, Raja, Claes, Szwejczewski, & Martinez, 2012). I analyzed interview data to identify emerging themes as the interviews progressed. Based on the work of Marshall, Cardon, Poddar, and Fontenot (2013), to achieve saturation, interviews continue until no new insights or themes emerge. The sample set included 10 purposely

identified study participants. I continued to conduct interviews until no new insights or themes appear in the data. I achieved saturation after 5 interviews.

Transition and Summary

In Section 2, I discussed my role as the researcher, and described the participant population, and sampling process. The purposefully chosen sample of 10 interviewees came from departments at the study company with responsibility for ensuring product quality and compliance, and governance over the processes implemented to embed a culture of quality. Participants are under the protection of the Belmont Report ensuring the safe treatment of human participants (HHS, 1979). The research study review and approval process implemented by the Walden University Internal Review Board (IRB) ensured that my research study complied with the requirements of the Belmont Report.

After obtaining IRB approval, data collection began with final confirmation of interviewee participation and execution of the informed consent form. The data collection process included interviews, observations, archival records, and documents. Data analysis included coding of the data and analysis using the Wordij program to identify themes and patterns that identify the strategies leaders use to embed a culture of quality.

In Section 3, I present the findings of my research study by restating the research question and presenting a detailed analysis and discussion of the findings. The findings include a presentation of the themes, an analysis against other peer-reviewed studies, and a discussion regarding the link between the findings and the conceptual framework. In addition, I discuss the potential application of the findings to the professional practice of

business, and the implications for social change. The final elements of Section 3 include

recommendations for action and further research, personal reflections, and conclusions.

Section 3: Application to Professional Practice and Implications for Change

Introduction

The purpose of this qualitative case study was to explore the strategies healthcare manufacturing leaders use to embed a culture of quality and compliance within their organization to assure sufficient production of marketable products to meet customer demand and be profitable. A quality culture reflects the attributes required for an organization to ensure a commitment to producing saleable products that meet customer requirements (Mosaad, 2014). A challenge for leaders in any organization is to identify strategies that influence and drive a culture of quality and compliance (Deselnicu & Matveev, 2014; Yap & Webber, 2014).

In this section, I present the findings of a single case study of a pharmaceutical intermediates company where I explored and identified strategies leaders used to influence a culture of quality. The targeted study sample consisted of 10 leaders in one division of the company based in different geographical locations of the United States where the products include chemical intermediates for use in consumer healthcare, medical, and pharmaceutical products. I found that the combination of an integrated quality and compliance platform using data collection and analysis allowed the use of TOC to identify and eliminate constraints.

Presentation of the Findings

Following the qualitative method, I conducted 10 interviews of leaders within one organization, enabling an in-depth exploration of the strategies used to embed a culture of quality within their organization. The overarching research question for this single case

study was: *What strategies influence quality and compliance in an organization assuring production of marketable products and meeting customer demand?* The study participants had a minimum of 5 years of experience in leadership roles in quality, compliance, operations, and governance. To ensure the privacy of the study participants, I replaced their names with the following codes: RD1, OD1, OD2, GD1, GD2, RM1, RM2, QM1, QM2, and RT1 where the letters in each code refers to the part of the organization where each participant works. During the interviews, participants responded to eight interview questions in developing data for this study. Due to the open-ended structure of the interview questions participants shared a diversity of experiences and details.

I collected additional data from the following: (a) the 2014 Annual Report; (b) the Supplier Code of Conduct document; (c) the Product Stewardship training requirements document; (d) the combined organization chart for Health, Safety, & Environment, Product Safety, and Quality & Compliance Department; (e) the Corporate Social Responsibility training curriculum; and (f) the Product Safety Code strategy document. I also collected data from observations made during a tour of the corporate headquarters. I reviewed publically available information including: (a) the 2014 Health, Safety, Environment, and Quality Policy; (b) the 2013 Sustainable Development Report; (c) the 2016 Product Responsibility Statement; (d) the 2016 Responsible Care® Statement; and (e) the 2016 [redacted name of branded program] Statement.

The data reaches saturation when the interview responses begin to repeat, with no new information or coding themes surfacing (Fusch & Ness, 2015). I reached saturation

at five interviews and I continued to collect data from all 10 participants utilizing the planned study group.

The steps followed for the data analysis included transcription, cyclical review for themes and issues, coding, and synthesis. I transcribed the 10 interview transcripts myself, noting potential themes and coding, and repeating the review process as the interviews progressed. Themes emerged through the analysis of the transcripts. I found that the major themes and subthemes supported the research question and included leadership, culture and habits, communications, training, and management systems. All of the participants agreed on all themes, except Participant QM2, who had a different perspective on the importance of communication. These themes align to the conceptual framework used for this study, the theory of constraints, reinforcing the need to identify and remove barriers throughout the organization to embed a culture of quality and compliance. I compared the themes, the literature review, and conceptual framework to assess the reliability of the study.

Wordij Analysis

I used Wordij to analyze how the language used by interviewees in the transcripts could express meanings. Using this analysis creates a visual diagram showing the relative intensity and relationships of the words in the document undergoing analysis (Lim, Berry, & Lee, 2016). By using Wordij, I was able to show pictorially how the themes emerged from the responses of the study participants as a visual network. Figure 1 displays the Wordij analysis using a target word of quality and a seed word of culture aligning the analysis with the central research question. One of the challenge when using

semantic analysis is the potential difficulty to bring certain words into prominence in the

analysis since the software tool does not fully represent the characteristics of how

individuals think (Morais, Olsson, & Schooler, 2012). In my analysis, I used 40 nodes

that resulted in a pattern showing general support for the themes. The semantic word

relationships identified in the analysis, shown in Figure 1, reflected the themes and the

link between quality and culture with management (black dot, solid line),

communications to customers and employees (gray dot, dashed line), and management

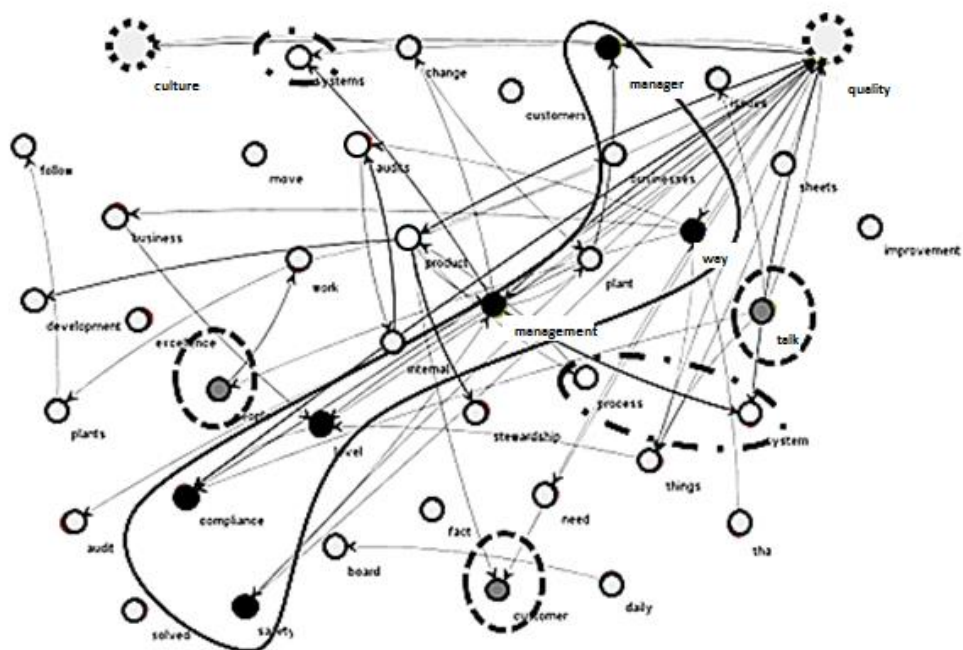systems and data analysis (white dot, dash/dot line).

Figure 1. Wordij based analysis showing word relationships

My goal in running this analysis was to look at the interview data from the perspective of a graphic display that indicated links between different words. I used a file that contained the interview participants' words as the basis for this analysis. By creating a Wordij droplist, I filtered out common words that did not add value to the analysis. I also eliminated terms that might identify the participants and organization. Wordij uses a sliding window of three words before and after each word position to create an occurrence distribution (Danowski, 2012, 2013). The master file contained 6,971 words that included 695 unique words detected by the Wordij analysis. Within this list of unique words, the tone of the organization's commitment to quality and compliance became clear in the nine words that occurred at a frequency of over 50% (Table 1). Peng, Zhang, Zhong, and Zhu (2012) noted that during interviews, participants could potentially use different words to describe the same concepts, for example, the use of the singular and plural form of certain words. I did not standardize these words prior to the analysis in order to maintain the different words used by participants as part of the analysis. The use of these words by participants demonstrated the relative intensity of participant responses and aligned to the themes. The Wordij analysis reinforced the theme analysis showing that the participants focused on the importance of management engagement across levels and business units, the value of the company's branded organizational way program to influence the organizational culture, and the importance of communicating with people and customers. The words *quality*, *compliance*, and *culture* dominate the sematic network of the participants' words, linking frequently to terms that align with the themes.

Table 1

Wordij Analysis for Word Occurrence above 50%

Word	Occurrence Rate
Quality	113
Product	100
Compliance	91
Management	70
People	69
Way	67
Customer	63
Level	61
Business	59

Theme 1: Leadership

Participant responses to the first and second interview questions were similar regardless of their role in the organization contributing to this theme. Ten out of 10 participants discussed the leadership philosophy and programs in their organization as starting at the top and moving down through the organization. Two of two operational directors discussed the value of participative leadership at the manufacturing site level where operators were empowered to take action to eliminate production issues.

In describing the leadership role of management in the organization, participants described the global, branded program that served as a framework to establish their way of doing business as a critical strategy that sets the global standard for quality and compliance. Executive leadership within the study company formally adopted a branded program establishing their way of doing business with quality and compliance positioned as a primary behavior. Participant RD1 stated, **"**Quality and compliance leadership at

[organization name] is our way of doing business and starts at the top with a strong

commitment from our President and moves throughout the global organization."

Participant GD1 explained their holistic approach to quality, stating, "We need to do

things in a quality way as we produce our quality products and a quality way needs to

ensure environmental safety, worker safety, and public safety."

Nine of the 10 participants discussed the company's integrated approach to

quality and compliance with participant OD1 explaining,

We look at the quality systems as one part of the manufacturing process, um we

also look at environmental, regulatory, and health and safety. All would be part

of that management system and um we try to take a holistic view of all of those

systems when we're talking about quality, safety, manufacturing, customer focus,

competitiveness, and continuous improvement.

Participant QM1 linked management leadership to quality culture stating:

We have deployed certain leadership practices globally that help us ensure a

quality culture including a [branded program] defining our organizational

philosophy where the main pillars are quality and excellence, and sustaining a

global ISO 9001 certification for our 26 manufacturing plants.

Participant OD2 further explained, "But in our organization we are fortunate that it really

does start from there. Our CEO goes out of his way on a regular basis to state which

direction everyone should be running in."

While the participants described strong support from top leadership, participant

GD1 observed opportunities for continued improvement stating that, "I think the various

businesses have evolved to where they really live certain aspects of [name of branded platform] and less so in other aspects and what those aspects are vary from business to business." The participants took pride in the visible engagement of their company president with participant OD1 noting, "We are fortunate to have the leadership of our president sending a consistent message of quality and compliance, enabling the effectiveness of the messages we deliver at the plant and reinforcing the culture." Participant RT2 expressed that, "And I've always found that changing culture takes such a long time and you don't always see it happening until it happens. You really just need to be persistent." In driving accountability for quality and compliance, Participant RD1 explained,

> And that implementation and [name of branded program] are incorporated, everyone is trained, everyone is rated on performance, and that is a portion of our performance as a company, as a division, and as individual departments, is incorporated into our salary structure. So everyone has a very significant stake in the game from the person on the line and the admin staff all the way up to the executive levels.

During the tour of the headquarters site, I observed the leadership philosophy expressed in informational postings throughout the office area and in the break room.

Cultivating a culture where employees take responsibility to ensure that products meet customer expectations requires leadership strategies that minimize the inclination for employees to engage in risky behaviors (Hirschauer, Bavorova, & Martino, 2012). Leadership strategies that drive product quality link to other business strategies that

maximize profit including the strategic interaction between firms and strategic

performance incentives for managers (Veldman & Gaalman, 2014). Leaders should

engage with internal employees, customers, and stakeholders to embed a culture of

quality and compliance. The leaders in the study company expanded this notion to

encompass quality, compliance, health, safety, and environment. Veldman and Gaalman

related how customers preferred features that integrate into the product developed for sale

identifying the potential impact of leadership decisions on product quality.

Theme 2: Culture and Habits

Ten of 10 participants discussed the importance of habits as an important aspect

of their culture of quality and compliance. In addition to the words culture and habit,

participants also used the words mindset and attributes or described specific behaviors.

Nine of 10 participants used the word culture, seven of 10 participants used the word

habit, one participant used the word mindset, and one participant used the word attribute

in describing the behaviors the branded organizational way program and management

systems drive within the employee population.

In response to interview questions 2 and 4, the participants discussed habits as

attributes reflecting more of a mindset with participant OD1 indicating, "I would rather

not define what we do as a habit more of more of a mindset." Participant OD1 further

clarified that,

> It's just very simple mindsets performance management removing barriers from
>
> performing at a level where we can sustain not only our business but, um I would
>
> say um, I'm missing a word, and be a predictable supplier to all of our

customers.

Participant RD1 said, "I think when you when you look at habits, compliance needs to be something that is unconscious, so if you look at the different stages of learning and awareness, you have to reach the final stage of unconscious awareness." Participant RT2 discussed the time needed to influence changes to an organizational culture stating,

I think the one thing we did not really talk about is the sort of the time it takes to change a culture and to reach the culture that you want. I think that's always something that doesn't always get looked at, um because you know it's very organic and people are very different and there's always different ways to get across to people. And I've always found that changing culture takes such a long time and you don't always see it happening until it happens. You really just need to be persistent.

To embed a culture of quality, leaders establish work routines and habits that link quality to organizational performance (Polites & Karahanna, 2013), to ensure that employees use internal procedures and adhere to quality processes. Neal et al. (2012) posited that there is a positive behavioral association in relation to goals and actual habit performance, and a nonlinear relationship between the influences of goals on habit performance. Green (2012) examined how cultivating an employee culture with behaviors that supported compliance to standard operating procedures, process requirements, product inspections, error elimination, and regulatory compliance required leadership strategies to integrate behaviors aligned to these requirements, and behaviors that constructively managed deviations.

Theme 3: Communications

In response to interview questions 3, 4, and 7 participants discussed the value of clear communications between organizational departments and customers to ensure quality and compliance. Overall, nine of 10 participants specifically discussed communications strategies and programs used by the study organization. Participants described the use of different communications methods such as training, product safety data sheets, one-to-one coaching, attendance at business unit meetings, and direct engagement with customers. In addition, participants identified the processes used to inform partners of requirements, and to seek input about real or perceived constraints. These communications processes used by the study company targeted development and reinforcement of quality and compliance skills, acknowledging that there is always room for improvement. Participant OD2 made it clear how important communication was in saying:

> Communication, regardless of how many years we say communications is important, we find over, and over again, that we fail to communicate effectively. Especially within a large organization but even, you know, when there is a site like this one with as few as 60 employees having people spread out over shifts makes it incredibly difficult to ensure that everyone hears what you intend for them to hear. So, communication is something that we press, over and over again, to try to encourage excellence in communication.

Participant QM2 discussed the importance of clear communications with both internal and external customers explaining that:

A lot of it comes down to asking questions and that goes both ways. Whether it's

asking questions to the customer or asking questions internally as to there's

something you don't understand there's something we're getting involved in here

but maybe we shouldn't.

Participant OD1 described the organization's approach to communications indicating

that:

When I'm talking with our customers about what their needs are, sometimes

they're not very well defined and we have to pull that out. I think that's probably

one of the more difficult conversations we have with customers and quality

topics are What is it that you need?

In describing the communications strategy for internal and external customers,

Participant RT1explained, "It is important to focus on communication that reflects an

open mind, responds to customer needs in a style that is clear, consistent, concise, and

timely with internal and external customers, partners, and stakeholders." Participant OD2

linked clear communications with an understanding of customer perceptions indicating:

Close communication with customers assures we are able to produce products at

the quality they expect; by routinely requesting feedback from customers,

employees, and visitors we are able to see ourselves through the eyes of others

and understand their perception of us. By understanding these perceptions we can

identify opportunities for improvement.

Participant RM1 reinforced the value of communications with customers stating, "we've

learned from customers, we've learned from suppliers".

Zelnik et al. (2012) identified that implementation of the QMS depended upon management support for the QMS and involvement to drive employee satisfaction, motivation, and communication. Participant RM1 explained,

> I think the most difficult part, and it does involve communicating, ah when you communicate to someone you actually have to convince them that you are communicating positive and not only is it positive for you but it's positive for them in their job and their self-worth.

Participant RM1 reinforced the link between communications, positive thinking, and self-worth to enable a culture of quality and compliance.

The participants emphasized the importance of employee training by linking training to successful communications on quality and compliance requirements and performance expectations. Participant RM1 indicated that, "Leadership strategies focus largely on training and education at all levels of the organization". Participant QM1 framed in the relationship between quality and compliance, and training, explaining further that they, "…provide training at various levels starting at the management level to make sure that we understand our roles and responsibilities and also understand the focus of the company." Participant RM1 noted that, "Leadership strategies focus largely on training and education at all levels of the organization." Participant RD1 added to the organizational view on training by explaining that, "You need to look at consistency, you need to look at repetition, you need to look at the, at the importance of establishing a mechanism for training."

Several participants discussed specific details of their training approach. In further clarifying one of the goals in their training, participant RT1 indicated,

I wanted to emphasize that they recognize that even making small changes, even from a process or a chemistry point of view might not be significant, is very significant from the regulatory or compliance side and we've kind of trained them to understand that need and to recognize those differences.

Participant OD1 discussed the training strategy as including two parts,

"Oh, there are a couple of different strategies. One is obviously make sure they understood what you said by going through a test or a short test. Ah. We do that both from a computer based standpoint and ah written on paper just to make sure that they ah have learned the things that we have conveyed. That's the primary thing. One of the things you can do on a manufacturing level, is that we actually have, out on the floor, for example, if we have an operator who has been trained on-the-job, quote unquote, and you can also demonstrate that you have learned the skill by demonstrating it on-the-job.

Several participants reflected on how to improve their training process. Participant RT1 noted,

So I thought about the idea of instilling the idea through training and also through dialog with the different cross functional groups in our organization, the idea that product stewardship should be part of every process, every part of the organization.

Participant OD1 discussed the need to continue to improve their approach to training: "I don't think in this organization that we have either we have optimized the ability to train adult employees. This is certainly something we recognize as a habit we need to be better at."

The need for effective training is critical to enabling production of quality and compliant products. Polities and Karahanna (2013) posited that employee training to communicate the manufacturing standards and procedures that deliver compliant and quality products may be misinterpreted and result in employee mistakes. Barriers to successful implementation of a quality culture included a perception of a lack of value, a lack of time and financial resources, insufficient leadership commitment, and ineffective training across the employee population (Davis et al., 2014).

Theme 4: Management Systems and Data Analysis

Participant answers to the fourth, fifth, and sixth interview questions consistently identified management systems that included programs, and data collection and analysis as one of the strategies used to embed a culture of quality and compliance. Ten of ten participants discussed the importance of global management systems in providing a framework for quality and compliance. Participants used the terms process, program, and system to describe the global initiatives used to provide structure to their quality and compliance culture. They referred to the Responsible Care® program, product stewardship, manufacturing excellence, ISO standards, product and employee safety, and customer service (Table 2).

Table 2

Minor Management System Themes

Minor Themes	% of participants
Responsible Care®	40
Product stewardship	40
Manufacturing excellence	30
ISO standards	40
Product and employee safety	90
Customer service	90

Ten of 10 participants emphasized the value of data analysis in identifying trends and issues to eliminate barriers to achieve quality and compliance requirements. Five of 10 participants mentioned the use of the SAP suite of business tools for use in data analysis, four of 10 participants referred to data collection and analysis as part of the manufacturing excellence process, and three of 10 participants referred to traditional spreadsheet programs for data analysis.

Programs

The global programs mentioned by study participants included the Responsible Care® program, a global initiative unique to the chemical industry; product stewardship, manufacturing excellence, ISO 9001, product and employee safety, and customer service. Participant OD1 discussed how all of the systems tie together:

We look at the quality systems as one part of the manufacturing process. We try to take a holistic view of all of those systems when we're talking about quality, safety, manufacturing, customer focus, competitiveness, and continuous improvement.

Participant RM1 stated:

We have a product stewardship process that influences leadership decisions and

structures cross-functional communications on our processes during product

development and through to commercialization helping us to examine the impact

of our products based on the hazards they pose and our ability to sell them.

The International Standards Organization quality management systems standard (ISO

9001) is one of the management systems used by the study organization mentioned by 5

out of 10 participants. Participant QM1 indicated:

I guess I should have started off by letting you know that our group within

[Organization Name] is ISO 9000 certified globally for the 26 or so plants that we

have worldwide. At each plant site we have an ISO representative and it's usually

 the QC manager at the plant and I will work directly with that person when we

conduct internal audits and self- assessments.

Participant RM1 discussed the relationship of the quality standard, the Responsible Care

Management System (RCMS), and ISO indicating, "I think that's what drives the quality

standard, the RCMS, really drives more on the compliance side I guess but on a day to

day basis um most effective would be ISO." Participant OD1 discussed that in addition

to the global ISO 9000 certifications:

"We have a very large push from some of our personal care customers to try and

at least meet what they require, as what they call cosmetics grade requirements. I

think its EEFCI European Standard. It's a new thing for us and we've been fairly

good complying under that standard."

Participants OD1 and OD2 discussed the value of using the manufacturing excellence process to identify constraints to producing quality products. All of the leaders at the manufacturing site level mentioned the manufacturing excellence program as a program critical to remove barriers and enable employee engagement. I expected this result since the manufacturing excellence program specifically focusses on manufacturing site performance. Participant OD1 described the manufacturing excellence program as follows, "It really is a program that while it's management driven the involvement is really on the individual level." Participant OD1 added to the description of the manufacturing excellence process explaining,

> . . . there are certain barriers that are occurring every minute or every hour on the shop floor that are creating an environment where the operations group can't perform. So, we take that information on a daily basis actually on a shiftly basis and move it up into an informational meeting that we have every day to say, *Where did we fail, Where did we almost fail?* and *How are we going to correct those issues moving forward?*

The philosophy of Participant OD1 aligns directly to the theory of constraints methodology. Participant OD2 described the manufacturing excellence process as focused ". . . on communication and the use of white boards for ah for detailed communication and performance monitoring." Participant OD1 described the process for site employees: "People can walk past write their own issues on the board, update KPIs, all of these things. We use a number of tools, but to be honest we struggle with that, like many organizations do."

Participant GD2 discussed the challenges to effective implementation of key leadership programs indicating,

> I think people get too wrapped up in their day to day um their day to day
> responsibilities and unless they're devoting time unless there's a one hour
> program on [name of a branded program] I think they just worry about getting the
> product out, they focus on getting the line up and running after a shut down.

Data Analysis

All of the participants described the use of the data collected in these programs for data analysis. With this data the participants looked for trends and themes that identified constraints and potential, future challenges. Ten of 10 participants identified the SAP business solution software modules for compliance categories as the global tool used by organizational leaders for data management and analysis. Participant RT2 stated,

> To identify opportunities for improvement, the company uses shared database
> platforms to house data. Those platforms are used to track and trend data
> identifying inconsistencies in quality/compliance and trends in issues that can
> then be address as a whole across the business.

Participant RT1 explained,

> We use a combination of structured and unstructured processes to drive business
> decisions, receive input from the organization, and collect data for proactive
> trending and analysis. In addition, we use a phase gate system to guide the
> technical, business, marketing, and regulatory aspects of process.

Participant QM2 noted,

Every order gets run through our SAP system; they're all part of this giant

conglomeration of tools. All of the product orders, all that chain, are trackable

and you can see what went wrong and where and how we can go back and fix it in

the future.

Using management systems, an organization sets standards through which they

are able to enhance economic effectiveness, and ensure quality and compliance (Heras-

Saizarbitoria & Boiral, 2013). Winter (2013) emphasized that each individual contributes

knowledge that, if removed from the whole, would disrupt the continuity of the routine of

the organization. Zelnik et al. (2012) identified that implementation of the QMS

depended upon management support for the QMS and involvement to drive employee

satisfaction, motivation, and communication. Application of the findings of Zelnik et al.

allows leaders to identify possible strategies and leadership behaviors. To continue to

improve, the organization should learn from mistakes, conduct analysis, and take action

to eliminate the cause of the mistake (Rai, 2011).

Theory of Constraints

The results from this study align to the conceptual framework, the theory of

constraints (TOC). The TOC provides a conceptual framework for businesses to find

problems, identify strategies to solve them, and implement the strategies (Ying-Chyi et

al., 2012). When organizations apply the TOC, leaders define the framework for analysis

from the perspective of the company as a system. When applying the TOC, leaders

define goals within the system and rely on a series of subsystems with the potential to

have one or more constraints (Pacheco, 2014; Spector, 2011). These activities align to

the theory of constraints identifying *What must be changed? What is the change goal? How does one implement this change?* (Ying-Chyi et al., 2012, p. 4688).

        Based on the responses of the participants, leaders at the study company engage in activities that define performance frameworks and collect data to identify constraints to producing quality and compliant products. Within each of the management systems, participants described the opportunity to collect data that identifies constraints to eliminate to improve quality and compliance. The global, branded program has complementary audits to ensure effective implementation of the harmonized quality and compliance platform. Participant GD1 listed the opportunities to use data in identifying constraints to target for improvement and elimination,

> Responding to customer complaints, responding to out of spec product data results, OOS investigations, regulatory inspections leading to enforcement like notices of violation, or otherwise. Those always give rise to knocks on the head and maybe this is more focused on the compliance area, monitoring and identification of industry enforcement trends you know which then leads to you know peeling off the layers of the onion to see where we stand with regard to these enforcement trends and that can sometimes root out some soft spots.

Participant RT1 described one communications strategy as "asking questions" from which to gain insight into barriers to remove in enabling quality and compliance aligning to TOC in the use of questions to identify and then eliminate barriers. Participant OD1 described the questions used to eliminate barriers as, *Where did we fail, Where did we almost fail?* and *How are we going to correct those issues moving forward?* The

manufacturing excellence program, used at the site level for data gathering and constraint elimination, aligns directly with TOC.

Applications to Professional Practice

A number of factors influence the success of strategies leaders choose to influence a culture of quality and compliance. Leaders understand that to ensure a sustainable enterprise they must meet customer demand by delivering products that meet quality specifications and deliver expected business results (Liu & Xiong, 2015; Roman, 2014). Through a branded program, the study organization had integrated product quality and compliance into a holistic approach integrating business, quality, and compliance drivers into a unified organizational platform. The branded program established by the study organization encompasses a corporate social responsibility policy that speaks to social, economic, and environmental values where "performance and responsibility are inseparable" ([Study company branded program], pg. 1).

Liu. Wong, Shi, Chu, and Brock (2014) noted the positive link between harmonized corporate social responsibility platforms and customer perceptions of product quality. The strategies used by the study company include management of customer perceptions and also focus on integration of habits and knowledge that lead to organizational decisions at all levels aligned with the internal quality and compliance platform. Leadership strategies that drive product quality link to other business strategies that maximize profit including the strategic interaction between firms and strategic performance incentives for managers (Veldman & Gaalman, 2014).

Leaders at the study organization identified communications and training as additional strategies that enabled their culture of quality and compliance. The effectiveness of leadership communications influences other aspects of organizational effectiveness and include employee engagement and knowledge transfer (Benito-Bilbao, Sánchez-Fuente, & Otegi-Olaso, 2015; Romle, Razak, & Shamsudin, 2015). Polities and Karahanna (2013) posited the importance of training on manufacturing standards and procedures to eliminate the potential for employee mistakes in order to deliver compliant and quality products.

Leaders in the study organization emphasized the role of top leadership in communicating the branded company way of doing business. The branded program established quality and compliance expectations, and training requirements across all levels. Participants described their use of a range of methods including one-to-one coaching, business meeting presentations, classroom and on-the-job training, internal customer collaboration, and asking questions to ensure clear communication of, and training on, quality and compliance needs and expectations. With external customers, participants emphasized the need for direct contact with the customer to enable clear communications and ensure a true understanding of quality expectations for any given product.

Barriers to successful implementation of a quality culture include a perception of a lack of value, a lack of time and financial resources, insufficient leadership commitment, and ineffective training across the employee population (Davis et al., 2014). My findings from this study identified strategies leaders use to influence a quality and

compliance culture. In particular, my findings identified the value of weaving quality

and compliance into a unified matrix to establish a holistic approach to endowing the

organizational culture with the behaviors and habits that drive quality and compliance

across business unit boundaries. To treat any aspect of quality and compliance as a

separate element of the culture may undermine the overall effectiveness of quality and

compliance programs, leaving room for employees to doubt the value top leadership

place on these requirements. Organizational leaders should send a unified and consistent

message on the value and expectations across the business for quality and compliance. In

the words of participant OD1, "I expect professional results from my employees and what

I've found more times than not is that if you don't provide a professional environment for

those employees don't expect to get professional results out of them."

Implications for Social Change

The findings from my study may contribute to positive social change and

improved business practice by providing tools and skills needed by business leaders to

ensure product quality and business profitability. Defective products, when recalled from

the market, result in lost revenue, potentially increased product liabilities, and decreased

customer satisfaction (Garstenauer et al., 2014; Hofmann & Oldehaver, 2015;

Rosencrance & Wu, 2015). These product quality issues affect brand equity and long-

term market share, and may influence business survival due to lost sales (Nagaich &

Sadhna, 2015; Rosencrance & Wu, 2015). Without a commitment to quality and

compliance, an enterprise may produce substandard products driving higher business

risks, and in drug, medical, and consumer healthcare products, increasing the possibility

of unintended side effects and health affects (Hofmann & Oldehaver, 2015).

The purpose of this qualitative, single case study was to explore the strategies

leaders use to influence a culture of quality and compliance. Findings from my study

may contribute to positive social change by providing tools and skills needed by business

leaders to ensure product quality and compliance, deliver safe products to customers, and

drive sustainable enterprises. In addition, the findings provide examples of programs that

can strengthen organizational capabilities. De Brentani and Kleinschmidt (2015)

discussed how integrated management systems in an organization might cultivate a

culture of quality and compliance through execution of focused, short-term initiatives that

drive a sustainable, long-term platform.

Organizational capabilities align to specific and actionable skills that enable

short-term success (de Brentani & Kleinschmidt, 2015) building toward a sustainable

culture. Such tools and skills enhance the ability of leaders to develop and implement

strategies for manufacturing employees that embed a culture of quality. Use of these

skills and strategies affect social change by ensuring that products sold meet quality and

compliance requirements, deliver the intended effects, and ensure business profitability.

This success may drive business stability and growth by providing employment

opportunities to the local community. By consistently delivering quality products to the

market, the organization builds trust within the customer base that the products sold

deliver the features promised by the company.

Recommendations for Action

Organizational leaders can take positive steps to influence a culture of quality and compliance. The actions of top leadership can establish a harmonized platform across the business and enable the leadership actions of others, across levels, in the organization. Dust, Resick, and Mawritz (2014) posited the link between leadership behaviors and leadership effectiveness where employees are empowered and engaged in the identification of organizational goals and values.

I recommend that leaders use the strategies discussed in the findings to guide employees to embed a culture of quality and compliance. The first recommendation is that leaders should set a unified quality and compliance strategy embedded into an overall business policy to set the tone of their commitment quality and compliance. By unifying quality and compliance into an overall business strategy and goals, leaders can inspire employees to engage proactively in organizational goals (Dust, Resick, & Mawritz, 2014).

The second recommendation is for leaders to communicate and collaborate across organizational boundaries. Quality and compliance professionals must actively engage with business unit and manufacturing site leaders beyond the boundaries of organizational audits. Shepherd (2012) posited a framework explaining how leaders could set strategies that influence individual decisions by linking employee consciousness to decisions of free will. While a sustainable enterprise is profitable, business unit leaders must understand the requirements for production of quality and compliant

products in order to avoid business interruptions that prevent the enterprise from providing products that meet customer needs.

The final recommendation is for leaders to identify the behaviors necessary to produce quality and compliant products. Neal et al. (2012) posited that specific cues within an organization might trigger habits and an associated behavior establishing a potential link between behaviors that influenced organizational routines and culture. By defining desired behaviors, leaders can set strategies to integrate the behaviors into the culture as habits adopted by all employees. These habits become inherent to a way of doing business that integrates quality and compliance objectives across business units.

Leaders in any manufacturing or service enterprise may benefit from implementation of the findings from this study given that each enterprise has defined a quality product, must comply with applicable regulations, and ensure that consumers receive products that meet expectations to drive business profitability. Creating a company culture mindful of quality and compliance requirements enables leadership decisions aligned to the quality and compliance values and requirements. My goal is to publish the findings of this study to disseminate the results to for-profit healthcare and consumer manufacturers. In addition, I plan to identify suitable conference and seminar opportunities that would enable effective communications to quality, compliance, and business professionals.

Recommendations for Further Study

There was a considerable amount of quantitative research with a framework based on total quality management studying the effects and constraints in supply chains and

manufacturing environments. In this study, I proposed viable models to use in further analysis and evaluated strategies to influence a quality and compliance culture. I recommend that future research focus specifically on some of the elements identified as key to embedding a culture of quality and compliance including habits and behaviors, management systems, training, communication, and leadership. I suggest further, qualitative exploration of the interrelationships between leadership engagement, and employee empowerment, training, and communication effectiveness in influencing a culture of quality and compliance. The research results indicated that participating leaders felt that top leadership engagement in communicating expectations and accountability for quality and compliance opened channels of communication on quality and compliance requirements throughout the business.

I recommend additional research of organizations or manufacturers with integrated quality and compliance platforms. Such platforms establish equal weight to quality, health, safety, environment, and process safety compliance in a harmonized corporate social responsibility platform. While top leaders know to set clear expectations, driving development of sustainable habits that enable cross-communications between quality and compliance professionals and business unit leaders sets the framework for a culture of quality and compliance. Use of a qualitative research approach would provide an opportunity to explore the learned behaviors of employees and potentially identify suitable topics for quantitative research analysis to examine the phenomenon of a culture of quality and compliance.

I suggest additional research using a qualitative research design to explore the lived experiences of employees in both the service and manufacturing sectors to capture their unique experiences. Additional research using a larger base of study participants would enable the researcher to better manage potential method bias and increase the reliability and validity of the study. These studies would allow capture of additional data on the strategies that influence a culture of quality and compliance enhancing the transferability of the results. I also recommend that researchers consider conducting similar studies on strategies for leaders to influence a quality and compliance culture using a broader group of case study organizations. A larger study group would allow the researcher to study strategies used by different enterprises and across different industries.

Reflections

Completing the Doctorate of Business Administration curriculum and doctoral study process was a great learning experience providing continuous access to tools I could immediately apply in my work environment. During the process to create my doctoral study, I worked to minimize personal error and bias, and maximize the capturing of the lived experiences of study participants. This translated directly into the work environment where project teams need to develop and deliver solutions without error or bias, and need to listen and learn from their collective, lived experiences. As an auditor, I was familiar with the use of open-ended interview questions. Using a qualitative research design, I was able to refine my skills to focus on the development and selection of the right questions.

Now that I hold a global role, my business process includes the need to track global holidays and customs to maximize team productivity and create project timetables that are not in conflict with employee vacations and holidays. This aspect of planning became critical with regard to progress on my doctoral study. With the timing for the interviews falling into the 2015 Thanksgiving and Christmas holiday period, and conflicts with vacations and business trips, most of the interviews were postponed into 2016. This delayed the start of data collection by six weeks. Office relocations that affected some of the participants necessitated flexibility in scheduling the interviews. Study participants were very understanding and worked in collaboration with me to schedule the interviews as early as possible in January 2016.

Conclusions

The purpose of the single case study was to explore the strategies used by leaders to influence a culture of quality and compliance leading to production of saleable products that meet quality and compliance requirement, and assure business profitability. The conceptual framework of the theory of constraints served to guide the scope and data analysis for this study. Ten leaders from a supplier of healthcare, pharmaceutical, and medical device intermediates participated in one-to-one, telephone based interviews. I used member checking to support the credibility and trustworthiness of my interpretation of the top three responses based on the interviews. I reached saturation after five interviews when the data became repetitive with no new information added from subsequent interviews. Additional sources for methodological triangulation offered relevant data and included observations during a tour of the headquarters site, and

supporting information from company policies, procedures, annual reports, and publically

available compliance information.

After completion of coding and analysis of the data, four themes emerged

including: (a) leadership emphasizing the need for top management to discuss and

reinforce expectations; (b) culture and habits in an organization that drive desired

behaviors; (c) communications with employees and external customers to ensure a clear

understanding of quality and compliance expectations; and (d) management systems and

data analysis where programs establish a global structure for quality and compliance, and

enable data collection and analysis. Participants discussed how the holistic approach to

quality and compliance used by the organization integrating behaviors, communications,

management systems, and data analysis enabled the culture of quality and compliance. In

this study, I explored the strategies used to influence a culture of quality and compliance

that could affect the ability of an organization to produce quality product, meet customer

expectations, and deliver profitability. The findings from my study may contribute to

positive social change and improved business practice by providing tools and skills

needed by business leaders to ensure product quality.

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Appendix A: Letter of Invitation

Name

Company
Location
Address

Dear _____,

My name is Betsy Macht and I am a candidate for the Doctor of Business Administration (DBA) in Global Supply Chain Management, at Walden University. I am contacting you to invite your participation in my dissertation research study, which explores the influence of leadership behaviors on a quality culture, and the link to production of saleable products and profitability. Study participants will include directors, managers, and technical leaders from the compliance, quality, operations, and corporate governance departments, and you were selected to participate based on your role. Since your participation is voluntary you only need to respond to this invitation to participate.

The study allows me to fulfill the requirements of the DBA program adding value through identification of strategies leaders may apply in embedding a culture of quality and compliance at their enterprise. The study findings may contribute to positive social change and improved business practice by providing tools and skills needed by business leaders to ensure product quality. I am conducting the study under the guidance of Dr. Anne Davis, a Walden faculty member and chair of my dissertation committee.

I will contact you to arrange an opportunity to provide an overview to the study and arrange for a short telephone interview scheduled at a time convenient to you. The interview includes seven questions and is anticipated to take no longer than 60 minutes. Participation is voluntary and the research process ensures full confidentiality of your responses and company identification.

If you have any questions or concerns about this research study, please email me

at [redacted]. Thank you in advance for your willingness to participate.

Regards,

Betsy J. Macht
DBA Global Supply Chain Management candidate

Walden University
College of Management & Technology

Appendix B: Case Study Protocol

Overview of the Case Study

The research study focuses on advancing an understanding of the underlying influences driving business success when trying to embed a culture of quality and compliance. This success is driven through production of marketable products to meet customer demand and business profitability. Results from my analysis of data derived from interviews of study participants, field notes, recording of verbal cues, observations, and archival documents may identify strategies leaders could use to embed a culture of quality and compliance. The central research question for my study is *What strategies influence quality and compliance in an organization assuring production of marketable products and meeting customer demand?*

Data Collection Procedures

To enhance the credibility and trustworthiness of the research study I have defined the data collection procedures. The company representative sponsoring the study will also participate in an interview, and will provide a tour of the headquarters site. The company representative opens the door to the identified participants. The following section includes the procedures for data collection including interviews, field notes, recording of verbal cues, observations, and archival.

Initial Communications

Company Representative

After receiving IRB approval (**Research Study IRB #: 12-09-15-0225280B**), I arranged for an initial teleconference meeting with the study sponsor to finalize the plan

to move forward with the study. The letter of cooperation (Appendix C) was previously executed and submitted along with the IRB research study application. During this meeting the list of participants was finalized and the study company representative agreed to contact the study participants to introduce me, explain the nature of the study, and reinforce the voluntary nature of participation. We finalized a day and time for a visit to the headquarters site for a tour where I made visual observations and reviewed archival documents associated with a culture of quality and compliance.

Participant

After confirmation from the organizational sponsor that initial contact was made, I proceeded to contact the study participants by email beginning by introducing myself and providing background on the study. I attached a formal invitation to participate and the participant informed consent form as separate documents. After this initial email conversation, I arranged a day and time to conduct the telephone based interviews. Initial contact with each participant was to introduce me as the researcher, allowing me to provide an overview of the study, review the elements of the informed consent process (Table 1), provide an opportunity for questions, and come to agreement on a date for the interview. The study procedures established that each participant who agreed to participate in the study would:

- read, sign, and submit the informed consent form,
- participate in a single, 60 minute, recorded telephone interview with the researcher that would occur at the time of their choosing, and

- be given the opportunity to review a copy of my interpretation of the three prominent concepts in their responses to the questions to confirm the accuracy.

The participant consent to participate process included the following elements:

1. Each interviewee participated voluntarily with the right to withdraw, without bias, at any point.

2. The researcher clearly stated the study rationale and objectives prior to the interview to ensure participant understanding of the study purpose.

3. Interviewees received a copy of the participant consent form and submitted a signed original or Portable Document Format (pdf) copy with electronic signature prior to the start of the interview.

4. Interviewees indicated agreement to participate in a semistructured, 60-minute interview at their choice of location with the potential for follow-up interviews scheduled at a mutually agreed-upon time and place.

5. Interviewees indicate agreement in the informed consent form that the researcher can record the interview and take hand written notes.

6. Interviewees agree that the content of the interview could be included in a doctoral study and possible publications in the future.

7. Researcher clarifies that the participant will receive the interview questions no more than 3 days in advance, and that they will receive my interpretation of the three most prominent concepts after the interview.

8. Verification that the interview will remain confidential, that coding of participant information ensures confidentiality, and validates the procedures to ensure the confidentiality and security of study data.

9. Provide clarification to the interviewees that participants will not receive compensation for their participation in the study.

Data Collection Process

The data collection process includes a series of steps starting with formal approval by the sponsor to conduct the study, and concluding at completion of the interview and document review.

The study includes seven interview questions and follows a semistructured, telephone interview format. Each participant will receive a copy of the interview questions no more than three days in advance of the interview. The 60-minute interview process will include a short introduction and opportunity for questions, an interview covering the seven questions, follow up questions as needed to clarify or expand upon participant answers, and an opportunity at question seven for the participant to offer information not covered in the earlier questions. I will digitally record each interview and take handwritten journal notes.

The steps in the data collection process include:

1. Contact study sponsor to execute Letter of Cooperation (Appendix C).

   a. Review criteria for participant participation

   b. Receive names and contact information for study participants.

   c. Complete arrangements for site tour and document review.

    d.   Identify options available to identify alternate study participants.

2. Contact study participants.

    a.   Send invitation to participate (Appendix A) and Consent Form within one week of initial meeting with study sponsor.

    b.   Schedule the initial telephone interview with study participant within two weeks of transmittal of invitation.

    c.   If a participant declines, I will contact the study sponsor to identify a suitable replacement.

3. Review publically available quality and compliance information on XYZ Corporation.

4. Conduct interviews

    a.   Set up recording device.

    b.   Set up computer and open MS Word for note taking.

    c.   Close other computer applications.

    d.   Assign code to participant.

    e.   Contact participant at agreed upon time.

    f.   Opening comments

        i.   Thank you for participation.

        ii.   Confirmation regarding Consent with reminder that participant can end the interview at any point.

        iii.   Provide a short introduction of the researcher.

        iv.   Ask interview questions.

    v. Close with invitation to share anything interviewee would like to add that interview questions did not cover.

    vi. Close with a thank you and a reminder that the study participant will receive a follow up email with my interpretation of the three most prominent concepts from the interview to confirm the accuracy of the statements.

5. Engage in a continuous review of the interview process and questions to ensure alignment with the research question as allowed through a semistructured interview process.

  The interview protocol (Appendix D) for this study includes eight questions exploring the relationship between a culture of quality and critical success factors including production of marketable products, meeting customer demand, and profit. These semistructured, open-ended questions will guide my interview process while allowing flexibility to pursue interview specific issues and concepts as they arise.
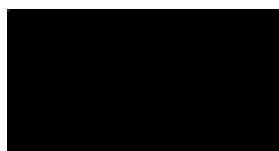
Appendix C: Letter of Cooperation
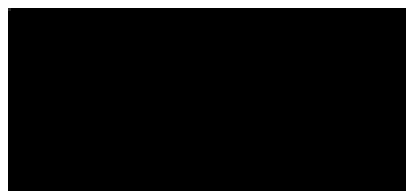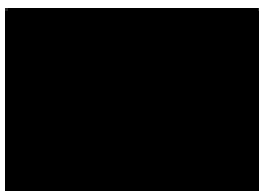
Dear Ms. Macht,

Based on my review of your research proposal, I give permission for you to conduct the study entitled Strategies to Influence a Quality Culture within ████████ ████████. As part of this study, I authorize you to interview directors, managers, and technical leaders within Solvay. Individuals' participation will be voluntary and at their own discretion. Neither the company name, nor individuals' names will be revealed. I also agree to provide a tour of the corporate office, and grant permission to review data and information available at our corporate office relating to quality and compliance with the understanding that all data will be disguised so no product information, trade secrets, or intellectual property will be revealed.

I understand that as part of the study I will need to provide company phone numbers and email addresses for each of the potential participants for use in arranging for and conducting interviews. We reserve the right to withdraw from the study at any time if our circumstances change.

I confirm that I am authorized to approve research in this setting and that this plan complies with the organization's policies.

I understand that the data collected will remain in your possession, entirely confidential and may not be provided to anyone outside of the student's supervising faculty/staff without permission from the Walden University IRB and myself.

Sincerely,

Appendix D: Interview Protocol

Interview Protocol	
What you will do	**What you will say—script**
Introduce the interview and set the stage—often over a meal or coffee	Hello, I want to thank you for agreeing to participate in my research study. For the last few years, I have worked on a Doctorate in Business Administration emphasizing global supply chain management. In this study, I will explore the link between the leadership strategies needed to embed a culture of quality and compliance, production of marketable products, and business profitability. I would like to give you some background on myself. I have a B.S. Civil/Environmental Engineering from Penn State, and an MBA - Strategies for Sustainability from Walden University. My doctorate focuses on one of the most critical business factors for a regulated global supply chain, quality, and compliance. In preparation for this interview, you signed an Informed Consent form. Do you have any questions that you would like to ask me before we start? I will ask you 8 questions and will record your responses. This conversation is confidential and your identity and that of your company will be protected using a code developed for this study. Identifying characteristics will not be included in the study report. If at any time you feel you cannot answer a question, please let me know and we will move on to the next question.
• Listen for non-verbal queues • Paraphrase as needed • Ask follow-up probing questions to get more in-depth responses	1. What leadership strategies have you used to embed a culture of quality and compliance within your company to assure production of marketable products?
	2. What habits has your organization identified as critical to sustaining a culture of quality and compliance? For example, a habit is an action or behavior you want to see employees do over and over, without thinking.
	3. How do you determine where there are opportunities for improvement of your quality

	culture?
	4. How do you choose programs to address and correct internal and/or external failures assuring production of marketable products and achievement of business profitability goals?
	5. Which appraisal programs do you find most effective in reinforcing a culture of quality and compliance and why? By appraisal, I am talking about the proactive programs or activities that you use.
	6. What prevention programs do you find most effective as part of your leadership strategies and why? By prevention, I am looking at the programs and actions you take after a nonconformance has been found. How do you use that information? How do you prevent it from happening again?
	7. How do you shift your culture, when needed, to maintain a culture of quality and compliance, and assure production of marketable products?
	8. What other information could you provide on quality culture that might be helpful in completing this study?
Wrap up interview thanking participant	Thank you for participating in my research study. I appreciate the time you have taken to help me complete my studies to achieve a Doctor of Business degree. I will follow up with you in a week and will send my interpretation of the three most prominent concepts from your interview via email.
Arrange follow-up member checking process using either phone or email.	I would like follow-up with you as part of the research process. In this email, you will see my interpretation of the three most prominent concepts from your interview. I would like to solicit your feedback either during a phone conversation or email conversation to assure that you feel my interpretation is correct.
Share a copy of the interpretation for the three prominent concepts from the interview by email. Follow up conversation using	Today I will share a succinct synthesis of your response to each question. Please provide feedback regarding the accuracy of the synthesis.

phone or email format.	1. Concept 1: Question and succinct synthesis of the interpretation—perhaps one paragraph or as needed
Bring in probing questions related to other information that you may have found—note the information must be related so that you are probing and adhering to the IRB approval.	2. Concept 2: Question and succinct synthesis of the interpretation—perhaps one paragraph or as needed
Walk through each question, read the interpretation and ask: Did I miss anything? Or, What would you like to add?	3. Concept 3: Question and succinct synthesis of the interpretation—perhaps one paragraph or as needed