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Strategies for Compliance with Government Regulations in a Pharmaceutical Company

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This is to certify that the doctoral study by

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Abstract

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MS, North Carolina Central University, 2010

BS, University of Ilorin, 1989

Doctoral Study Submitted in Partial Fulfillment

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Abstract

Pharmaceutical companies accrued fines of over $30 billion within 25 years because of noncompliance with regulations. Noncompliance with regulations results in fines and an adverse impact on company profitability. Some pharmaceutical company managers lack effective strategies to ensure overall company compliance with regulation. Based on complexity leadership theory, the purpose of this single case study was to explore strategies pharmaceutical company managers used to ensure compliance with regulatory requirements in Nigeria. The target population was functional managers purposely selected because they had successfully implemented strategies for compliance with the regulatory requirements in Nigeria. Data were collected through face-to-face and telephone interviews with 4 company managers and from company records, regulatory documents, and websites. Analysis of data involved using computer-assisted qualitative data analysis tools and content analysis to code and identify patterns and themes. Findings revealed 3 prominent themes: establishment of regulatory affairs unit and engaged leadership; hiring of qualified of employees, training, and continuous learning; and strategies to navigate through barriers to enhance regulatory compliance. The implications for positive social change lie in the availability of affordable pharmaceutical products with implications for the overall health of communities. Compliance with regulatory requirements helps to ensure that pharmaceutical companies develop high quality and safe products, which are critical in healthcare leading to the prevention and cure of diseases, which will ultimately improve and save people's lives.

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Dedication

First, I dedicate my study to Christ, my provider, my source of inspiration, and the very present help in time of need. Second, to my family, Moji, Efi, and Uje for their love and support, who have encouraged me in my unending search for knowledge. To my mom, dad, brothers, and sisters for their fervent prayers. Finally, to my close friends who encouraged me to remain steadfast during the study.

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Section 1: Foundation of the Study

Compliance with regulations is critical to business performance and assurance of safety and product performance in the pharmaceutical industry (Ding, Eliashberg, & Stremersch, 2014; Proches & Bodhanya, 2015). In recent years, regulatory noncompliance in the pharmaceutical industry is on the rise and is becoming a challenge to company leaders and managers (Page, Cyr, & Richardson, 2015). Wang, Zheng, Ren, and Sun (2016) found that the U.S. Food and Drug Administration issued 997 warning letters to medical products manufacturers in specific areas of the manufacturing process during 2007 to 2014. The regulatory requirements for pharmaceutical products are always evolving, a condition that presents an ongoing challenge to managers in pharmaceutical organizations (Thach, 2015). Noncompliance with regulations results in huge fines and a significant amount of settlement with a considerable impact on company image and profitability (Mulinari, 2016). Having a strategy in place to ensure personnel compliance with regulation is critical to the avoidance of the adverse impact of noncompliance in the sector (Sabel, Herrigel, & Kristensen, 2017).

Background of the Problem

The increasing number of litigations and violation citations in the pharmaceutical industry are indications of widespread problems with business operations in the sector (Rodwin, 2015). As regulation becomes precise, encompassing, and complex, reports of increasing incidence of noncompliance is on the rise because of rising costs and lack of knowledge of regulations (Lemmens & Gibson, 2014). Nielsen and Parker (2012) noted

that despite the importance of compliance with regulations, not much is known about companies' compliance with regulations.

Complying with regulations requires personnel knowledge and understanding of regulations to avoid violation or noncompliance (Mendoza, Dekker, & Wielhouwer, 2016). Nielsen and Parker (2012) rationalized that motivation is vital in the consideration of the topic of regulatory compliance in companies. As such, company personnel have different motivations to ensure compliance with regulations, meaning that the attitude of personnel to compliance is dependent on several factors including customers, capital, skills, technologies, trade associations, and communities (Lynch-Wood & Williamson, 2014).

The increase in noncompliance and the resulting impact on pharmaceutical companies resulted in the need for an effective strategy to ensure managers and subordinates take steps that lead to overall compliance as they perform critical roles in the product lifecycle (Arora, Christman, Mays, & Schmidt, 2013). Herzberg (2015) posited that several factors are involved in personnel motivation, and a greater understanding and application of those factors results in the desired outcome. Further research on regulatory compliance strategies in pharmaceutical companies is necessary to provide pharmaceutical managers strategies that other managers in pharmaceutical companies used to ensure compliance with regulatory requirements.

Problem Statement

Noncompliance with government regulations in the pharmaceutical industry is on the rise and impacts pharmaceutical companys' profitability (Page et al., 2015). The US

FDA reported a 64% increase in the number of current Good Manufacturing Practice (cGMP) noncompliance from 2007 to in 2012 (Wang, Zheng, Ren, & Sun, 2016). Almashat, Wolfe, and Carome (2016) found that pharmaceutical companies paid over $30 billion over 25 years for various violations in the United States with the resultant impact on company profit. The general business problem is that noncompliance with regulation has a negative impact on company revenue, brand value, product development, product approval, and a number of regulatory investigations. The specific business problem is that some pharmaceutical company managers lack strategies to ensure compliance with regulatory requirements.

Purpose Statement

The purpose of this qualitative single case study was to explore strategies that managers in pharmaceutical companies use to ensure compliance with regulatory requirements. The target population for this study consisted of 4 pharmaceutical managers in a Nigerian pharmaceutical company who successfully implemented strategies for compliance with the regulatory requirements in Nigeria. The implications for social change include the potential to improve the abilities of managers to ensure compliance in a regulated environment, which might lead to increased access, availability, and affordability of pharmaceutical products by individuals with limited access to good healthcare.

Nature of the Study

I used the qualitative research method in this study. A qualitative method allows a researcher to study a phenomenon in depth using open-ended questions that enable

researchers to discover new, rich, and nuanced phenomena based on participants' experiences (De Massis & Kotlar, 2014; Yin, 2014). Researchers in qualitative research focus on perceptions and experiences taken from only a few representative participants; hence, researchers cannot generalize the outcome of a study to a population (Starman, 2013). I used the qualitative method to explore and understand the strategies used by the research participants to ensure compliance with regulatory requirements.

The quantitative method is not suitable for studying participants' experiences or nuanced phenomena; rather, it involves data collection through sampling or experiments to test hypothesis, analyze data using statistical or mathematical forms, and the results are generalizable (Bernard, 2013; Brockington, 2014). Mixed methods, a combination of both quantitative and qualitative research (Dumbili, 2014), was not suitable for this study because I did not test or build theories.

I selected a qualitative single case study design for this study. Scholars use case study to gather in-depth information and enable review and examination of a bounded system involving a real-life phenomenon (Morse & McEnvoy, 2014; Yin, 2014). A case study methodology was most appropriate for this study. Case study is a strategy available to researchers for studying topics with relatively few previous studies (Yin, 2014). In addition, researchers use ethnographic or phenomenological design in qualitative business research (Yin, 2014). In an ethnographic study, the researcher studies beliefs, the way of life, and culture of a group of people through observation or participation (Ferguson, 2016). Ethnographic approach was not suitable for this study because my focus was not on the culture of the people. In phenomenology, the researcher examines

lived experiences of individuals to understand the root meaning of a phenomenon (Gill, 2014). I did not select phenomenology for this study because I did not seek to explore lived experiences of those experiencing a phenomenon. I concluded that case study approach would be appropriate for this study because I explored the strategies used by managers in a single pharmaceutical company to ensure compliance with regulatory requirements.

Research Question

The research question for this study was the following: What strategies do pharmaceutical company managers use to ensure compliance with regulatory requirements.

Interview Questions

1. What is your role in ensuring compliance with government regulations in your company?
2. What strategies do you use to prevent noncompliance with government regulations?
3. How do you communicate regulatory requirements within your company?
4. What specific strategies do you use to ensure regulatory compliance?
5. What challenges do you encounter in implementing strategies for compliance with regulatory requirements?
6. How do you address the challenges to the implementation of strategies for noncompliance with government regulations?

7. How do you assess the effectiveness of your strategies to prevent noncompliance?

8. What other relevant information about compliance with regulatory requirements can you provide?

Conceptual Framework

The theory that I used as the conceptual framework of this study was the complexity leadership theory. Marion and Uhl-Bien developed the complexity leadership paradigm in 2001 (Marion & Uhl-Bien, 2001). Uhl-Bien, Marion, and McKelvey (2007) extended the works on complexity leadership by addressing complex interactive dynamics from which adaptive outcomes emerge. Uhl-Bien et al. used the complexity leadership theory to explain a leadership paradigm based on enabling the learning, creative, and adaptive capacity of complex adaptive systems. The key constructs of complexity leadership theory are: (a) administrative leadership based on strict control and bureaucratic hierarchy; (b) adaptive leadership based on creative problem solving, generating new conditions and learning; and (c) action-centered leadership that involves immediate decision-making mechanisms used in crises and dynamic productivity.

The complexity leadership theory provides a lens through which I explored effective strategies that managers use to ensure compliance as they pertain to an increasingly dynamic of instability emanating from regulatory requirements. The complexity leadership theory is an appropriate framework for this study. Hazy and Uhl-Bien (2015) noted that complexity leadership-inspired research resulted in new insights into the mechanisms for studying leadership in a dynamic environment by focusing

leadership efforts on behaviors that help improve organizational performance. According to Murray (2017), leadership involving interactive model facilitates collaboration across networks and the performance of a task. Baltaci and Balci (2017) highlighted how administrators respond to environmental dynamics and relationships necessary for organizational survival from the perspective of complexity leadership theory.

Operational Definitions

Complex system: A complex system consists of many entities that display a high level of interactivity (Cordon, 2013).

Compliance: Compliance is an array of behavioral and attitudinal responses of individuals or corporations to regulations (Mendoza et al., 2016).

Interaction: Interaction is a dynamic mechanism of interdependent behaviors and relationships leading to the emergence of unrecognizable subsets when perceived as a linear combination of the initial agents (Proches & Bodhanya, 2015).

Regulations: Regulations are a variety of government rules or authorities that affect individuals and organizations (Baldwin, Cave, & Lodge, 2012), which governments institute to strike a balance between the benefits and risks of new products (Sorenson & Drummond, 2014).

Assumptions, Limitations, and Delimitations

Assumptions

Assumptions in research are statements that researchers hold as factual but are unproven (Marshall & Rossman, 2016). My first assumption was that each participant would provide accurate and truthful information. My second assumption was that

participants would provide accurate descriptions of the strategies used by the company to ensure compliance with regulatory requirements. My final assumption was that the data and documents obtained from the organization would be current and help answer the research question.

Limitations

Limitations refer to potential weaknesses of a study that are out of researcher's control (Ritchie, Lewis, Nicholls, & Ormston, 2014). The first limitation of this study was that I explored only one pharmaceutical organization. The second limitation was the inability to generalize the findings, given that the study was qualitative. The third limitation was restricted access to some data due to the need to protect company intellectual property and maintain confidentiality, which limited the available information to the researcher. A researcher driving the course of a discussion may influence the response of participants.

Delimitations

Delimitations are distinctive features resulting from restrictions or boundaries in the scope of a study and the concerted efforts of the researcher to narrow the scope during the development of the study plan (Childers, 2014; Marsall & Rossman, 2014). An important delimitation in this study was the use of purposive sampling to select research participants. The choice of Nigeria as the geographical location of this study was a delimitation as well. Another delimitation was the intentional restriction of participants in the organization to those who were directly involved in management functions and exercising supervisory role.

Significance of the Study

The study findings may be of value to businesses because of the understanding it may offer fundamental strategies that result in regulatory compliance. Given that the pharmaceutical industry is among the highly regulated industries, managers and employees in the regulated industry may use the findings to reduce or eliminate the incidence of noncompliance with regulations. As other scholars have noted, using efficient strategies results in safer pharmaceutical products and potential for higher profitability (Page et al., 2015).

Contribution to Business Practice

The associated costs of compliance with government regulations constitute a critical burden in the pharmaceutical industry, and compliance with government regulations is critical to the business success of pharmaceutical companies ((Eger & Mahlich, 2014; Liberti et al., 2016). Responding to regulatory requirements is of paramount importance to the success of many business organizations (Rollings, 2017). Researchers show that noncompliance with regulatory requirements impacts companies' turnover (Nielsen & Parker, 2012). Pharmaceutical company managers may use the results of this study to develop new strategies required to ensure compliance with regulations, leading to the emergence of the desired outcome and economic activities. The findings from this study may provide insights on strategies that may help functional managers minimize regulatory noncompliance and increase profitability. Functional managers may gain insights on strategies to minimize regulatory noncompliance and increase profitability based on the findings of this study.

Implications for Social Change

Social change results from interdependencies between businesses and the environment as they interact at various levels (Harper & Leicht, 2015). Social change is more prominent in successful companies creating socially desirable outcomes such as generating consumer goods that can contribute to the development of human welfare, as with the availability of new medications and filling gaps in social provision (Konda, Starc, & Rodica, 2015; Ney, Beckmann, Gräbnitz, & Mirkovic, 2014). Developing a strategy to for compliance with regulations enables pharmaceutical organizations to play key roles in ensuring cost reduction of pharmaceutical products. Reduction in costs emanates from compliances reducing associated costs with noncompliance. Muzaka (2013) viewed the availability of pharmaceuticals as a social function that represents bargaining among government, business, and society. Strategies to improve adaptation to regulatory changes may lead to the affordability of pharmaceutical products in most markets, particularly in developing countries given that strategies are crucial to the supply and availability of pharmaceuticals to the population (Niessen & Khan, 2016).

A Review of the Professional and Academic Literature

The purpose of this study was to explore strategies that managers in pharmaceutical companies use to ensure compliance with government regulations. In this literature review, I provide a comprehensive, critical analysis and synthesis of complexity leadership, rival theories, and a general review of the pharmaceutical regulation. The literature review consists of three key themes: (a) complexity leadership theory paradigm,

(b) supporting and rival theories, and (c) the role of regulation in the pharmaceutical industry.

The literature came from multiple databases, journals, and search engines. In seeking sources, I used keywords such as *complexity theory, compliance, congruency, Nadler and Tushman, regulation, organizational learning, organization ambidexterity, pharmaceutical regulation, and drug approval.* The search strategy included using Boolean operator keywords to search databases including Google Scholar, Science Direct, ProQuest Central, EBSCOhost, ABI/Inform Complete, Emerald Management, SAGE Premier, and PubMed. I identified additional peer-reviewed publications by reviewing the bibliographies of articles retrieved from databases. The literature search resulted in 233 articles, of which 221 articles (95%) were peer reviewed. Of the peer-reviewed articles, 187 (85%) had publication dates within 5 years of my anticipated graduation year of 2018.

Complexity Leadership Theory

Complexity leadership theory (CLT) is an innovative approach to perceiving and managing complex organizational behavior (Baltaci & Balci, 2017), particularly in an era of a knowledge economy (Uhl-Bien et al., 2007). Marion and Uhl-Bien (2001) introduced complexity leadership as an application of complexity theory to the study of organizational behavior and the practice of leadership. Complexity leadership theory, according to researchers, is an emerging theory viewed from different angles including social systems. Research into the theory continued to expand to understand how micro processes affect follower and leader outcomes (Dinh et al., 2014). Researchers using

several approaches have conceptualized organizational complexity in relation to size and technology, design structure, and interdependence among agents within and outside an organization (Walton, 2014). The interactions of the components in an organization result in emergent properties and these interactions are nonlinear such that a change in one component may lead to a large or negligible impact on the whole organization (Gerrits & Verweij, 2015). While changes in laws and regulations of a project may appear to be the same for all organizations in a particular industry, the result in each organization might be different. As such, it is difficult to predict the type of adaptations required by each organization based on external changes or turbulence experienced by organizations (Melton, 2017). Complexity leadership scholars view leadership as emanating from collaboration, complex systems thinking, and innovation mindset to improve cost and quality (Weberg, 2012).

Complex leadership theory is a framework that scholars use to account for the development of creative and adaptive strategies and behaviors. The strategies permit control structures suitable for coordinating organizations and generating results appropriate to the vision and mission of the system (Uhl-Bien et al., 2007). Scholars of CLT distinguish between technical and adaptive leadership challenges encountered in an organization. The resolution of a technical challenge is through the application of specific technical skill but the solution to adaptive challenges is through emergence based on interactions of individuals in the organization (Bailey et al., 2012). Uhl-Bien et al. described the three elements of complex leadership, while Hazy and Uhl-Bien (2015) further enhanced the complex leadership functions based on Uhl-Bien et al. proposition.

Uhl-Bien et al. grouped leadership into (a) administrative, (b) adaptive, and (c) enabling leadership. Proponents of complexity leadership theory explained in broad terms the three broad types of leadership: (a) administrative leadership, predicated on traditional, bureaucratic views; (b) leadership that structures and enables conditions; and (c) adaptive leadership. Hazy and Uhl-Bien (2015) explored complexity study and clarified leadership influence in the enabling of organizations to perform and adapt. Confronting an increasing level of uncertainty in business environments, organization leaders have felt compelled to adapt by mirroring external conditions within the internal environment (Fitzgerald, Ferlie, McGivern, & Buchanan, 2013; Tong & Arvey, 2015). Uhl-Bien et al. (2007) itemized four critical assumptions of complexity leadership theory: (a) the informal dynamic entrenched in context-the nature of interactions and interdependencies among agents, hierarchical divisions, organizations, and environments; (b) leadership as an emergent, interactive force leading to adaptive outcomes; (c) adaptive leadership that occurs in emergent, informal adaptive dynamics in organizations; and (d) adaptive leadership that requires exploration, new discoveries, and adjustments.

Hazy and Uhl-Bien (2015) surmised that leadership is not confined to an individual but a form of social and relational organizing among different independent individuals forming a system of activity. Given the massive regulations imposed on pharmaceutical companies amid globalization and technological developments, organizational leaders face complex competitive landscapes driven by regulatory changes (Duggal, Kashyap, & Kakar, 2014; Palumbo et al., 2015). Organization leaders' traditional approach to leadership often relied on leaders exercising control to determine

and direct the future, whereas complex systems leaders facilitate behaviors that enable organizational effectiveness rather than control (Marion, Christiansen, Klar, Schreiber, & Erdener, 2016). The theoretical framework of this study has several implications for leaders in the pharmaceutical industry, as it may create an alternative approach for leaders to ensure compliance with regulatory requirements. Scholars apply complexity leadership theory to the study of knowledge-based organizations where knowledge about a product or service is a major source of competitive advantage to generate unique contributions to the business (Uhl-Bien et al., 2007). Baltaci and Balci (2017) noted that leadership in organizations is a significant mechanism capable of managing the turbulence resulting from changes in technology and innovation.

Other researchers offered a different view of leadership based on a complex perspective of organizations (Hazy & Uhl-Bien, 2015; Marion et al., 2016). Murphy, Rhodes, Meek, and Denyer (2017) showed that leaders as enablers disrupt existing patterns of behavior, promote innovation, and draws conclusion from emerging events. Given that leaders operate in many contexts, Uhl-Bien et al. (2007) argued for a shift from the control mechanism perspective to advocating for the development of a leadership framework in a fast-paced and unstable environment. Baltaci and Balci (2017) noted that CLT is an alternative approach to study contemporary organizations to thrive in a volatile, unstable, and chaotic environment. The three primary aspects of complexity leadership theory based on the identification and exploration of strategies are adaptive leadership, administrative leadership, and enabling (action-centered) leadership. The three aspects generate behaviors that promote (a) creativity in organizations, (b) learning,

and (c) adaptability in organizations when appropriate complex adaptive system dynamics thrive within a bureaucratic setting.

Complexity leadership theory reflects a significant portion of the core concept of complexity theory (Marion & Uhl-Bien, 2001). Comprehending complexity leadership requires an understanding of the fundamentals of complexity theory (Uhl-Bien et al., 2007). Complexity leadership researchers view leadership as an identifiable behavior of social and relational organizing between independent heterogeneous individuals coalescing into a system of action rather than approaching leadership in the context of an individual (Hazy & Uhl-Bien, 2015; Uhl-Bien et al., 2007). The applications of complexity concepts to management account for the pattern of social interactions between independent heterogeneous agents as they aggregate into a system (Hazy & Uhl-Bien, 2015). The complexity approach to leadership is about the relevance of the overarching organizing effects of individual units, agents, or practices and the impact of complex systems. Complex adaptive system problems require new learning, innovation, and new behavioral patterns that fit into the paradigm of leadership development in which groups learn their way out of a problem. Management development, however, is the application of established solutions to known problems.

Using complexity leadership theory, scholars can study how interacting components, whose components are diverse, with a capacity to learn to generate desired outcomes (Uhl-Bien et al., 2007). Decision-making processes in organizations involve a cross-functional management approach that comprises planning, discussions, and resolving issues and implementing decisions for success. Each member of an

organization brings specialized knowledge about their function to the organization leading to high functioning teams. In complex systems, given the dictates of complexity leadership theory, the rules controlling the local interactions change as both internal and external factors change.

System thinking provides a professional and scholarly alternative approach to solving and analyzing complicated issues in different fields (Clancy, 2015; Tong & Arvey, 2015). Walton (2014) provided examples of complex systems across multiple organizations or systems that included school, healthcare, and manufacturing facilities. Scholars of systems approach view large organizations such as healthcare organizations and pharmaceutical entities as complex systems, suggesting that a different strategic approach is necessary for studying such organizations (Caffrey, Wolfe, & McKevitt, 2016). Hazy (2014) found that human interactions are complex systems with the leadership performing the functions of organizing a human activity, including unifying individuals into organized groups and developing a vision, ethics, and identity for the team. Another function emanating from leadership in complex systems involves changing rules to spawn ideas and plans of action (Uhl-Bien et al., 2007), allowing for creativity and problem-solving to thrive in the organization. Lastly, leaders change rules in complex systems to foster the convergence of divergent individual perspectives and activities into a viable and expected outcome. Organization leaders must deal with complexities to avoid adverse impact on their organization's success (Hazy & Uhl-Bien, 2015).

Researchers from different fields argue that organizations' paradigms need to move toward complex systems in which they and their agents can evolve together

(Caffrey et al., 2016; Clancy, 2015). Certain elements of complex organizations may themselves be complex, while other elements oscillate between multiple complex systems (Byrne, 2013). The interaction of components in a complex organization results in emergent phenomena not explained by evaluating each component in a complex system (Bone, 2016). A complex systems approach to problem-solving enables researchers or practitioners to consider wider ramifications consisting of management, leadership, interventions, and the implementation context of these elements (Caffrey & Munro, 2017).

Complexity is a critical component of organizations that affects their success (Hanisch & Wald, 2014). The literature on complexity thinking is diverse, traversing different disciplines including development, political science, management, biological science, and physical science. Complexity theory has its roots in physics, mathematics, and biology, but it has expanded into organizations to inform strategic management and organizational dynamics. Chandler, Rycroft, Malone, Hawkes, and Noyes (2016) identified five core concepts of complexity theory: (a) self-organization, (b) interaction, (c) emergence, (c) system history, and (d) temporality. Revolving around the construct on complexity are the concepts of chaos, symmetry, entropy, modularity, hierarchy, nonlinearity, connectivity, equilibrium, synchronization, schemata, self-organization, and self-regulation (Walton, 2014). The interaction of components in a complex system such as in pharmaceutical organizations results in an emergent pattern that is difficult to understand by evaluating individual agents in the organization (Naghshineh et al., 2014).

Organizational functions and operations are more complex given the increasing diversification and the number of organizational stakeholders (Baumann & Siggelkow, 2013). Likewise, in heavily regulated environments, many leaders in organizations follow a management system in which regulatory activities lead to an unpredictable emergent disturbance that makes it difficult for people to adapt to the change (Battiston et al., 2016). Using complexity theory has several benefits for understanding complex organizations operating in highly regulated industries such as healthcare (Thompson, Fazio, Kustra, Patric, & Stanley, 2016). Complexity theory is an alternative approach to learn how systems adapt to a disturbance such as regulatory changes through self-organizing in a way that permits critical system components to endure over a period. The core of complexity theory rests on the understanding of resilience, which is the degree to which the system can absorb disturbances as it changes (Bone, 2016). Scholars use the core concepts of complexity theory as a theoretical framework to evaluate strategies in healthcare to explain the resistance to change.

The components of complex systems exhibit high levels of interactivity mostly at the nonlinear level (Poutanen, Siira, & Aula, 2016), with such systems exhibiting fragile behavior (Clancy, 2015). Fragile organizations are readily susceptible to external disturbances. Under heavily regulated industries, interactivities result in random events initiated by an external trigger or disturbance; organization leaders should learn from other leaders how to lead fragile systems (Cordon, 2013). Nevertheless, some organizational leaders adapt to changing components and environments through self-organization, learning, and reasoning giving rise to complex adaptive systems

(Nooteboom & Termeer, 2013; Uhl-Bien et al. 2007). From the perspective of complexity leadership theory, ability to change and adapt over time through the process of learning is critical to the success of an organization in a regulated industry (Caffrey et al., 2016; Mendes et al., 2016).

Scholars, including Bone (2016), employed complexity theory to explain emergent behavior in previously unexplained changes occurring in different systems. The results of various studies illustrate the presence of emergence where changes are traced but difficult to explain by analyzing an individual agent. Looser organizational constraints promote emergent behavior, and people in learning organizations are more amenable to complexity as they facilitate adaptive changes (Cordon, 2013). Healthcare organizations are ideal for the application of complexity theory due partly to the diversity of organizations and interactions among agents in organizations (Thompson et al., 2016). Within each healthcare organization, with emphasis on pharmaceutical product manufacturers, most processes involve interaction between individuals in manufacturing, marketing, regulatory, professional, and the organizational systems in care delivery.

Complexity theory provides scholars of strategy a framework to explore the complexities inherent in complex organizations some lessons from the healthcare systems (Caffrey et al., 2016). Complexity theory has advantages as a theoretical tool in that it pulls together different viewpoints to develop key concepts and articulates them in a systematic approach to explain patterns, behaviors, or phenomena in organizational change and policy implementation (Byrne, 2013; Caffrey et al., 2016). Thompson et al. (2016) suggested that applying complexity theory to complex systems indicated that

agents will act, respond, and adapt to changes and environments based on their individual experiences and viewpoint.

Four elements highlight the interrelatedness of leadership in organizations through the lens of complexity leadership: (a) network conditions, (b) shared leadership, (c) organizational learning, and (d) leader skills and knowledge (Clark, 2013). The implication of Clark and Uhl-Bien et al. (2007) suggestions is that leaders in pharmaceutical organizations cannot predict complex adaptive systems by a standard linear equation due to of the interactions between multiple agents of the organization. Leadership development in complex organizations, including pharmaceutical companies, emerges from nonlinear and disorderly interactions among the agents (Mendes et al., 2016). Thomson et al. (2016) opined that adequate functioning of each inter-dependently connected agent or aggregate depends on the productive state of other actors. The interactions are strategic because of actions or decisions by one agent influence reactions by others, which reflect interdependence (Hazy & Uhl-Bien, 2015). I described the three elements of CLT in the following paragraphs: (a) administrative, (b) adaptive, and (c) enabling leadership.

Administrative leadership. The management team in an organization is the administrative leaders where interpersonal influence is predominant (Marion & Uhl-Bien, 2007). Uhl-Bien et al. (2007) noted that a top-down, bureaucratic leadership models in the last century, thought to be effective in the physical production of goods but not conducive to a knowledge-based economy. Scholars of the traditional concept view leadership as a deliberate influence on others to attain the desired goal (Epitropaki, Kark,

Mainemelis, & Lord, 2017). The contemporary command and control structure of leadership is ineffective.

Marion and Uhl-Bien (2013) outlined the key organizational outcomes of administrative leadership are: (a) discipline orientation, (b) consistent routines, (c) role clarity, (d) clear chain of responsibility, (f) efficiency, and (g) performance. Under this leadership approach, the leaders establish specific tasks and deliverables while using discretionary control over resources to bolster successful projects. The leader deploys resources, e.g., budgets as structural incentives while simultaneously setting challenging but attainable goals. Marion and Uhl-Bien noted that such leaders provide understandable roles, targeted training, and follow-up on expected activities while providing resources and autonomy for the group.

Adaptive leadership. Adaptive leadership is a set of strategies and behaviors used to facilitate the emergence of solutions from the interactions of individuals in the organization confronting a challenge (Anderson et al., 2015). The impact of environmental change results in internal action within the organization that allows for the possibility to grapple with threats and challenges (Blomme, Kodden, & Beasley-Suffolk, 2015). The changes create the need for managers and other leaders to adapt for the organization to survive and the strategies deployed by managers to adapt include communication, active participation, and influence techniques (Bloome et al., 2015). As managers face external turbulence and complex problems, they require continuous

adjustment to make the organizations thrive, but many organization leaders cannot cope with the change required.

One of the core propositions contained in CLT is adaptability, which enhances performance and innovation that occurs in regular interactions of individuals acting in response their environments (Uhl-Bien et al., 2007). Adaptability is a fundamental component of complex leadership theory, helping organization leaders to respond better to the demands of the environment and formulate strategies favorable to innovations (Nooteboom & Termeer, 2013). However, certain factors, including employees, organizational characteristics, and culture, influence decisions within organizations (Bourke & Roper, 2014). Bourke & Roper (2014) also found significant and consistent evidence that the impact of knowledge formed by experiential learning has potential commercial, organizational, and healthcare delivery benefits in a health organization.

The local actions interconnect leading to the emergence of a powerful phenomenon, but the interconnections are difficult to make because of organizational bureaucracy and silos (Uhl-Bien & Arena, 2017). Scholars of CLT addressed the central question of how organizational leaders enable the emergence of solutions to thrive in a complex and dynamic environment under a bureaucratic setting. The focus is to facilitate the transfer of ideas across a system by creating a link and brokering. Uhl-Bien and Arena noted that organizations consist principally of two systems; an operational system (drives formality, standardization, and business performance) and entrepreneurial system, which drives innovation, learning, and growth. The conflict emanating from the tension between the operational system for administrative efficiency and entrepreneurial systems

striving for learning, creativity, and growth is fundamental to innovation and adaptability (Mazzei, Ketchen, & Shook, 2017).

Adaptive organizations enable adaptive space by enabling brokerage across various groups or acting as a catalyst to generate new ideas and promote the development and sharing of an idea in an entrepreneurial setting. There is an evolution in the regulation of each industry necessitating efficient strategies to manage relationships within and outside businesses because of enforcement by regulatory authorities (Riggs et al., 2016)**.** Despite the abundance of research into leadership studies, researchers paid little attention to the regulation of businesses at the level of interactions between individuals in and outside of the business or even among followership (Mendes et al., 2016). Understanding regulatory dynamics and providing guidance and interpretation within an organization are fundamental strategic skills that leaders in a regulated industry must cultivate and continually improve upon (Sravika et al., 2017). Byrne (2013) suggested that applying complexity theory to regulated organizations enables leaders and other agents to act, react and adapt based on their worldview, essential for successful registration and launch of products. The implication is that for any regulation, individual reactions and the sum of their actions are unpredictable and affect the success of such organizations (Caffrey et al., 2016). The sum of individual actions affects the trajectory of an organization; as such, Caffrey et al. noted that daily decisions or reactions to regulations influence the entire organization. Furthermore, successful people in a dynamic and regulated environment must develop and implement strategies that

encourage interactions among agents promote regulatory knowledge and skills of managers and employees within the organization.

Enabling leadership. The enabling leaders in the CLT paradigm facilitate and enable the conditions in which an emergent event occurs. The emergent events and changes are not directly from the leaders but facilitate individuals within organizations that catalyze and function towards a common goal. Leaders enable the conditions in which an emergent event occurs, rather than a person and the change are not the direct from the leaders. Uhl-Bien et al. (2007) found that enabling leadership occurs across organizations and enabling behaviors more common among middle managers. Galuska (2014) noted the difficulty in creating the required environment conducive for engaging the leadership capacity of each individual in the system to optimize performance while continuing to meet the many administrative, regulatory, and financial requirement within the organization. The key elements of enabling leadership are: (a) the promotion of complex adaptive system dynamics that enable conditions that result in adaptive leadership and emergence, (b) the management of the entanglement of formal, top-down, administrative functions and informal, emergent, adaptive functions within organizational settings with different levels of complexity.

Supporting and Rival Theories

The focus in the new leadership development paradigm is the emphasis on social capital where interpersonal skill development for both the leader and followers is germane (Haslam et al., 2017). Dinh et al. (2014) revealed that scholars often focused much of their studies of leadership on individual leadership models geared towards the

style theories of leadership. Researchers use the organizational learning theory to explore external influence on organizations is the organizational learning theory. Learning is critical for organizations to remain adaptive and how organizational leaders and followers learn is critical in addressing the challenge resulting from external turbulence for an emergent solution to evolve (Chadwick & Raver, 2015). The increasing level of turbulence, uncertainty, interdependencies, and interrelatedness is generating some levels of complexity placing key constraints on traditional or conventional leadership constructs (Clark, 2013; Uhl-Bien et al., 2007). Most leadership theories relate to individual leaders exercising interpersonal influence and power to gain commitments and motivation of others to achieve organizational objectives (Clark, 2013). Organization leaders must consider all resources and capabilities in their quest to be successful (Waddell & Pio, 2015).

Organizational learning theory. The core of organizational learning is the collective learning by members of an organization involving the discovery of relevant new knowledge and dispersing the knowledge to individuals in the organizations to improve internal processes and external adaptation (Ratnapalan &Uleryk, 2014). Scholars of complexity leadership theory adduce to the point that in a dynamic system, the need for leaders to align their strategies, structure, and process with its external environment as well as relationships are critical (Mthuli, Bodhanya, & Sobratee, 2017). Stettina and Horz (2015) noted that small groups and teams, such as project teams, committees, and top management team members perform much of the work in organizations.

Leaders can influence collective learning by encouraging and nurturing procedures that increase creative ideas and giving members opportunities to explore new approaches to performing a task (Chadwick & Raver, 2015). Complexity leadership scholars stress the importance of learning as a key ingredient of enabling leadership, which is a major component of complexity leadership theory (Horvat & Filipovic, 2017). Ratnapalan and Uleryk (2014) argued that in complexity theory, discussions about systems are difficult to address without focusing on the ability of the agents to learn. To understand the complex environment, there is the need to promote learning and organizational learning framework is a key factor for organizational competitiveness and survival (Chadwick & Raver, 2015).

Over the past few decades, there is a growing acceptance among scholars of organizational learning as a business strategy (Palos & Stancovici Veres, 2016). Organizational learning is a mechanism of knowledge acquisition and organizations as social systems with a culture that promotes or impedes learning. The business aspect involves attaining competitive advantage through learning, psychological, and behavioral aspects of individual learning and cross-cultural comparisons of organizational learning (Mendes et al., 2016). Organization leaders focus on organizational learning to operate efficiently and maintain a competitive edge through creativity, innovation, and adaptation to change (Popova-Nowak & Cseh, 2015).

Organizations leaders modify their organizations to acquire new knowledge through learning practices, creating a supportive learning environment that improves the learning skills of members who apply knowledge of such learning to modify strategies

(Onyema, 2014). The release of regulation or guidelines often lead to conditions of uncertainty (Riggs et al., 2016), and under conditions of uncertainty, team learning is paramount, contributing to the ability of agents in organizations to improve their aggregate understanding of a given situation. Team learning helps to accentuate the relevance of complexity leaders as a catalyst to learning.

Complexity leadership scholars reinforce the importance of learning for adaptation, enables employees to perform and work towards the mission of the organization (Naqvi, Khan, & Butt, 2015). Given the challenges that leaders and followers face because of regulations in the pharmaceutical industry, learning within the organization offers an opportunity for developing a clear process for sustainability (Berson, Da'as, & Waldman, 2015). Motivation is a key element that influences employees learning and knowledge sharing within an organization as noted by Naqvi et al. (2015). Raina and Roebuck (2016) acknowledged the need for leaders to assign tasks understandably, communicate effectively, and use multiple channels of communication when dealing with subordinates. The thinking among organizational learning scholars is that by creating a culture of organizational learning, organizations can deliver on quality products and outcomes through continuous improvement from learning (Ratnapalan & Uleryk, 2014). Organizational learning affects the long-term sustainability of an organization with a collateral impact on various outcomes (Berson et al., 2015).

Organizational learning theory is a conceptual framework used by scholars to understand how to improve a company’s performance through individual’s learning, which in turn affects groups and the entire organization (Santos-Vijande et al., 2012).

Organizational learning functions through learning mechanism of institutionalized structural and procedural arrangements, which promote the learning process (Cirella, Canterino, Guerci, & Shani, 2016). The mechanisms afford organization members the opportunity to gather, process, disseminate, and utilize data and knowledge relevant to the organization. The knowledge gained by members stays within the organization through the dissemination of lessons learned to various groups or units, even with changes in team members. Organizations perform different activities and functions designed to promote efficient learning (Seidel, 2015).

Organizational learning involves the creation of new knowledge with influence on people's behaviors relative to their work with ultimate impact on the performances resulting from the creation of new knowledge (Naqvi et al., 2015). Similarly, Ratnapalan and Uleryk (2014) found that learning has important implications for innovation processes, competitive advantage, growth, and profitability of the organization. Schilling and Kluge (2009) identified a series of barriers including behaviors as barriers to organizational learning that hinder organization members from adapting to the decision-making challenges confronting them. Individuals remaining stagnant in an organization or position over a long period often find it difficult to learn. A key role of organizational learning is to foster efficiency and effectiveness required for organizations to be successful (Santos-Vijande et al., 2012). The role of organizational learning is critical because the learning and knowledge base of an organization results in a competitive advantage. Furthermore, Ratnapalan and Uleryk noted that organizational learning provides the setting for integrating the different agents and components into a united

policy to advance healthcare delivery. Organizational learning provides a framework for complex, interdependent dynamic systems where each component learns and performs its activities cooperatively for the production or delivery of desired products (Argote, 2013).

Argote (2013) identified three sub-processes in the study of organizational learning including creating, retaining, and transferring knowledge. The appropriate decision strategies or processes need to align with the statutory guidelines that must include knowledge of clinical, safety, manufacturing, and pharmacovigilance requirements as enshrined in the guidelines. Company leaders must formulate strategies on how individuals learn regulatory agencies' periodic reviews, safety updates, and adverse event reporting. Sieweke and Zhao (2015) developed a theoretical framework for analyzing organizational learning, with the core of the framework based on the interaction of organizational experience and the context leading to the emergence of knowledge. The introduction of organizational learning has spurred interest among practitioners and academics as a strategic concept to improve a firm's success since the 1980s (Waddell & Pio, 2015). Discussions on organizational learning theory emerged in the 1960s sequel to a change in the thinking among managers that organizations are organic systems emphasizing relationships between and within groups. The organizational learning philosophy stemmed from the seminal work of Cangelosi and Dill, which Argyris and Schon extended and Peter Senge popularized in 1990, gaining

widespread application in academics and practice (Hu, Found, Williams, & Mason, 2014).

Organization learning theorists lend credence to how organization members learn. Dasgupta (2011) identified the processes involved and key factors related to the concepts of organizational learning. The four key variables of how organizations learn include (a) its experience, (b) copied from others, (c) creation and promotion learning environment, and (d) what is involved in the development of a conceptual framework. Dasgupta (2011) further noted that organizational learning has both a weakness and opportunity for creating new standards in a dynamic business environment. Healthcare administrators avail themselves of the learning organization concept and promote collaborative learning among teams as they strive to improve patient safety (Corrigan & Curtis, 2017). Through organizational learning, companies can increase organizational effectiveness and efficiency through shared knowledge and understanding.

Researchers also view organizational learning as a system of collective education with the capacity to transform operations, performance, and outcomes in healthcare organizations (Ratnapalan & Uleryk, 2014). Teams working in healthcare comprise of individuals with varied backgrounds working together to deliver the objective of the organization. Through organizational learning, different inter-professional team learning and systems-based organizational learning facilitate goals that are vital to managing the learning requirements in complex, interconnected dynamic systems. Five key aspects of the concepts and practices are collectivity of individual learning, systems, culture, knowledge management, and continuous improvement (Ratnapalan & Uleryk, 2014; Tan,

2015). Organizational learning is an ongoing phenomenon occurring through formal and informal learning that leads to organization change (Pallet & Chilvers, 2015; Ratnapalan & Uleryk, 2014).

Organizational learning theory has inherent flaws. Senge focused on distributed leadership, which lacks cogent theories, neglects issues of practice and issues of power (Beauregard, Lemyre, & Barrette, 2015; Caldwell, 2012). Caldwell (2012) argued that one could conceptualize Senge's learning organization as a limited mix of systems thinking and learning theories that result in a perception of organizational learning as a model of distributed leadership. Managers' characteristics have high impact on the level of learning within a firm, but leaders who integrate both technical and administrative backgrounds promote higher learning among employees (van Hoof, 2014). Van Hoof recommended a blend of learning method and supply networks as a useful means of encouraging the implementation of company plans through organizational learning. One of the key elements of complexity leadership is the flexibility requirements for team members in organizations to adjust their activities due to changes in internal and external conditions of the organizations without affecting quality and safety of their products (Mendes et al., 2016). New regulatory requirements, new knowledge creation, technology advances, and market changes, for example, add new burdens to pharmaceutical companies, requiring that they comply with new regulations, organization policies, and procedures to incorporate new knowledge. Researchers' understanding of organizational learning should grow with the continuation of research on current topics, particularly in areas of knowledge creation and organizational capabilities. Organizational forms and

technological developments will create both challenges and opportunities for organizational learning.

In a modern dynamic industry, improving organizational culture is essential given the frequent changes in the business environment. Organizational culture comprises an amalgamation of goals, roles, attitudes, assumptions, communication practices, and more (Belias & Koustelios, 2014). Business organization processes include various activities and functions with the involvement of many stakeholders (Bauman & Siggelkow, 2013). The nature of the leadership within an organization defines the culture within it, but culture is the accumulated outcome of collective learning that begins with leadership (Shahzad, Luqman, Khan, & Shabbir, 2012). Culture is a combination of shared values, beliefs, and norms that affect the thinking, views, and behaviors of employees toward each other and to persons external to the organization (Giorgi, Lockwood, & Glynn, 2015). Organization culture facilitates work attitudes and behaviors to improve the effectiveness of organizations (Liden, Wayne, Liao, & Meuser, 2014). Similarly, Belias and Koustelios (2014) noted that attitudes and behaviors in turn, influence the employees' approach to the assimilation and manner of response to external factors and decision-making.

To create a culture of organizational learning, organizations deliver quality products and outcomes through continuous improvement from learning (Ratnapalan & Uleryk, 2014). Tang and Yeh (2015) suggested that company culture, current skills, expertise, organizational structure, the motivation for learning, accommodations for steady change, and leadership all influence learning. Employees learn about the cardinal

values of organizations through signs, symbols, stories, ceremonies, organizational language, and social practices that affect the organization as it cultures matures (Shahzad et al., 2012). The core of organizational culture is that people are in the organization because each organization attracts and retains individuals with different personalities, values, and ethics. The synergy of four essential components defines organizational culture: (a) characteristics of the people associated with the organization, (b) organizational ethics, (c) organizational structure, and (d) nature of the employment relationship (Yukl, 2012). The activities of people in the organization result in organizations with different cultures, success, and failures (Belias & Koustelios, 2014). Improving organizational culture is a difficult quest for various organizations and their people (Yukl, 2012). If employees are committed and share similar value and norms as their organizations, the organizations achieve their overall goals (Shahzad et al., 2012). The leaders where the culture of organizational learning thrives have a supportive climate where employees' ideas and initiatives blossom (Che-Ha, Mavondo, & Mohd-Said, 2014). Leaders of such organizations also exhibit and foster a culture where members are tolerant of employee's errors (Che-Ha et al., 2014).

The global environment, defined by increasing complexity, uncertainty, nonlinearity, and accelerated change, is increasingly affecting new organizations. The literature on organizational learning, innovation, and culture traditionally connects these concepts through linear causality, with the assumption that any one of them is the cause of another, an approach that is static and contradictory to complexity theory approach (Chiva, Ghauri, & Alegre, 2014). Leaders in organizations face a high state of

complexity, and how leaders in those organizations handle these complexities is drawing the attention of scholars (Albert, Kreutzer, & Lechner, 2015). Leaders require adequate knowledge of the processes and how to relate with the stakeholders involved in the operations to make informed decisions about the requirements of activities (Proches & Bodhanya, 2015). Scholars are showing interest in the interactions among activities leading to the creation and sustenance of competitive advantage (Albert et al., 2015).

The Congruence Model of Organizational Behavior

Another competing theory I considered for this study as a guide for analyzing the course of action in this study is the Nadler-Tushman congruence model of organization developed in the early 1980's by Nadler and Tushman (1980). Nadler and Tushman using the congruence model developed a roadmap to analyze organizations as consisting of interacting components, existing in congruence or fit with one another. Marino, Aversa, Mesquita, and Anand (2015) suggested that an organization is a system composed of interdependent parts or building blocks, components, or subsystems operating within an environment. Nadler and Tushman noted that problems arise in organizations when there is misalignment or lack of fit among components in the organization. Amis (2018) posited that in successful organizations, the leaders and followers must be able to respond to external forces affecting the company by redefining and reorganizing the company to be in harmony with the environment.

The core competencies of successful organizations are the ability of the people in the organization to continually adapt to change and master the environment under the prevailing conditions (Smits & Bowden, 2015). Company executives, managers, and

employees position their organizations in a flexible state changing the shape of the organization in response to external influences (Harraf, Wanasika, Tate, & Talbott, 2015). The components of organizations are (a) task, (b) people, (c) structure, and (d) technology. Nadler and Tushman developed the congruence model for team members to effectively respond to external disturbances on a company as scholars began shifting their focus from external planning to internal resources of organization (Seong, Kim, & Szulanski, 2015).

The goal of Nadler and Tuschman (1980) was to develop a framework more useful as an analytical tool with emphasis placed on the transformation process and interdependence of components in organizations. Nadler and Tushman viewed organizations as consisting of components that interact with each other. The components attain a state of relative stability, consistency, or fit with each other. The elements of the company can fit together in a state of harmony leading to the efficient functioning of the company or loosely fit resulting in problems, dysfunctions, and poor organizational performance.

The idea of congruence of components is traceable to the work of George Homans work on the social process in organizations highlighting the importance of interactions and consistency among critical components of organizational behavior (Hsiao & Chiou, 2017). Additionally, Nadler and Tushman (1980) drew from the works of other scholars including, Seiler, Lawrence, Lorsch, and Seldon. Nadler and Tushman submitted that Lawrence and Lorsch emphasized relationships between differentiation and integration each organization in response to environmental requirements and the

relative economic performance. As such, the key components of the Nadler-Tushman congruence model relate to the questions of: (a) inputs to the organization, (b) outputs the organization produces, (c) key components of the transformation process, and (d) the manner of interaction of the components (Nadler & Tushman, 1980).

Toplis and Randell (2014) revealed that managers must understand their businesses from the four pillars of Nadler and Tushman model and, they must be sensitive to change, able to reorganize and redefine the company in line with external forces and demands to make them more efficient. Pharmaceutical companies consist of different related components, functioning in a state of harmony despite inputs from the environment to transform inputs into products (Almici, 2015). Using the Nadler-Tushman model, scholars posit that organizations exhibit key elements of systems theory, which provided a means of thinking about organizations as complex and dynamic (Seong et al., 2015). The main characteristics of systems are: (a) internal interdependence, (b) capacity for feedback, (c) equilibrium, (d) adaptation, and (e) equifinality. Nadler and Tushman improved on the limit of system theory as a problem solving, which led to their formulation of a practical model based on the open system paradigm called the congruence model of organizational behavior.

One of the challenges that managers in regulated industry is adapting the strategy of their organizations, and they must selectively adapt. Day and Shiemaker (2016) underscored the importance of selectively adapting and refining organizational capabilities in periods of rapid change. Amis (2018) noted the importance of leaders being able to position their companies such that the adaptation strategy does not

negatively affect their ability to respond to severe changes in the environment. Organization managers' may successfully coordinate various resources within the organization for explorative and exploitative functions that may provide managers with new opportunities. Under the high regulation, there is little understanding of *how* leaders and managers coordinate various actions in response to regulatory requirements (Pilbeam, Doherty, Davidson, & Denyer, 2016). Leaders and managers in organizations are responsible for coordinating resource allocation, addressing the routine and changes emanating from inputs or environment.

The concept of congruence and ambidexterity. According to Nadler and Tushman (1980), the concept of congruence model is a measure of the fitness of components in the organization. Congruence theory researchers view organizations as most effective when the components fit together, and this view in strategy extends to include the fit between organization and the environment (Wadongo & Abdel-Kadrr, 2014). However, O'Reilly and Tushman (2013) argued that different organizational forms require different strategies and external inputs. O'Reilly and Tushman (2013) noted that companies operating in a turbulent environment require a change in structural alignments requiring managers to strike a balance between exploitation by focusing on existing viability and exploration for future existence. Tushman and O'Reilly (1996) posited that organizational managers create ambidextrous organizations to achieve the desired structural alignments. Junni, Sarala, Taras, and Tarba, (2013) added that ambidexterity has a positive impact on the success and survival of organizations, based on the ability to transform and adapt the organizations in the face of uncertainties.

Ambidexterity as a strategy is relevant in a turbulent environment. In the volatile and uncertain environment, ambidexterity helps organizations to maintain strategic flexibility through association existing environment and adaptive to a possible disturbance. Tushman and O'Reilly (1996) found that the ability of organization managers to address several activities within the organization concurrently was critical to the survival of such organization. In highlighting the importance of organizations operating in a turbulent environment, managers in such organizations need to develop a coordination mechanism consistent with the key theory of ambidexterity (Heracleous, Papachroni, Andriopoulos, & Gotsi, 2017).

The regulatory demands imposed on healthcare organizations limit the speed of product development and market entry of pharmaceuticals and the success of such organizations (Redden, 2016). The pace of innovation in the pharmaceutical industry and the response of various regulatory agencies are creating turbulence that is forcing company managers and leaders to implement strategies leading to the adaptation of their companies at a faster rate (Redden, 2016). Dunlap, Marion, and Friar (2014) established that pharmaceutical companies in the face of turbulence and change adapt to through various forms of adaptation and ambidexterity.

The Pharmaceutical Industry

Pharmaceutical organizations are highly regulated in many markets; pharmaceutical products require regulatory approval for the development and distribution (Duggal, Kashyap, Singh, & Kakar, 2014; Liberti et al., 2016). The complex maze of regulations in the pharmaceutical industry affects every sector of pharmaceutical

companies, presenting fundamental obstacles to business activities and successful leadership (Riggs et al., 2016). Pharmaceutical companies belong to an industry where the core products affect the lives and well-being of the population (Palumbo et al., 2016). The pharmaceutical industry consists of organizations involved in any of the following activities: (a) research, (b) development, (c) manufacturing, (d) distribution, and (e) marketing of pharmaceutical products (Almici, 2015). The spending on these core products accounts for a significant proportion of the cost of healthcare (Hassali et al., 2014), accounting for 20% to 60% in developing countries. Almici (2015) articulated the importance of the pharmaceutical industry to the economy of nations with a particular focus on the European pharmaceutical sector. The demand for medicinal drugs has forced stakeholders to demand higher scrutiny of pharmaceutical industry executives by regulators (Handoo, Arora, Khera, Nandi, & Sahu, 2012). The use of ineffective, low quality and adulterated pharmaceuticals results in deleterious health conditions to the public (Amadi & Amadi, 2014). The implications of Amadi and Amadi (2014) conclusion were the negative outcomes of ineffective pharmaceutical products influence the confidence of stakeholders in the healthcare system of a country. Individuals from multiple disciplines are the critical components of pharmaceutical organizations. All individuals are interdependent with one another within larger interconnected teams. The interdependence results in the development of safe and quality pharmaceutical products that satisfy regulatory and other stakeholder demands. The interdependence warrants that leaders and managers of pharmaceutical organizations need to be flexible to incorporate

changes in activities, particularly responses to a changing regulatory environment without compromising product quality (Seidel, 2015).

Nigerian pharmaceutical market. Nigeria is a densely populated country with a population estimated to reach 207 million by 2020 (Business Monitor International, 2016), indicating an increasing need for pharmaceuticals. The growing population is a serious challenge to stakeholders on the provision of high quality and cost-effective drugs (Ogbonna, Ilika, & Nwabueze, 2015). The country also has a high incidence of disease, poverty, malnutrition, and a growing pharmaceutical industry saddled with the provision of safe and effective products for this increasing population (Ogaji, Olawode, & Iranloye, 2014). While reviewing capacity utilization in the pharmaceutical industry in Nigeria, Ogaji et al. (2014) noted the critical impact of the pharmaceutical industry on the healthcare system of the country particularly concerning essential drug supplies.

Business Monitor International (2016) estimated that the Nigerian pharmaceutical market in 2016 was worth $905 million and projected value of $941 million by 2020. Nigerian pharmaceutical companies, contribute 60% of the pharmaceuticals to the Economic Community of West African States (ECOWAS). However, other ECOWAS countries such as Ghana are making efforts to increase their participation in pharmaceutical product manufacture (Akomea, Sorenson, & Amponsah-Efa, 2014).

The Nigerian government has provided infrastructural incentives to the health sector for the last 20 years in an attempt to solve the problem of drug shortages in the country. Some of the incentives to promote the pharmaceutical industry were the establishment of agencies and task forces like the National Agency for Food and Drugs

Administration and Control (NAFDAC), Essential Drug List, and National Drug Formulary Acts (Ogaji et al., 2014). Nigeria's poor pharmaceutical regulatory environment is a major hindrance to investment in the sector (Business Monitor International, 2016). The literature on pharmaceutical regulation in the sub-Saharan nations is sparse, and how leaders react to regulations affecting the pharmaceutical industry is still in its infancy. The emphasis in available publications was more on the politics of pharmaceutical regulation (Olugbenga, 2013). Similarly, other scholars in pharmaceutical regulations like Amadi and Amadi (2014) focused their studies on the regulatory agencies approaches to combating adulterated drugs without much discussion on the implications of regulatory changes on businesses. Nevertheless, Nigerian pharmaceutical industry leaders continued to operate on a difficult business terrain in an evolving regulatory landscape (Olugbenga, 2013). Nigerian pharmaceutical companies, as a reflection of other ECOWAS nations, are under a myriad of burdens directly linked to product registration issues, particularly in foreign markets (Akomea et al., 2014). Consequently, regulatory challenges were a critical drawback to sales expansion across borders in the region, which further explains the importance of regulations as a major driver of pharmaceutical companies' successes in Nigeria and other ECOWAS countries, despite their search for wider markets.

Interdependence in the pharmaceutical chain. The pharmaceutical product chain is complex, often with different agents and components involved before reaching the end user of the product, creating both opportunities and challenges to company leaders (Almici, 2015). According to Almici (2015), the main stages involved in

providing pharmaceutical products to consumers as articulated are (a) the development stage, involving the selection of products to develop, the population, and the disease state to target; (b) registration and marketing authorization required in different markets before the introduction of pharmaceutical products into markets; (c) the manufacturing process, involving the production of pharmaceutical products according to set standards and procedures; and (d) distribution aimed at regular supply and storage of pharmaceutical product in good conditions to end users and minimizing losses due to spoilage and expiry.

Interdependencies among agents at various stages of the value chain affect the strategy and business decisions of pharmaceutical leaders (Caffrey et al., 2016). The processes or activities involved in the management of a successful pharmaceutical company leading to a steady supply of products comprised of a complex interrelationship among the agent and components, both internal and external (healthcare professionals, employees, regulatory authorities, vendors, and researchers). Managing agents and their interactions or interconnections in an organization are crucial in a complex organization (Silva, Silva, & Leite, 2016). The relationship among the agents is relevant for the emergence of desired outcomes, as leaders must rely on the functioning and efficient management of relationships to achieve the desired result. Silva et al. (2016) highlighted the importance of effective management of agents and activities within a healthcare delivery system. Agents need extensive knowledge and experience accumulated during professional exercises and through managerial practices to facilitate smooth interactions (Proches & Bodhanya, 2015).

Challenges and opportunities often accompany the introduction of pharmaceutical products into any market and opportunities with a projection of improved healthcare delivery, reduced costs to consumers, and social change (Brodszky, Baji, Balogh, & Péntek, 2014). The complexities of the manufacturing process, complexities of performing clinical work, and adhering to regulatory agencies guidelines are some of the challenges to overcome (Clancy, 2015). However, in many developing countries, the healthcare industry is still in its infancy and not well organized as in advanced economies like the United States, EU, Japan, and Canada. Hence, knowing and complying with regulations in those regions of the world are challenging to both local and international pharmaceutical company leaders and other stakeholders (Olugbenga, 2013; Van Norman, 2016).

Pharmaceutical regulatory framework. Regulations are an array of rules that affect individuals and organizations, which governments use to maintain a balance between the benefits and risks of new therapeutic products (Sorenson & Drummond, 2014). Pharmaceuticals are among the most heavily regulated products, with many regulations in place to protect the health and well-being of the population (Handoo et al., 2012). Because governments at all levels are responsible for protecting their populations, they will often use regulations as the tool to achieve this responsibility. Regulations are also tools that governments and their agencies deploy to accomplish the goal of licensing safe, effective, and high-quality therapeutic products (Balasubramanian, Muthukumaran, Hariram, Nandhini, & Saisugathri, 2016). The tight weave of regulatory and business activities necessitates a high-level review of complex decisions critical to the success of

pharmaceuticals and organizations in highly regulated industries like pharmaceuticals (Naghshineh et al., 2014). Regulatory authorities also use guidelines to control Pharmaceuticals at every stage of the pharmaceuticals chain (Balasubramanian et al., 2016).

Governments establish laws, regulations, and effective national regulatory authorities to ensure that the manufacture, distribution, and use of pharmaceuticals by citizens are safe (Maynard & Bloor, 2015; Ogbonna et al. 2015). The rise and rapid rate of change in regulations implied that leaders in a highly regulated industry like the pharmaceutical industry would need to remain current on regulatory guidelines to ensure complete compliance. Business leaders must also understand the impact of regulations on their business environment to assess potential threats and opportunities in decision-making (Riggs et al., 2016), while Anyakora et al. (2017) submitted that regulations influence the availability, affordability, and quality of pharmaceuticals.

To perform efficient regulatory control, governments often deploy regulatory tools through specialized agencies to protect consumers in most commercial activities, including telecommunications, energy, financial, food, tobacco use, healthcare, and the environment. Examples of government efforts to protect citizens using regulations include the financial regulations stemming from laws enacted in many countries to address the cause of the problems in the banking sector following the global financial crisis of 2007-2009 (Thakor, 2015). Another example was the 2009 Affordable Care Act, enacted in the United States to increase access to affordable healthcare (Lu, 2014). The ultimate rationale for regulating commercial activities was to overcome market failures,

inefficiencies, monopolies, and protect consumers, and these objectives apply to pharmaceutical regulations (Lu, 2014; Mourlon-Druol, 2016).

The requirements for company leaders to comply with rules stem from (a) legislative and regulatory agencies (e.g., the Sarbanes-Oxley Act, and Affordable Care Act 2009), (b) industry standards and codes of practice (e.g., ISO 9000, IEEE), and (c) business partner contracts. Business leaders continue to struggle to comply with mandates and timelines required by these mandates. Understanding regulatory dynamics is one of the key strategies needed for organizational leaders to be successful and efficient in satisfying stakeholders' demands while complying with regulatory requirements (Malerba & Orsenigo, 2015).

The regulations of pharmaceuticals are fraught with challenges, including issues of manufacture, quality, safety, and tolerability (Mintz, 2015). Regulators use evidence-based approaches to regulations consisting of technology assessment to verify claims relating to the safety, efficacy, and cost-effectiveness of therapeutic products (Sorenson & Drummond, 2014) that further constrain company leaders. Many leaders are unsure how to engage with or relate to regulatory agencies, neither understanding the details in the regulation of interest nor the benefits of using a particular regulatory process (Broekhuizen, Groothuis-Oudshoorn, van Til, Hummel, & Ijzerman, 2015). Lack of understanding may result from the drug regulatory agencies saddled with the responsibility for regulating drugs, devices, foods, and cosmetics in their countries. The responsibilities of agencies like the US Food and Drug Administration (FDA) and the Nigeria National Agency for Food and Drug Administration and Control (NAFDAC) are

similar to those of several other government agencies, but the resources and demands of each agency are different (Handoo et al., 2012). Stakeholders, including manufacturers, distributors, and consumers, find it frustrating and confusing to determine which regulatory agency and how to engage regulators in obtaining market approval for their pharmaceutical products (Broekhuizen et al., 2015).

Pharmaceutical regulatory systems. Most countries have established pharmaceutical legislation and regulatory requirements for the development, and market approval for the introduction of pharmaceutical products into their countries (Balasubramanian et al., 2016). While reviewing regulatory guidelines, Balasubramanian et al. (2016) stated that the level of sophistication in the requirements and depth of items required for each country varies, depending on the level of their socio-economic development. The requirements may be in the form of dossier submission for the complex requirements to a simple notification letter to gain approval (Duggal et al., 2014). These requirements formed the basis for leaders to have individuals available who can analyze and understand the commonalities and differences in the requirements of each country if they are to succeed in this era of globalization (Duggal et al., 2014).

In developed economies like the United States, EU, Japan, and Canada also classified as regulated markets; regulations are well structured and clear. The rest of the world such as Brazil (Latin America), Tanzania (Africa), Russia, and others are emerging markets (Handoo et al., 2012). Regulated markets have defined regulatory requirements and regulatory agencies that ensure the agencies regulate the manufacture and

distribution of pharmaceuticals under strict quality standards to protect consumers in the entire pharmaceutical products chain (Parvizi & Woods, 2014).

The concerns about the pharmaceutical industry developing medicines without addressing genuine unmet needs, performing research without due consideration for research participants, unsubstantiated claims, withholding negative results, adverse events, abuse of intellectual property laws, and off-label marketing practices has resulted in high regulation of the industry via a rigorous registration process for drugs (Schramm, Herbst, & Mattie, 2014). Hence, the ability of medical product manufacturers to formulate a balanced regulatory strategy is expedient for conducting a fair review of medical products leading to improved understanding of the medical product development and approval processes (Bujar, McAuslane, Walker, & Salek, 2017).

In many markets, gaining approval or licensing of pharmaceutical products depends on the company capabilities gained from the performance of similar pharmaceutical products (Yousefi, Mehralian, Rasekh, & Yousefi, 2017). Studies on the decision-making process in the pharmaceutical industry have centered principally on research and development (Pace, Pearson, & Lipworth, 2015). Decision-making in the pharmaceutical industry is rife with uncertainty and decisions about what drug to develop or market and is an important organizational element that requires input from regulatory persons in the organization (Jekunen, 2014).

The process of regulatory decision-making is the approach that leaders adopt in regulated organizations involved in pharmaceuticals to conform to regulatory requirements. The term *process* relates to the *how* and is an essential component of a

company resource that helps eliminate non-essential uncertainties from a plan (Dinh et al., 2014). The concept of regulation implies a specific array of instructions, deliberate government interventions, or socioeconomic controls designed to prevent or restrict unacceptable acts, activities, and processes (Baldwin et al., 2012). Society today is more industrialized, richer than at any other time, and more regulated from every aspect of human activity with different theories on the impact of regulation on economics, health, and social progress of countries in Western Europe and North America (Baldwin et al., 2012).

Scholars from a host of fields, including law, economics, political science and public policy, sociology, healthcare, management, and social administration engineered discussions on regulation (Baldwin et al., 2012). Likewise, scholars and industry professionals have written on various aspects of regulations including concepts, challenges, and suggestions, but the literature on leadership in pharmaceutical companies functioning in a wave of regulations is still evolving. Researchers in the fields of economics and political science often associate regulation with efficiency, accountability, transparency, and high productivity, with social welfare implications (Baldwin et al., 2012). These criteria may lead to wealth creation and are an integral part of economic theories of regulation classified into two broad groups: (a) public interest theories of regulation and (b) private interest theories of regulations. On the contrary, Dechezlepretre and Sato (2017) argued that regulations cause substantial reductions in the growth of output and effect on labor and capital.

The reason for the rising interest in pharmaceutical regulation may not be universal but a result of peculiar needs of the market (Amadi & Amadi, 2014). Amadi and Amidi (2014) stated that counterfeit drugs as the primary reason for the interest in national pharmaceutical regulation in developing countries. This contrasts with the highly regarded regulatory systems in the EU, United States, Canada, and Japan, where the rise in regulation is the result of new product development and their contribution to healthcare outcomes (Macdonald et al., 2015). The increase in regulatory activities affects drug development phases as well as various agents and choices made about regulatory decisions (Herwig, Garcia-Aponte, Golabgir, & Rathore, 2015). As a result, having knowledge of a business environment and the impact of regulatory decisions on product positioning are vital to a product's performance in the market (Mehralian, Nazari, Akhavan, & Reza, 2014). Likewise, in-depth knowledge of regulations by company leaders or their designee and their motivation to embrace regulatory changes companywide saves time and errors in drug approval submissions or licensing (Naghshineh et al., 2014).

Drug approval process. The FDA, European Medicines Agency (EMA), National Agency for Food and Drug Administration and Control (NAFDAC) are the agencies responsible for the evaluation of drugs developed by pharmaceutical companies for use in the United States, EU, and Nigeria respectively and for granting of marketing authorization to pharmaceutical companies (NAFDAC, 2016; Naghshineh et al., 2014). Pharmaceutical products require regulatory clearance before introduction into markets for the safety of the populace and various government agencies regulate all aspects of the

product lifecycle (Bedi, Krishan, & Singh, 2017; Warier & Mehta, 2016). Regulations for market access, manufacturing, and advertising are critical because of the need to protect the safety and efficacy of products. To highlight the importance attached to pharmaceutical products, many countries have developed a drug registration system that involves licensing and inspection of manufacturers and importers of pharmaceuticals for sale (Balasubramanian et al., 2016).

Regulatory agencies are responsible for the scientific evaluation of medicines for use in their markets to satisfy the following criteria: (a) efficacy, (b) safety, (c) quality, and (d) clinical use information (Warier & Mehta, 2016). The licensing or market authorization process for pharmaceutical products is a critical component of pharmaceutical laws in most countries. The registration of pharmaceuticals in resource-limited countries is often to ensure reliable product flow from reputable manufacturers and distributors (Amadi & Amadi, 2014; Olugbenga, 2013). Warier and Mehta (2016) found a lack of uniformity in regulatory approval among leading national medical product regulatory agencies.

Although each country or market has an approval process designed for the needs and resources of that country, each country's regulatory process evolved differently in accordance with requirements and resource availability (Parvizi & Woods, 2014). Each of the stages of the drug approval process has multifaceted requirements, which sponsors must fulfill to advance to the next stage in the approval process (Handoo et al., 2012). The requirements contribute significantly to the high cost of drug development or marketing in a particular market. Pharmaceutical products already approved in countries

with developed regulatory systems, as obtained in the United States, EU, Canada, and Japan often require less documentation to gain market authorization in other countries (Balasubramanian et al., 2016). A broad overview of the regulatory process for the approval of pharmaceutical products is provided in Figure 1.

Figure 1. Overview of the regulatory processes in pharmaceutical licensing.

Many of the drug approval processes in the EU are similar to those of the United States (Van Norman, 2016) as shown in Figure 2.

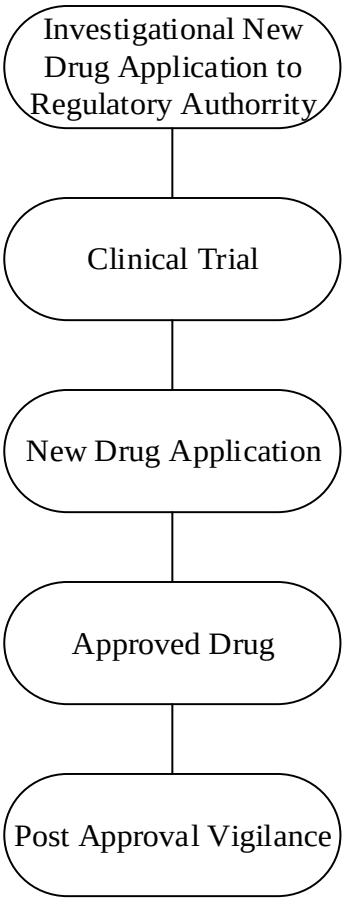

Figure 2. Typical drug approval procedure in the United States.

The evolution of Nigerian pharmaceutical regulations. The National Agency for Food and Drug Administration and Control (NAFDAC) is the agency charged by the national government to regulate drugs in Nigeria (Amadi & Amadi, 2014). The National Agency for Food and Drug Administration and Control Decree Number 15, 1993 established the agency, and functions to regulate food, drugs, cosmetics, and medical devices. The interest in the formation of a drug regulatory agency in Nigeria began in 1988 following the promulgation of the Counterfeit and Fake Drugs Decree No. 21 of 1988 to combat the growing problem of fake drugs (Ofuani, Kuye, & Ogundele, 2015).

NAFDAC has nine primary functions as contained in the NAFDAC Act (Food and Drug Administration and Control, 2016) including:

- Conduct appropriate tests and ensure compliance with standard specifications designated and approved by the Council for the efficient control of the quality of food, drugs, cosmetics, medical devices, bottled water, chemicals and their raw materials as well as their production processes in factories and other establishments.
- Undertake appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water, and chemicals and establish appropriate quality assurance systems, including certificates of the production sites and the regulated products.
- Undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water, and chemicals and establish relevant quality assurance systems, including certification of the production sites and the regulated products.
- Compile standard specifications and guidelines for the production, importation, exportation, sale, and distribution of food, drug, cosmetics, medical devices, bottled water, and chemicals.

The establishment of various regulatory agencies reinforced the revelation that Nigerian government has the responsibility to protect the people by ensuring that pharmaceutical organization leaders and followers to ensure compliance with regulatory requirements (Ofuani et al., 2015).

Transition

In Section 1, I introduced the topic, problem statement, and purpose of this study. The general business problem is that noncompliance with regulation has a negative impact on company revenue, loss of brand value, product development, product approval, and regulatory investigations. As such, some pharmaceutical company managers lack strategies to ensure compliance with regulatory requirements. The conceptual framework for this study hinges on complexity leadership theory based on the work of Uhl-Bien et al. 2007. Researcher use complexity leadership theory to understand interactions, uncertainty, and unpredictability in organizations that arise from multiple interactions. The literature review component revolved around three themes namely, complexity leadership theory, (b) support and rival theories, and (c) the pharmaceutical industry.

Section 2: The Project

In this study, I explored strategies that managers in pharmaceutical companies use to ensure compliance with regulatory requirements. Using a single case study, I explored the strategies the managers in the company use to be successful in Nigeria. In Section 2, I present a detailed approach to the methodology and data collection processes I followed and the technique to ensure quality in data gathering and analysis. As the primary researcher, I identify the research method and design to accomplish the purpose of the study after an in-depth review of scholarly articles and seminal sources. I justify the selection of research participants, describe my role as the researcher in the study process, and the selection of the population, sampling technique, and sample size. Lastly, I discuss the ethical approach to the research study, the data collection and data organization process, the analysis process, and my approach to ensure reliability, and validity of the study.

Purpose Statement

The purpose of this qualitative single case study was to explore strategies that managers in pharmaceutical companies use to ensure compliance with regulatory requirements. The target population for this study consisted of four pharmaceutical managers in a Nigerian pharmaceutical company who have successfully implemented strategies for compliance with the regulatory requirements in Nigeria. The implications for social change include the potential to improve the abilities of managers to ensure compliance in a regulated environment, which might lead to increased access,

availability, and affordability of pharmaceutical products by individuals with limited access to good healthcare.

Role of the Researcher

The researcher in a qualitative study functions as the primary instrument for collecting data through interviews, field observations, and document analysis (Yin, 2014). Stake (2013) noted that the researcher is the key driver of the study, whereas Docherty (2014) posited that the researcher is responsible for selecting and shaping the theoretical concept of the study. My role as the primary researcher was to design the study, select research participants, and to provide them with information about the research process. In addition, I collected and analyzed the data.

Roulston and Shelton (2015) noted that a researcher should be familiar enough with the study area to understand the central concepts and methodological concerns relevant to the study. As the primary researcher, I have worked in the pharmaceutical sector for the past 9 years in various capacities. Presently, I perform regulatory functions while serving to ensure compliance with various government regulations. My role in international regulatory affairs is to provide regulatory support within the organization for the registration and maintenance of the company products and facilities with appropriate regulatory authorities. As the researcher, my contacts with business leaders and pharmaceutical industry managers afforded me insight into the nature of those that I

recruited as participants because of my involvement in international regulatory issues in the pharmaceutical/medical industry.

The Institutional Review Board (IRB) required researchers to adhere to the IRB regulations when conducting research (Tsai, 2013). I followed the guidelines of the Walden University IRB, and the ethical principles and guidelines for the protection of humans as outlined in the Belmont Report. The three basic ethical principles in the Belmont Report include respect for persons, beneficence, and justice (Miracle, 2016). The Belmont Report protocol provides researchers with information to protect the rights of research subjects or participants (Kawar, Pugh, & Scruth, 2016). In complying with the principles of the Belmont Report, researchers obtain informed consent, assess risks and benefits, and select participants. The informed consent process includes disclosing information about the research study, ensuring participants' comprehension of the information, and emphasis on voluntary participation (Miracle, 2016). As the researcher, I conformed with (a) the ethical principles of the Belmont Report, (b) the guidelines of Walden University IRB, and (c) the ethical standards of the company. As such, I ensured that I ethically conducted this research by commencing data gathering only after receiving IRB approval. I explained the principle of informed consent to participants and obtained the signed informed consent forms before starting the data collection. In addition, I safeguarded participants' identities, provided participants the informed

consent form, and treated all participants fairly and equally. Lastly, I ensured the highest ethical standards, including not plagiarizing or falsifying data.

Evers, Hiligsmann, and Adarkwah (2015) noted that bias might occur in a research study at the planning, data gathering, data analysis, or presentation stage. A researcher's understanding of bias is critical because this helps the researcher to evaluate the literature critically to minimize potential errors in the study. Malone, Nicholl, and Tracey (2014) advised researchers to minimize systemic bias while trying to eliminate a specific bias. Researchers introduce member checking in their research design to avoid bias (Elo, Kaariainen, Kanste, Polkki, Utriainen, & Kyngas (2014). To mitigate research bias, I designed and adhered to an interview protocol (Appendix A) and used member checking in the research design. By following the interview, protocol helped me to ensure that I treated all participants equally, sensitive to contrary views and did not allow my views to influence those of participants.

Researchers use interview protocols in qualitative studies for data consistency and reliability (Baskarada, 2014). A good interview protocol enables the interviewer to gain insight into participants' lived experiences and learn their opinions (Jacob & Furgerson, 2012). The interview protocol enhances the reliability of a study as it includes an introduction, purpose, prompts, interview questions, and a blueprint of the case study report, case study questions, and references (Baskarada, 2014). Researchers using interview protocol to collect data can conduct their research by speaking with other individuals, a factor that may lead to a better understanding of the human condition. I

used the interview protocol to guide me through the interview process and ensured that all participants received the same information from me as the researcher.

Participants

The choice of participants in a research study affects the success and validity of that study (Marshall & Rossman, 2016; Yin, 2014). Researchers establish eligibility criteria in a study to ensure that participants have the requisite insight sought in the study and indicate their interest to participate (Rengerink et al., 2017). Participants in this study were managers who have successfully managed or demonstrated effective coordination of regulatory activities within the selected pharmaceutical company in Nigeria. In this case study, the participants were members of a leading indigenous, publicly traded pharmaceutical company with significant supervisory responsibilities for managing individuals to achieve the who have leadership roles and other responsibilities in the company value chain, particularly with regulatory responsibilities.

Gaining access to initial contact with participants in qualitative research is essential to the goal of a study (Keshavarz, Ftahikenari, Rohani, & Bagheri, 2014; Peticca-Harris & de Gama, 2016). In a qualitative study, a few gatekeepers may be the principal obstacles to accessing key participants that have relevant information (Peticca-Harris & deGama, 2016). Collaborating with the gatekeepers and having an in-depth knowledge of the desired populations are ways to overcome the challenges gatekeepers pose (Anuruang, Davidson, Jackson, & Hickman, 2015). I worked around the gatekeepers by leveraging my professional relationships and discussing my study with acquaintances

who have direct access to the senior executives of the company to gain access to the company.

Researchers need to develop healthy relationships with potential participants to gain their confidence because interviewing requires building a relationship with the interviewee (Haahr, Norlyk, & Hall, 2014). Gaining participants' trust is critical to building and maintaining a working relationship with the participants and enhancing their willingness to participate in the research (Andrighetti, Semaka, & Austin, 2017). Seidman (2012) posited that contacting each participant directly through their organizations before starting the interview would assist in building the groundwork for the actual interviews. Bristol and Hicks (2014) noted that providing participants with informed consent forms helps in gaining participants' trust. Upon gaining access to the company, I recruited the participants through targeted direct email correspondence using the channels provided by the corporate affairs unit. The email contained a description of the intent of the study and sufficient information to help prospective participants to decide whether to participate in this study. I assured participants that the interview would not place them in a vulnerable situation that may jeopardize their positions or harm their ability to perform their jobs.

Research Method and Design

Three methods are potentially available for conducting research: qualitative, quantitative, and mixed-method (Yin, 2014). Following Yin's (2014) work on case study designs, I determined that the qualitative method was the most appropriate for exploring

the strategies pharmaceutical company leaders use for compliance with regulatory requirements.

Research Method

The research method may be any of the following three methods: quantitative, qualitative, or mixed method (Marshall & Rossman, 2016). I performed a qualitative single case study for gathering in-depth information from participants to explore the strategies that managers use to ensure compliance with regulatory requirements. Research scholars emphasized the importance of a detailed literature search before deciding on the research method for a study (Baskarada, 2014).

Qualitative researchers study phenomena using open-ended questions that provide rich and nuanced information based on participants' experiences, perceptions, and history in their natural setting (De Massis & Kotlar, 2014). The emphasis of qualitative research is based on perceptions and experiences taken from only a few participants; hence, the outcome of the study is not generalizable to an entire population (Grosse, Dixon, Newmann, & Glock, 2016; Starman, 2013). Because the qualitative method allows for open-ended interview questions, the research participant is not constrained and is allowed to capture the often-neglected information (De Massis & Kotlar, 2014). Qualitative research is subjective, and the key focus is on participants' perceptions and experiences relevant to exploratory study (Starman, 2013). The qualitative method will enable me to collect information on participants in their natural settings and learn about their individual experiences and interpretations.

Qualitative method researchers seek to understand the circumstances associated with activities, processes, and interactions in shaping and reshaping phenomena (Patton, Hong, Patel, & Kral, 2017). Researchers employ the qualitative method to explore underlying reasons that managers choose a particular knowledge set (Yin, 2014). Other justifications for the choice of qualitative method include a researcher's ability to explore various situations and mechanisms in an organization or circumstance. With qualitative data, researchers can improve the description and explanation of complex concepts in a clear and concise manner (Bradley, Curry, & Devers, 2007). De Massis and Kotlar (2014) explained that researchers use qualitative methods for an in-depth understanding of issues, which is appropriate for exploratory questions Similarly, De Massis and Kotlar (2014) stated that the qualitative method is suitable for events where the number and observations available do not readily lend itself to consistent measurement and statistical analysis.

Researchers use quantitative methods for research that involves statistical data, measurements, sampling, and analysis of relationships between variables (Bernard, 2013). Quantitative researchers seek to count occurrences, establish a statistical connection among variables, and generalize findings from a sample to an entire population (Counsell, Cribbie, & Harlow, 2016). The quantitative method was not appropriate for this study because the study did not involve the testing of hypothesis or building of theories.

Mixed method is a methodology for conducting research involving quantitative and qualitative methods in a single study to collect and analyze data when one a single

method is insufficient for researchers to understand a phenomenon (Dumbili, 2014). The mixed method approach requires time and resources for data collection and processing (Venkatesh, Brown, & Sullivan, 2016). Mixed method was not suitable for this study because the purpose of this study was not to combine quantitative and qualitative methods to understand a phenomenon.

Research Design

The research design is a plan that serves as a guide to researchers in the process of data collection, analysis, and interpretations (Yin, 2014). The study design influences the conclusions drawn from a study (Proches & Bodhanya, 2015). Qualitative researchers can choose from a plethora of possibilities that include case study, phenomenology, ethnography narrative, and grounded theory shared across the social and health sciences (Yin, 2014). The most appropriate research design for this study was the single case study. Case study may be a single or multiple case and can be explanatory, descriptive, or explanatory (Stake, 2013; Yin, 2014). I used a single case study design in this study to gain a deeper understanding of the phenomena in response to the research question. The rationale for selecting one pharmaceutical company was to explore the strategies that managers in the pharmaceutical company use to ensure compliance with regulatory requirements. The justifications for the choice of single case study included studying a critical case, an extreme case, a representative or typical case, and, revelatory or longitudinal case (Yin, 2014).

Case study involves an in-depth data collection from various sources of information including interviews, observations, documents, field notes, and audiovisual

materials (Yin, 2014). Case study design affords researchers the opportunity to collect data in their natural settings through multiple sources of information such as interviews, observations, documents, and note taking (Morgan, Pullon, Macdonald, McKinlay, & Gray, 2017). Qualitative research scholars posited that the purpose of a case study is to provide insightful descriptions of an individual system, phenomenon or situation using qualitative and quantitative methods for data gathering and analysis (Stake, 2013; Yin, 2014).

Organizations benefit from the rich, holistic descriptions of a phenomenon in its natural state with the use of a case study design (Hyett, Kenny, & Dickson-Swift, 2014). Case study has the distinct advantage of generating robustness by advancing the knowledge and understanding of specific phenomenon while providing in-depth feedback to research questions (Morse & McEnvoy, 2014). Case study was suitable for this study to gain an exhaustive understanding of participants' experiences in organization processes and business transformation. Yin (2014) made an argument for case study when the heart of the study hinges on *how* and *why* questions.

Two factors are important in a case study: the number of cases in the study and the number of units of analysis. Stake (2013) noted that the nature of a case study may be intrinsic (unique), instrumental (improve), and collective (for generalization). The unit of analysis of the study relates to a phenomenon occurring in a confined framework (Yin, 2014). The case of this study involved compliance with regulatory requirements in a pharmaceutical company, and the unit of analysis were managers in a pharmaceutical

company involved directly or remotely in any aspect of the pharmaceutical product's chain.

Researchers use ethnographic or phenomenological design in qualitative business research (Yin, 2014). In an ethnographic study, the focus of the researcher is on beliefs, behavioral pattern, and culture of a group of people (Ferguson, 2016). Ethnographic researchers conduct their study by observing what participants are doing and saying, or participate by following participants wherever they go or do their biddings (Ingold, 2014). The sources of data are from sources such as participants' observation, field notes, and interviews (Gioia, 2014). Ethnography was not appropriate for this study because my focus was not on the culture of the people.

In phenomenology, the researcher investigates lived experiences of individuals to understand the universal and underlying context of a phenomenon (Gill, 2014). Phenomenology researchers focus on the description of the experiences of participants and is suited for studies where collected data was from lived experiences of the participants (Cassel, 2017). I did not select phenomenology for this study given that I did not seek to explore lived experiences of those going through a phenomenon.

Data saturation in a qualitative study is the point in data analysis where the collection more data will not result in additional information related to the research question (O'Reilly & Parker, 2013). Factors including the purpose of the study, population, research design, method of analysis, and available resources influence sample size (Hennink, Kaiser, & Merconi, 2017; Malterud, Siersma, & Guassora, 2015). According to Fusch and Ness (2015), data saturation occurs when no new themes emerge

from the data gathering. I ensured data saturation at the stage where the data collection process became counter-productive and until the interview data from participants became repetitive.

Population and Sampling

The population of this study was functional managers from regulatory, operations, distribution, and marketing departments from a pharmaceutical company based in Nigeria. Purposive sampling is suitable for selecting participants given the convenience, access to participants, and contributions to identifying participants with valuable information (Lucas, 2014; Palinkas, Horwitz, Green, Wisdom, Duan, & Hoagwood, 2015). Researchers use purposive sampling to explore and to collect a variety of data based on the experiences of selected participants, with the assumption that participants will provide a significant amount of information related to the topic (Bernard, 2013; Roy, Zvonkovic, Goldberg, Sharp, & LaRossa, 2015). I used purposive sampling to select participants from the population. Bernard (2013) noted that, with purposive sampling, researchers could recruit participants with an experience that is specifically related to the study and in a situation where the number of participants was limited. The use of the purposive method to recruit participants ultimately ensures that a qualitative study results in the collection of data relevant the topic (Suen, Huang, & Lee, 2014).

Researchers are not unanimous on the sample size for qualitative research, but most scholars suggest that data saturation is a key determinant of sample size (Hennink et al., 2016). A small sample size affords the researcher the benefit of analyzing the complexities of the data by providing better and richer insight into a phenomenon

(Galvin, 2015). I interviewed 4 participants until I reached saturation and no new themes or information emerges. Dworkin (2012) noted that 5 to 50 participants in qualitative research are adequate whereas O'Reilly and Parker (2013) strongly opposed the use of saturation as a marker of sample size.

Fusch and Ness (2015) stated that failure to reach data saturation in qualitative research influences the overall research quality and suggested that researchers consider a research design that is explicit about data saturation. Researchers attain data saturation in their studies when; ample information is available to repeat their studies, and the ability to obtain more data and further coding are not achievable or practical (Fusch & Ness, 2015; Morse, 2015). In addition, presenting the same questions to multiple research participants leads to data saturation (Malterud et al., 2015). I ensured data saturation by interviewing participants until data became repetitive.

Researchers focus on the selection of participants to ensure that they have those individuals who can provide accurate information about the topic of study (Bernard, 2013). The participants had the knowledge and expertise on how leaders and managers ensured compliance with the regulation. Participants provided the interview locations within the company facility, where they felt most comfortable without distraction during the interview process. Earp, Mitchell, McCarthy, and Kreuter (2014) noted that the interview setting is vital to the quality of the research, whereas Yin (2014) emphasized that researchers should conduct a case study in the natural setting of the case.

Ethical Research

An informed consent form is a regulatory requirement for participants to confirm their willingness to participate in a study after they know all aspects of the study that are relevant (Rubinstein, Karp, Lockhart, Grady, & Groft, 2014). I obtained Walden University (IRB) approval with the approval number 11-10-17-0371674 to conduct the study. Upon Walden University (IRB) approval, I sent an informed consent form to each participant to review after accepting the invitation (Appendix B) to participate in the study. Participants who chose to participate in the study signed the consent form and returned it to me. Participants can withdraw from a study at any time without giving any reasons (Rubinstein et al., 2014). Participants had the opportunity to withdraw from the study, by contacting me via phone or email to express their desire to withdraw. I would have accepted the request and then delete all their information relating to the study.

Participants participated freely in the study without any offer of incentives to avoid coercion and effect on the quality of the study. As such, I did not offer incentives for the study. Kennedy and Ouimet (2014) reported mixed outcomes on the use of incentives to increase participation rate in a study. Researchers need to understand the ethos of ethical standards and guidelines including avoidance of financial inducement in research (Polacsek, Boardman, & McCann, 2017). Ethics is an essential component of the research, that relates to the integrity of the researcher and others associated with the study. I earned a certificate entitled Protecting Human Research Participants (Appendix C) to assure that I understood the ethical protection of participants. Pisani et al. (2016) highlighted measures that researchers use to assure adequate protection of participants

including (a) adequate informed consent, (b) safeguarding data, and (c) minimizing intrusiveness and fatigue. I took steps to protect participants through data protection, maintaining confidentiality, adhering to IRB guidelines, respect for participants, and the use of informed consent. O'Keefe and Rubin (2015) noted that researchers are bound to keep the identity and confidentiality of research participants and must de-identify all information to avoid bias and to obtain an accurate analysis.

I stored all my data in secure cloud storage and on an external hard drive kept in a secured/locked cabinet only accessible to me for 5 years. Researchers can destroy both physical and digital data after the 5-year period (Rubin & Rubin, 2012). I identified participants only by codes (e.g., P1, P2, P3, and P4 for participant 1, 2, 3, and 4 respectively) to maintain confidentiality and use a study number with their documents. Researchers can identify participants using codes to hide the participant's identity (O'Keefe & Rubin, 2015). I redacted all personal information on file, preserved the confidentiality of proprietary information from key participants in the company, and upheld ethical codes for researchers to protect participants' privacy.

Data Collection Instruments

The researcher conducting the interview is the primary data collection instrument in a case study (Marshall & Rossman, 2016; Roy et al., 2015). As the primary researcher, I collected, recorded, and transcribed the data collected from the interviews. Case study researchers may use a variety of instruments for data collection, including questionnaires, interviews, focus groups, and observations (Baskarada, 2014). Conducting interviews using teleconference enables researchers to gain access to participants in different

locations, provide real-time interactions and opportunity to experience visual cues (Redlich-Amirav & Higginbottom, 2014). Teleconferencing provides a similar experience as face-to-face interviews, but good technology and attentive participants ensure effective meetings (Goodman-Deane, Mieczakowski, Patmore, & Clarkson, 2015). Similarly, Redlich-Amirav and Higginbottom (2014) stated that teleconference is an appropriate interview setting because it provides simultaneous interaction between the researcher and participants.

Semi-structured interviews are flexible and afford the researcher a clearer understanding of the participant's viewpoints (Wolfe, Gotzsche, & Bero, 2013). Case study researchers obtain secondary data from multiple sources of evidence (i.e. company documents, government publications, and routinely collected data) or a combination of those with the primary data collection instruments (Ketokivi & Choi, 2014; Tijjani, 2014). I used archival records as the secondary data source to the case. The interview questions were concise so that respondents could easily understand the questions and respond. The interview form contained open-ended, in-depth interview questions that allowed for follow-up questions. I conducted interviews in person and via teleconference. I recorded the interviews digitally. Before data collection, I addressed ethical issues with participants using the informed consent form to assure each participant of their rights and confidentiality. I developed an interview protocol based on the framework adapted from Baskarada (2014) and Wolfe et al. (2013). I began the interview process by contacting the participants to schedule an appropriate time for a phone interview and sent the consent form. On the interview date after receiving the completed consent form and confirmation

of interview time, I introduced myself, provided a background of the study, reviewed the consent form, and obtained spoken consent to record the conversations. I informed the participants of the confidentiality of the interview to reassure them and to make them feel comfortable enough to offer their opinions and to provide truthful answers to probing questions. I started with open-ended questions and with follow-up questions as required. A phone interview process has the advantage of wide geographical access and offers the opportunity to gain access to research participants who might otherwise be difficult to reach (Ward, Gott, & Hoare, 2015).

To enhance the reliability and validity of data collection, I conducted transcript review and employed member checking. Qualitative researchers use member checking primarily for quality control to improve the accuracy, credibility, and validity of recordings of an interview (Birth, Scott, & Cavers, 2016; Morse, 2015). I collected secondary data from available literature including government reports, company reports, and publicly available data to triangulate the interview data. Multiple lines of evidence in the form of documentation, field notes, photos, excerpts from multimedia, archival records, and observations are essential components of a case study (Morgan et al. 2017; Yin, 2014). I reviewed company websites, publications, government agencies, social media, and related online resources to gather secondary data. Starman (2013) encouraged researchers to use multiple sources of data where appropriate to improve the outcome and validity of their research. Still using member checking, I augmented the data collection with follow-up questions and checked responses with respondents to ensure the accuracy of interpretation.

Data Collection Technique

Researchers are the primary data collection instruments in the qualitative study and have multiple options for data collection, including interviews, observations, document reviews, and archives (Morgan et al., 2017). In case study, data collection involves following case study protocol using multiple sources of data (Yin, 2014). I used in-person and telephone interview format to collect data, archival documents from the company, government agencies and industry group. The researcher's instrument for data collection is the semistructured interviews, which is a guided conversation and one of the primary sources of data in the case study (Baskarada, 2014).

A semistructured interview is flexible and allows the researcher to have a better understanding of the participant (Yin, 2014). Interviews are critical data collection instruments in a case study, given that interviews are conversations used by researchers to obtain that information they cannot easily get using other instruments (Baskarada, 2014). Case study researchers use structured, semistructured, or unstructured interviews. Semi-structured interviews are flexible and afford the researcher a clearer understanding of a participant's viewpoint (Wolfe, Gotzsche, & Bero, 2013). An advantage of conducting interviews is the chance for researchers to develop a relationship with participants (Yin, 2014). In addition, Baskarada (2014) noted that researchers use interviews for data collection to ensure the topic of research remains the focus of the study. I used semistructured interviews to explore strategies that managers in a pharmaceutical company used to ensure compliance with regulation.

Doody and Noonan (2013) and Yin (2014) articulated the advantages and disadvantages of using semistructured interviews in a study including: (a) participants may not stray away from the topic, (b) researchers can predefine the interview questions relative to the conceptual framework of the study, (c) possibility of using interview protocol allowing for interview confinement to the conceptual framework of the study, and (d) ability of researchers to explore all the areas required for the research. The key disadvantage of using semistructured interviews is the difficulty associated with processing data from it (Yin, 2014). Dasgupta (2015) noted that interviews are slow and present a concomitant challenge to connect and organize similar statements from different participants. Another drawback of this technique is that the researchers must ask questions carefully (Yin, 2014) and appraise what and how to present the questions in the right context (Baxter & Jack, 2008), which may result in investigator bias (Baskarada, 2014).

In conducting semistructured interviews, six key elements are required: (a) selecting the type of interview, (b) establishing ethical guidelines, (c) crafting the interview protocol, (d) conducting and recording the interview, (e) crafting the interview protocol, and (f) reporting the findings (O'Keeffe et al., 2016). I provided a detailed description of the data collection technique in Appendix A. Upon receiving IRB approval, the interview process began by contacting the chosen company contact person to obtain the contact information of potential participants in the study. After receiving the list of potential participants, I contacted them via email using the content in Appendix B. The letter contained a description of the study and an explanation of the requirements and

their rights, risks, and benefits. I avoided conflict of interest in all ramification in participants' selection process. I stuck to the interview protocol that I designed for this study to ensure consistency in my approach to each participant.

Researchers may enhance the validity of their study using multiple data sources including documents, archival records, direct observations, and physical artifacts (Yin, 2014). The key disadvantage of reviewing documents is that they may not accurately reflect the facts, for example, some of the documents may contain obsolete information (Baskarada, 2014). However, secondary data are easier to collect, save time and money (Marshall & Rossman, 2016). The second data source may provide additional information about the topic not captured through the primary data source. I obtained additional information from company reports and publications that are publicly available.

Researchers employ member checking to ensure an accurate reflection of participants' views (Cope, 2014). With member checking, participants contribute to the narratives of the findings before the publishing of the study (Noble & Smith, 2015). Through member checking, I enhanced the confirmability of every aspect of this study. I regularly checked participant's understandings of each question and paraphrase and summarize their responses to each question for clarification. Interview technique requires the researcher to listen attentively for any new or interesting data the participant provides (Yin, 2014). Hence, the researcher must have excellent facilitation skills and be an effective communicator.

Data Organization Technique

Researchers often organize the data into electronic file systems readily available and accessible for analysis (Gale, Heath, Cameron, Rashid, & Redwood, 2013). The next process after data collection is entering the interview transcripts into a storage system using the right tools (Bernauer, Lichtman, Jacobs, & Robinson, 2013). I took notes and recorded responses from interview participants using a digital audio recording device connected to cloud storage for time and cost effective secure data management. Working with digital systems shortens the time required for transcribing and analyzing data (Yin, 2014).

I organized each participant's audio-recorded responses, secured the raw data, and transcribed data in a location mostly accessible by me. I organized the data by keeping track of signed (a) consent form, (b) invitation emails, (c) transcripts, (d) recordings, (e) labeling systems, (f) company documentation, and (g) research journals. Yin (2014) and Stake (2013) acknowledged the relevance of methodically organizing research data. I stored all the research data in secure cloud storage and on an external hard drive kept in a secure/locked cabinet accessible only to me for a minimum of 5 years. I transcribed the interview recordings using MS Word document and then stored them in the same way.

Data Analysis

Triangulation is a critical component to strengthening research validity (Yin, 2013). Qualitative researchers assess and validate their research using triangulation (Johnson et al., 2017). Triangulation allows for analyzing the research problems from different perspectives (Johnson et al. 2017; Turner, Cardinal, & Burton, 2017).

Triangulation involves the use of multiple sources to study a case, minimizing the weaknesses of research design and enhanced understanding of the case (Turner et al. 2017). Baskarada (2014) identified four types of triangulation: (a) methodological triangulation, (b) data source triangulation, (c) investigator triangulation, and (d) theory triangulation. Methodological triangulation involves using more than one method for data gathering in the study of a phenomenon, which is beneficial in confirming research findings (Turner et al. 2017). Case study findings are more convincing and likely to be more accurate with methodological triangulation (Yin, 2014).

I used methodological triangulation to analyze the evidence from multiple data sources to identify themes that aided in the assessment, interpretation, and deduction from the information generated. Researchers find themes based on the responses to the interview questions. I used content analysis to analyze documents obtained from the study organization for triangulation. The content analysis consists of preparation, organization, and reporting and counts themes or codes, and can help to identify the most common topics (Baskarada, 2014). The components of data analysis include three activities: (a) data reduction, condensing data into themes; (b) data display, which is the organization of information to allow for deductions; and (c) arriving at conclusions and verification (Tijjani, 2014).

I used a computer-assisted qualitative data analysis tool called NVivo and Microsoft Excel to code, identify patterns and themes, and analyze study data. The next phase was transcribing the recorded interviews and emailing the transcripts to each participant to confirm that the content of the analysis corresponded to the views

expressed. Researcher studies the outputs from this software to establish any emerging patterns, insights, and concepts. I: (a) read in detail each transcription to understand the contents, (b) read each transcript over again to extract key themes and sentences relevant to the case study, (c) attributed meaning to each significant affirmation, (d) placed each meaning into group of themes, (e) supplemented the results with detailed description of case, (f) described the key structure of the case, and (g) validated the data. Sotiriadou, Brouwers, and Le (2014) presented guidance for conducting qualitative data analysis using an NVivo software program and screenshots of the data analysis process. I analyzed the study data using the framework method for the management and analysis of qualitative data.

The framework method is a type of thematic analysis or qualitative content analysis that defines the matrix output: rows (cases), columns (codes), and cells of abridged data, giving structure to which the researcher can methodically reduce the data so as to analyze it by case and by code (Ritchie et al., 2014). Researchers using thematic processes identify similarities and differences in qualitative data before concentrating on connections between various parts of the data, to arrive at descriptive and explanatory conclusions clustered around themes (Gale et al., 2013). Framework method is a flexible tool that a researcher can customize for use with many qualitative approaches with the objective of generating themes. The procedure for framework method of analysis occurs in seven stages: (a) transcription, (b) familiarization with the interview, (c) coding, (d) developing a working analytical framework, (e) applying the analytical framework, (f) charting data into the framework matrix, and (g) interpreting the data (Gale et al., 2013).

Researchers may develop themes using a database, which allows them to develop audit trails from data gathering, through analysis, and to the final deductions (Baskarada, 2014). The analysis of findings of a study using previous reports or studies and conceptual framework provide authors with the ideas for articulating themes and structures (Yin, 2014) for their research. I extracted themes from each unit of analysis using a conceptual framework selected as the guide theory for this study and information from published studies. Researchers identify gaps in previous research by extending existing theory while using a conceptual framework to guide the study (Marshall & Rossman, 2016).

Reliability and Validity

Evaluating the quality of a study is essential for practical utilization of the results and drawing useful conclusions (Noble & Smith, 2016), and the quality of any empirical study including case studies is dependent on construct validity and reliability (Yin, 2013). What follows is a description of the strategies to enhance the study reliability and validity.

Reliability

The concept of dependability relates to the accuracy, repeatability, and dependability of a qualitative study just as ensuring reliability in a quantitative study (Yin, 2013). Houghton, Casey, Shaw, and Murphy (2013) posited that researchers ensure dependability and assure high rigor and robustness of the research process and results by diligently recording the research methodology and decision-making. Researchers may improve dependability in the study by using member checking (Elo et al., 2014). I

allowed participants to check the accuracy of the interpretations of their interview responses by sharing the data interpretation with the participants to confirm that the interview data corresponded to the thoughts they expressed. I also ensured dependability by keeping reflective notes and memos through the interview process and data analysis. Morse (2015) asserted that member checking enhances dependability by improving the accuracy, credibility, and validity of data during interviews. Member checking also allows researchers to improve the quality of their study through validation of transcribed information with study participants (Birt, Scott, Cavers, Campbell, & Walter, 2016).

Validity

Validity is the extent of compliance with the interpretation of the event and the realities of the world (Houghton et al., 2013). Also, Houghton et al. (2013) noted that an account is valid if it accurately portrays the features of a phenomenon that it describes. A qualitative researcher measures the validity of their research by evaluating the credibility, transferability, confirmability and data saturation of the study.

Credibility in a qualitative study is the trustworthiness of the findings of the study (Noble & Smith, 2015). Researchers enhance the credibility of qualitative research findings through an accurate reflection of participants' views by using member checking (Cope, 2014). Likewise, Houghton et al. (2013) suggested that in a qualitative study, researchers could enhance credibility if participants can verify the descriptions the researcher presents. Qualitative researchers may assess and validate their studies using member checking by allowing the participants to review the interview interpretations (Wilson, Onwuegbuzie, & Manning, 2016). Using member checking, researchers can

highlight problems by examining data and address any problem to maintain the integrity of the research findings and strengthen the outcome of the study (Lishner, 2015). I allowed members to check their interview responses using the interview transcript data to confirm that the interview data correspond to the thoughts they expressed to enhance the credibility of the study and to reduce research bias.

Transferability is the extent to which researchers can apply the findings of a study to similar settings or groups (Cope, 2014). Furthermore, Elo et al. (2014) described transferability as the potential for readers of the study to transfer the research findings of the study to another given the detailed description of the critical aspects of the study. Key components of the research study including research method, description of participants, and steps taken during analysis (Cronin, 2014; Elo et al., 2014). Researchers use interview protocols to maintain data consistency (Baskarada, 2014). I ensured transferability by providing a rich description of the interview process in the interview protocols and adhering to the scripts in the interview protocols.

Confirmability refers to accuracy, neutrality of study data, and the process of comparing data collected from multiple sources (Houghton et al., 2013). Morse (2015) argued that confirmability is the extent to which other researchers corroborate the outcome of a study to ascertain that the results are true representations of the participants' responses and devoid of researcher bias. I ensured confirmability by leaving an audit trail that will readily be retrievable to allow for later inspection by other researchers. This will allow other researchers to check the pathway of decisions I made in the data analysis. The audit trail will include the list of questions, actual reports, notes, memos, study protocol,

transcribed text, bibliography, and related databases. Cronin (2014) suggested that researchers using multiple data sources overcome bias associated with a single data source thereby increasing confidence in the result and confirmability of the study.

Data saturation refers to the state where there is enough data to replicate a study (Fusch & Ness, 2015). Bernard (2013) noted that evidence of data saturation occurs when the researcher cannot obtain additional information and lack further coding. Malterud et al. (2015) argued that researchers attain data saturation by asking multiple participants the same questions in a uniform manner. I interviewed many participants to ensure data saturation until I reached the point where no new information is emerging from the data.

Transition and Summary

Section 2 includes a discussion of the research methods and design, detailing the use of a qualitative case study technique. The key elements of this section include my role as the researcher and the criteria for selecting participants for this study. I identify the study population and the choice of the purposive sampling method. The section also contains information about how the researcher ensured high ethical standards and used in-depth interviews as the data collection instrument. I also explain the method for data analysis and support statements with relevant scholarly peer-reviewed sources. In addition, I discuss the approach to mitigate bias while addressing the reliability and validity of the study. Section 3 includes a presentation of findings and applications of study findings to professional practice, including an analysis and discussion of the results. The section will also include the implications for social change, suggestions for action, and recommendations for further research.

Section 3: Application to Professional Practice and Implications for Change

In this section, I present the findings gathered from an in-depth exploration of the strategies used by pharmaceutical company managers to ensure compliance with government regulations. The findings comprise a description of participants' responses to semistructured interviews, document review, emergent themes, and correlation to the conceptual framework. In addition, Section 3 includes the application to professional practice, implications for social change, and recommendations for action. I conclude the study with the recommendation for further research, my reflections on the doctoral study journey, and conclusion.

Introduction

The purpose of this qualitative single case study was to explore strategies that managers in a pharmaceutical company use to ensure compliance with regulatory requirements. The overarching research question of this study was: What strategies do pharmaceutical company managers use to ensure compliance with regulatory requirements? I conducted in-depth interviews with four managers involved in regulatory issues in a company based in Nigeria to gain insight into the strategies managers use to ensure regulatory compliance. Fusch and Ness (2015) noted that researchers reach data saturation when no additional information emerges from subsequent interviews. I reached data saturation after interviewing the fourth participant.

To obtain additional information and to enhance the validity of my study, I triangulated the interview data with secondary data that I collected from the company, including: (a) internal corporate documents, (b) annual reports, and (c) company website

materials. I also reviewed publicly available documents with information about pharmaceutical regulations and guidelines in Nigeria that included (a) regulatory agencies' websites, (b) regulatory guidelines documents, and (c) newsletters to triangulate the study data. After receiving the IRB approval, before the interview began, each participant reviewed and signed an informed consent form. I conducted the interviews at the research establishment and via teleconference with each interview session lasting between 35 minutes to 45 minutes. Upon the completion of the interviews, I transcribed the recorded interviews and assigned codes to all participants. Each participant was assigned a code to protect their identity and maintain the confidentiality of the participants. The assignment of codes to protect participants aligned with the observation of O'Keefe and Rubin (2015), that researchers could identify participants using codes to redact the participant's identity. I assigned participants numbers from 1 through 4 with P1, P2, P3, and P4 for participants 1 through 4 respectively.

Presentation of the Findings

The overarching research question of this study was: What strategies do pharmaceutical company managers use to ensure compliance with regulatory requirements? I used semistructured interviews with eight probing questions and follow-up questions to allow participants to provide in-depth information about their experiences in regulatory compliance. I transcribed the interview audio recordings and was careful to ensure that interview transcripts reflected the contents of the audio recording. De Massis and Kotlar (2014) noted that researchers enhance the accuracy of interviewee transcripts by reading transcripts while listening to the interview recordings. After the transcription,

I followed up with transcript review for participants to validate the accuracy of the interview responses of their interviews. Some of the participants shared SOPs, employee training information, regulatory inspection sheet, annual reports, and general guidelines from authorities.

I used Microsoft Excel and NVivo 11 Pro for Window software to analyze data and to identify frequent themes and word patterns that participants provided during the interviews. The data from this study resulted in the emergence of three themes:

- Establishment of regulatory affairs unit and engaged leadership enhanced compliance
- Qualified employees and learning enhanced compliance with regulatory requirements
- Strategies to navigate through barriers to enhance regulatory compliance

Theme 1: Establishment of Regulatory Affairs Unit and Engaged Leadership Enhanced Compliance

The first theme to emerge from data analysis was that the establishment of a regulatory affairs unit and enabling leadership enhanced compliance with regulatory requirements in the company. All participants maintained that the establishment of a regulatory affairs unit in the company facilitated the coordination of regulatory activities. Each of the participants also emphasized the importance of engaged leadership and how engaged leaders have undoubtedly influenced the company managers' compliance with regulatory requirements. Two subthemes emerged from the main theme: (a) regulatory

affairs unit, and (b) engaged leadership. All the participants indicated that the two items contributed to the enhanced functioning of the regulatory affairs department.

Regulatory affairs unit. Analysis of interview data revealed that all participants (P1, P2, P3, and P4) considered the creation of the regulatory affairs unit as an effective strategy to enhance regulatory compliance. In particular, establishing the regulatory affairs unit played a critical role in enhancing managers' ability to ensure compliance with regulatory requirements. Because of the establishment of the regulatory affairs unit, managers and employees were more attuned to compliance with regulations (P1) and facilitated the building and maintenance of good relationships with various regulatory agencies (P3). Having a regulatory affairs team responsible for communicating and implementing regulatory requirements that govern the pharmaceutical industry within the company has helped to increase employees' compliance with regulation and minimize regulators citation. The managers' position on the establishment of a regulatory affairs unit strengthened Tanwar, MittalI, Gugnani, and Sharma (2015) assertion that regulatory affairs unit in the pharmaceuticals industry perform key function given the rise and need to respond to regulation in a competitive business environment. The regulatory affairs unit team members work on regulated projects and activities in the company to ensure compliance with various regulations that affect the pharmaceutical industry.

A key function of the regulatory affairs unit, according to P1 and P3, is the lobbying of critical stakeholders to ensure total regulatory compliance by the company. Effective lobbying of stakeholders may secure waivers and shorten the time required for the regulatory authorities to process documents, grant permits, and approve

pharmaceutical product distribution (Papaioannou, Watkins, Mugwagwa, & Kale, 2016). Regulatory affairs unit has a proactive plan on the ways to respond and implement changes to regulatory guidelines and regulations to ensure compliance with the changes in legislation (P1). Tanwar et al. (2015) reinforced the importance of having a regulatory affairs department to provide strategic and operational skills required to address regulatory requirements for the growth, safety, and effectiveness of pharmaceutical products to consumers. The unit interprets and disseminates regulatory guidelines across departments and to vendors, particularly those affected by regulatory guidelines and updates for their input, adjustments, and lobbying.

All participants (P1, P2, P3, and P4) agreed that one of the ways the regulatory affairs unit team performed their role was through the gathering of knowledge on pharmaceutical legislation and a consistent effort to scout for new knowledge on legislation. Having an adept and knowledgeable individual as the regulatory affairs unit manager to lead the regulatory compliance efforts of the company is crucial to the overall regulatory compliance strategy of the company (P3). P2 and P3 substantiated the claim, noting that, for the unit to function optimally, a qualified pharmacist with experience in regulatory and quality duties should head the department, liaises directly with regulatory agencies, and coordinate regulatory activities within and outside of the organization. Having a knowledgeable manager positively influences the coordination of regulatory and quality tasks of the company, as well as providing effective supervision of employees in the unit (P3).

The team members of the unit maintain proper documentation and records to provide a picture of the company's manufacturing, distribution, and marketing operations as a basis for planning to ensure compliances with regulation (P1). The finding that adequate record help ensure compliance with regulation aligns with the findings of Chaudhari, Yadav, Verma, and Singh (2014) who expressed that keeping adequate record and company documents was critical in compliance. The regulatory affairs team has a developed a system that allows for an efficient response to regulatory questions from regulatory agencies and other units of the company.

All participants communicated that the regulatory affairs unit interfaces with regulatory agencies, and also coordinate their visits to the facilities. The principal agencies that the regulatory affairs unit interfaces with are (a) the National Agency for Food, Drug Administration, and Control (NAFDAC), (b) the Pharmacist Council of Nigeria (PCN), and (c) the Standard Organization of Nigeria (SON) and other statutory agencies that indirectly impact the operations of the company. Chaudhari (2018) explained that, in an era where regulatory agencies closely monitor every aspect of pharmaceutical supply chain and information shared with consumers, the establishment of a department that liaises with regulatory agencies and coordinate regulatory activities was critical. P2 and P3 reinforced Chaudhari's assertion with their inference that the company seamlessly integrated the regulatory affairs unit into its strategic decisions. Inefficient interaction with regulatory agencies affects brand, sales, and market shares. Desai (2016a) posited that organizations establish close collaborative relationships with

regulatory agents to overcome uncertainty. Collaborations with regulatory agencies enhanced organizational compliance with regulatory requirements.

P3 spoke about the involvement of the executive board in the supervision of the regulatory affairs unit to help resolve complicated regulatory challenges. One of the ways the unit resolved these challenges was to escalate serious regulatory compliance issues to the leadership level. The functional head of the regulatory affairs unit escalates problems through the superintendent pharmacist on the executive board of the company. The superintending pharmacist reports complex issues that require the input of the management board members to the executive board. The board is the ultimate decision-making body of the company, charged with resolving all business matters not reserved for the general meeting of shareholders.

Engaged leadership. All participants (P1, P2, P3, and P4) identified engaged leadership as a significant strategy that enhanced compliance with regulatory requirements. Specifically, the engagement of the executive board of the company in regulatory decisions facilitated regulatory compliance. According to P1 and P3, the active involvement of the senior leadership in regulatory issues was an indication of the relevance attached to compliance with government regulations and product safety. Executive board participation and support was consistent with Galuska (2014) who revealed that producing excellent outcomes requires influence leadership at each level of a complex system. The board regularly assesses the performance of the regulatory unit via unrestricted access to information to ensure satisfactory coordination business activities according to codes and laws by the company.

All participants believed that three behaviors of the leaders bolstered efforts to ensure compliance with regulatory requirements. One of the behaviors was the creation of regulatory vision with concrete goals and objectives, which ensured that managers and employees understood the significance of regulatory compliance. Second, the participants in the study also highlighted that fostering strict compliance, by consistently adapting to regulatory requirements, promoted a conducive business environment. The finding on the promotion of a conducive business environment echoed the assertion of Chhotray, Siverstsson, and Tell (2017), that a company vision should mirror a culture that bolsters employees' daily activities and decisions. Third, the support of the executive board for regulatory compliance aided the overall compliance with regulatory requirements in the company. P3 believed that the leader's engagement with the decision-making on regulatory activities and resolving issues directly related to regulatory compliance, the regulatory compliance was obvious companywide. Blomme et al. (2015) noted that changes create the need for leaders to adapt for the organization to survive and the strategies deployed by managers to adapt are communication, active participation and influence techniques. In responding to regulatory developments, the leaders promptly adapt to changes and the dictates of those involved in regulatory activities.

In summing up the importance of engaged leaders, P1 and P3 mentioned that the support of the executive board members was important in implementing the requirements in any specific area affected by any regulation. The focus of the company's culture revolved around stakeholders' interests, sustainability, overall support, and alignment of company strategic goals, and this influenced the support of leaders for compliance with

regulatory guidelines and laws. The leaders set in motion strategies that allowed for the development of key regulatory compliance tools including corrective action and preventive actions (CAPA), standard operating procedures (SOP), and other internal compliance documents. Employees used the documents as a guide in their daily tasks as a way of having a uniform compliance approach to regulatory requirements. P3 stated.

> The primary way we assess the measure of noncompliance or (CAPA) is when the regulatory bodies audit us for assessment, the measure of noncompliance that we receive is an indication of the effectiveness of our internal systems. We also have our routine quality audit in our processes that take place from time to time. We observe how many non-compliances are being reported and whether this noncompliance is major or minor. Let us not forget that it is also mandatory for regulatory authorities to always come in from time to time to audit our system. These two measures give us a feedback.

A review of the document *Corporate Governance Practices* (D1) obtained from the company indicated that the executive board was involved in governance and ensuring that departmental leaders implemented strategies and programs that were supportive of regulatory compliance. D1 was a corporate governance document that served as an operating guide for compliance with codes, including best practices and ethical standards in all aspects of the company's operations. The document had information on the governance structure, responsibility of the leadership of the company, and maintaining amicable relationships with various stakeholders.

The information obtained from D1 corroborated the assertion of P1 and P2 about the involvement of the leaders and facilitating compliance with regulation in the company. An excerpt from D1 corporate governance document on the role of the executive board states,

> The company continued to subject its operations to routine audit by independent auditors that include the current Good Manufacturing Practice (cGMP) and the National Agency for Food and Drugs Administration and Control (NAFDAC). A committee led by an executive director review the report for appropriate implementation of the recommendations.

Krause, Semadeni, and Cannella (2013) asserted that board members commonly influence organizations and accomplish this through any of three primary processes: (a) offering advice to management, (b) procuring resources for the organization, and (c) monitoring management having in mind the interests of internal and external stakeholders. As detailed in D1, the executive management committees drive the daily affairs of the company headed by an executive director who reports to the board of directors. The contents of D1 reinforced all participants' assertion that the executive board was active in ensuring the accuracy, adequacy and timely rendition of the statutory returns and reporting to regulatory authorities.

As constituted, the management structure serves to ensure that a standard procedure for reporting any form of noncompliance by employees or any strategic business associates is in place to ensure the sanity of their operations and enhance their reliance on key operational supports. The company leaders considered this important to

ensure overall sustainability of the company. D1 further revealed that the leaders predicated their engagement in management and influencing activities on various government code of corporate governance, compliance requirements, various statutory rules, and good manufacturing practice. The influencing activities mirror the submission by Desai (2016b) that the board of directors' influence activities in an organization.

Correlation to the conceptual framework. The findings of Theme 1 relate to CLT. CLT was advanced by Uhl-Bien et al. (2007) and the key constructs of complexity leadership theory are (a) administrative leadership based on strict control and bureaucratic hierarchy, (b) adaptive leadership based on creative problem solving, generating new conditions, and learning, and (c) action-centered leadership that involves immediate decision-making mechanisms used in crises and dynamic productivity. Specifically, the finding on the establishment of a regulatory affairs unit in enhancing regulatory compliance relates to adaptive and administrative leadership. All of the managers noted that the establishment of a regulatory affairs unit facilitated adaptability to regulatory requirements because the regulatory affairs unit interfaces with regulatory agencies, and also coordinate regulatory activities within the company. Baltaci and Balci's (2017) highlighted the importance of activities coordination in organizations leading to adaptability to new conditions. The administrative leadership component of CLT to provides leaders with requisite skills to manage uncertainty rather than over-control of every aspect of the business (Waldman & Bowen, 2016). The unit facilitates the administrative activities of the company including coordination and planning of regulatory compliance tasks.

Theme 2: Hiring Qualified Employees, Training and Continuous Learning Enhanced Compliance with Regulatory Requirements

The second theme that emerged from data analysis was hiring qualified employees, training, and continuous learning enhanced compliance with regulatory requirements. All participants (P1, P2, P3, and P4) shared that the hiring of qualified individuals for the right jobs was critical to the overall regulatory compliance strategy. The hiring of qualified individuals stemmed from a comprehensive compliance strategy based on a well-structured hiring and selection program. Training and continuous learning instituted in the company improved the organization's compliance with regulatory requirements (P2). In addition, training created opportunities for employees to remain current and understand requirement in a dynamic regulatory environment. Recruiting qualified personnel has an impact on the ability of the workforce to be trained because regularly trained personnel had a positive impact in maintaining regulatory compliance in every operation companywide.

Hiring qualified employees. All four participants shared that the hiring of qualified employees was an essential component of their strategy on compliance with regulations. P4 explained that to ensure regulatory compliance the company must have the right people for the tasks. A comprehensive recruitment strategy involved an established hiring process for all positions in the company. Developing an adequate recruitment strategy that conformed to the company priorities, skills, and training were determining factors credited for the company's prominent level of success with regulatory compliance. P2 and P4 shared that employees who are lacking an adequate

background in related jobs, particularly in regulatory issues, undergo basic training on compliance to understand the pharmaceutical regulatory environment.

The approach to recruiting qualified employees involved generating an accurate job description touting the skill sets and personality attributes required for completing tasks and fitting in with the culture of the company. In addition, P2 and P4 indicated that the company recruitment team uses online recruitment techniques to evaluate key behavioral traits and the cognitive reasoning ability of the job candidates. The online recruitment techniques generated information that helped to narrow the field of candidates to those with a high possibility of fitting into the company's global compliance vision. Integrating this online recruitment method has the added advantage that the contemporary practice of employee screening through online platform influence recruiting decisions. The finding that online recruitment helped generate information about applicants that allowed recruiters make better decision aligned with the results of Melanthiou, Pavlou, and Constantinou's (2015). Melanthiou et al. (2015) found that a well-outlined system and strategic application of available information about applicants significantly aid the recruitment of personnel with the required skills and competencies. Using different approaches to identify the most suitable candidate for the company has a critical impact on the ability of the workforce to perform the required task. In discussing the recruitment of personnel in the company, P3 said,

> We have a robust system in place where we strive to recruit people with a minimum educational background from reputable institutions done through our human resources department. We do not compromise with the recruitment of

people with the right qualification to fill openings. We extend our search for the right candidate by using various mediums to reach out to the right application for any position in the company.

The highly regulated and knowledge-based pharmaceutical industry requires qualified personnel to operate in the complicated technical and high-demanding regulatory environment to be successful (P3). My findings about the recruitment of qualified employees are similar to those of Mehralian et al. (2014) who found that intellectual capital and intangible assets are critical tools in for the success of business entities in a knowledge-driven business environment. Likewise, Oseghale, Mulyata, and Debrah (2018) found that having intellectual capital was crucial for the success of the company, especially in the sub-Saharan African regions where a shortage of the right workforce is rife. P2 believed employees' experience was a contributing factor to their successful compliance strategy and the company compensates for the experience by recruiting individuals with relevant qualifications and then setting them on a training plan. P4 explained that the company regards human-related challenges as critical, and one of the ways they overcome the challenge is through the recruitment of qualified employees who subsequently undergo training and a continuous improvement path. P4 continued the explanation by saying "this is the way we overcome personnel-related challenges because if you do not have qualified personnel, you cannot trust the employee to perform their tasks."

All participants shared that, once recruited for the job, the company used training as a retaining strategy designed to ensure compliance with regulations. Although turnover

in organizations is not uncommon, retaining the right applicant is fundamental to avoid costs and diminished productivity. The company has a recognized human resources policy designed to create a work environment and that encourages the retention of employees (P3). Furthermore, P3 shared that the adoption of generous welfare packages, technical support, and continuous learning in the company led to the retention of employees. This finding on the adoption of a welfare package to retain employees was reinforced by Won, Wan, and Gao's (2017). Won et al. (2017) asserted that employees who had a comfortable corporate culture, satisfactory emotional and technical support, work autonomy, and personal development programs were motivated to stay in their position.

Msisiri and Juma (2017) found that effective employee retention depends on the continuous improvement of employees, the working environment, employee work-life balance, and the recognition and appreciation of employees. Haider et al. (2015) stated that adequate retention strategies were critical to retaining qualified employees. The study organization considered the retention of employees, particularly the technical staff, as an important task. Company leaders need to foster conditions that motivate employees to remain in the organization.

Training and continuous learning. P1, P2, P3, and P4 reported that the employees training and continuous learning of employees had a positive impact on compliance with regulatory requirements. All participants observed that company leaders instituted policies that foster knowledge acquisition by employees. Training was a key strategy used to ensure regulatory compliance (P3). P3 added that the company policy of

investing in capacity building and workforce development is to equip and retool employees in the performance of their jobs. Specifically, the company has an established training and learning process that enabled employees to gain access to adequate training and to develop their ability to accomplish desired regulatory requirements. All employees receive training related to their job function and responsibilities. In addition, employees receive general compliance training on the company's compliance program and code as well as policies and procedures (P2 and P4). Training facilitates employees' ability to perform their tasks in accordance with their job description. Training and continuous learning promote participative culture, interest in knowledge-sharing and internal capacity development.

According to P1 and P3, the company has a dedicated department charged with fostering the development of its workforce. Establishing training departments helps the company to realize its development goal of improving employee knowledge and skills that are beneficial to the organization. Employees receive training in different areas with an emphasis on their identified areas of weakness and deficiencies. The company conducted training in-house and those that needed further training went for external training both within Nigeria and outside of the country. The company's focus was to have employees performing daily operational activities undergo regular training in compliance with regulatory requirements. These findings align with those of Kroll and Moynihan (2015) who found that training plays critical roles in closing specific capacity gaps and facilitates the implementation of new guidelines by providing information about the guidelines, rationalizing the reasons for the guidelines, and offering employees the

capacity to operate under new guidelines. Setting up a training department serves as the coordinating center for the development and growth of employees and the company as a whole.

P3 shared that,

> We have in-house training and external training, both local and overseas, conferences, seminars, and others. It is a combination of both; there is a training routine, there is a full-fledged training unit in the organization. We have a learning and development unit that has the responsibilities to ensure that staff members are trained in the areas of their weaknesses and the area of their deficiencies. Both in-house and those that need to go for external training they go for external training both within Nigeria and outside of Nigeria.

The executive board placed a premium on continuous learning in the company to keep all employees and third parties attuned to the overall strategic regulatory compliance goal of the company. Given the importance that company leaders associate with regulatory compliance, the leaders ensure that employees receive adequate training on compliance and knowledge acquisition to comply with regulations. The company regularly reviews the training policy to ensure it meets employee and regulatory requirements. The leaders' disposition to adequate training is in agreement with the findings of Chhotray et al. (2017) who favored a leadership style that encourages the delegation of responsibility and empowerment of employees in a way that advances positive outcomes. Reflecting on training, Shin et al. (2017) stated that employees must develop new skills with the ability to handle new challenges. Because of the frequent

change in regulatory requirements, conforming to regulatory requirements demands that company leaders align training and development initiatives with strategic priorities particularly regulatory requirements.

P3 added that the company policy of investing in capacity building and workforce development is to equip and retool employees in the performance of their jobs. Employees receive specialized training, and leaders identify the need for additional training for those working in regulation-related departments. Specialized training, such as regulatory learning incorporates an extensive regulatory training curriculum through a design that combines feedback from training, compliance, and sales representatives. This strategy reflects Nag and Das's (2015) inference that an effective approach to training enhances an individual's knowledge base. Similarly, Jayakumar and Sulthan (2014) suggested that effective training programs enhance productivity. P3 mentioned that one priority for the company was to invest in areas that required the closing of knowledge gaps through continuous learning. The company achieved continuous learning by allowing employees to undergo both in-house and external training both locally and abroad, in the form of conferences, seminars, symposia, and other related training. P2 said,

> We train because we believe you need to be well informed as par what you need to do and also all these are clearly stated in our standard operating procedures and before you can be placed on the job it is expected that you are trained properly with relevant SOPs to be sure that even as you do that you are being monitored, you are being evaluated, and to be sure that you will comply, not even

only to the various regulatory requirements and some operational details on the job.

According to P2 and P4, the company employees embark on numerous types of training to understand regulatory requirements, company policies, and changes to guide their operational activities. P2 stated that the execution of any change begins with training on the use of internally developed company documents, such as the *Standard Operating Procedures* (SOPs). The SOPs serve as a training document and contains information about the training of employees on the job and continuous learning in the organization. The company regularly updates the SOPs to incorporate regulatory changes, and employees receive training on the SOPs on a quarterly basis to ensure that they understand current regulatory requirements. Particularly, continuous learning keeps employees refreshed to minimize the tendency for them to forget useful information (P2 and P4). Employees appreciate the training received regarding the implementation of regulatory requirements.

The introduction of new products and processes requires that employees receive adequate training with continuous learning programs about guidelines, required process training, post market surveillance, and product information (P1, P2, and P4). P2 gave an example of running a cold chain; employees in the chain undergo concise training in every aspect of the cold chain process with emphasis on regulatory requirements for effective control of storage condition, product quality, safety, and performance. While addressing the effectiveness of training and learning in the company, of P1 said,

> We look at that time compared to what it used to be before, maybe for past 4 or 5 months; I have not had any issue because it shows that the training is working. Maybe when we start seeing issues coming up. It also let us know people are losing focus, on this, which also take them back again for training, for us training is a continuous thing we do.

The company conducts auditing and monitoring activities designed to assess the effectiveness of training and compliance with regulations by measuring the levels of variations recorded (P2). An increase in deviations is an indication that employees involved in the specific area are losing focus suggesting that such employees should undergo further training, lending credence to the assertion that learning is continuous. Another way to evaluate the impact of training on compliance was the use of key performance index (KPI) to assess compliance and to implement actions leading to minimal or elimination of noncompliance.

For further analysis, enhanced understanding, and increased study validity, I also used secondary data in addition to the data obtained from interviewing participants. One secondary data source was an official release on the company's website (D2) that described the company's manpower development strategy. A review of the contents of D2 indicated that the company has a workforce and learning policy designed to equip employees with the required competencies and skills to perform effectively and efficiently on the job. The document revealed that the company training and development policy has two key objectives namely: (a) to drive a learning culture through strategic learning interventions that encourage employee growth and development and (b) to

improve employee productivity and personal effectiveness to achieve a sustainable competitive advantage. Stated in the D2 is that, "Various programs have been designed to realize the objectives which include, comprehensive staff orientation/induction program, internal and external training programs, departmental training, management roundtable conference, management retreats, seminars and workshops, job rotation, exchange programs with credible partners, etc." This excerpt from the company's webpage supported all of the participants' affirmations that robust training and a continuous learning policy has a positive impact on regulatory compliance.

A high-level overview of the company's recruitment policy posted on the company website also provided the roadmap for the recruitment and retention of people with the right skills and expertise. The website post on the company's recruitment policy supported the assertion of P3 and P4 that the company has a robust recruitment process aimed at hiring the most suitable job candidate. The recruitment policy as posted on the company website reads,

> The company has recognized that an efficient hiring and candidate selection process contributes to the company's success with unambiguous effect on the company's ability attain its desired goal. The organization attempts to engage and hire individuals with the requisite skills, expertise, qualifications, and vision to deliver the company's our objectives."

A review of the company *2015 Financial Statement* (D3) revealed that the company has a strong retention incentive. D3 is one of the financial documents that outlines the financial activities of the company. The incentives serve as part of the

employee retention strategy of the company and include salaries, pension, and gratuity, among others. Within this document is the policy statement that "the company incentive schemes are designed to satisfy each employee needs that include (a) bonus, (b) promotions, (c) generous healthcare plan, (d) housing and (e) a pension plan in line with the provisions of the Pension Reform Act 2014." The document also revealed that the company attaches high value to training and all categories of employees attend courses and seminars. These findings from D3 buttressed the assertion by P3 that one of the ways the company retains employees is by offering a generous welfare package and training.

Good Manufacturing Practice Guidelines for Pharmaceutical Products (D4) is a document I obtained from NAFDAC that included the guideline on training requirements in pharmaceutical organizations. Stated in D4 is that "part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by their marketing authorizations." The document reinforced the importance that the participants associated with training to ensure regulatory compliance. The guidance included in the document ensures the manufacturing of pharmaceutical products that are fit for their intended use, comply with the requirements of the marketing authorizations and do not place the populace at risk. D4 compelled manufacturers of pharmaceutical products to maintain sufficiently qualified personnel to perform all the tasks for which the manufacturer is responsible.

D4 also has provisions on training requirements for personnel in a pharmaceutical company including,

- The manufacturer should provide training in accordance with a written program for all personnel whose duties take them into manufacturing areas or control laboratories (including the technical, maintenance and cleaning personnel) and for other personnel as required.
- Besides basic training on the theory and practice of GMP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness periodically assessed. Approved training programs should be available. Training records should be kept.
- Personnel working in areas where contamination is a hazard (e.g., clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled) should be given specific training.
- The concept of QA and all the measures, which aid its understanding and implementation, should be fully discussed during the training sessions.
- Visitors or untrained personnel should preferably not be taken into the production and QC areas. If this is unavoidable, they should be given relevant information in advance (particularly about personal hygiene) and the prescribed protective clothing. They should be closely supervised.
- Consultants and contract staff should be qualified for the services they provide. Evidence of this should be included in the training records. Records should be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

NAFDAC training requirements provided the foundation the company used to establish written policies and procedures for the hiring of qualified candidates and training of employees to ensure compliance with applicable laws and regulations. The policies and procedures apply to all employees and third parties. Adherence to these procedures is a condition of employment. The company expects all managers to ensure that their employees and third parties receive training on their specific duties, policies, and procedures, including all applicable laws, guidance, and regulations.

Correlation to the conceptual framework. Theme 2 aligned with the conceptual framework of complexity leadership theory. According to complexity leadership theory, training and learning occur through interactions among agents and their functions (Uhl-Bien et al. 2007). Baltaci and Balci (2017) identified skills, knowledge, and organizational learning as a critical component of CLT. Baltaci and Balci found that adaptive responses require learning for improved efficiency in an unstable environment. Specifically, in the context of this study, training and continuous learning facilitated employees' ability to perform their tasks relative to their job descriptions. Company employees and leaders engaged in training and learning, which increased the level of regulatory compliance and presented a path for sustainability. Through the learning strategies used by the company, employees made sense of situations because learning occurred, and the knowledge created allowed the employees to adapt to regulatory requirements. Hence, training and continuous learning increased the company's regulatory compliance through shared knowledge and understanding.

Theme 3: Strategies to Navigate through Barriers to Enhance Regulatory Compliance

The third theme to emerge from data analysis was that having strategies to navigate through barriers to enhance regulatory compliance. All participants (P1, P2, P3, and P4) shared that barriers including (a) government barriers and (b) critical factors comprising finance, technical, infrastructure, and culture influenced managers to ensure compliance with regulatory requirements. Government barriers and critical factors influenced efforts to ensure compliance with regulatory requirements because of the burden that they placed on the company. Navigating through the barriers required strategies designed to help overcome each hurdle in the highly regulated pharmaceutical terrain. Overcoming these barriers required the company to adjust to regulatory and market realities while adapting to emerging issues for sustainable performance despite the barriers.

Government barriers. An analysis of interview data suggested that overcoming government barriers had a critical impact on regulatory compliance (P1, P2, P3, and P4). According to P2, the company encountered obstacles in their quest to fulfill regulatory obligations. Frequent changes in government policies and a multiplicity of guidelines, codes, and laws were obstacles identified by P1, P2, and P3 as critical to the company's ability to comply with regulations. The challenges the company encountered with government obstacles induced the leaders and managers to approach regulatory compliance in innovative ways by formulating strategies that were beneficial enough to outweigh the costs of those regulations for the company. Overcoming some of the

barriers require formulating a comprehensive approach that included the direct involvement of company leaders and representatives of the regulatory agencies.

Regulatory officers' own experience and biases affected conclusions on regulatory issues (P3). Dialogs with the assigned regulatory officer for a particular regulatory compliance project helped clear areas of concern to satisfy regulatory requirements. P1 cited an example where, upon the submission of an application to NAFDAC, officials of the agency insisted on facility inspection, despite having a valid GMP certificate valid for 2 years, in addition, the routine inspection conducted biannually. The double inspections led to complicated arrangements that greatly affected production as well as financial performance of the product because of delayed introduction of the product lines. P3 particularly expressed the displeasure of the company because of the complicated arrangements affect that overall business output of the company. Repeated inspection had an extensive impact on business operation and other activities in the facility because inspectors were not particularly concerned about the implication of timelines when they planned their site visits. P4 stated,

> Making an effort to comply with regulations sometimes helps but some government officials deliberately make things difficult. The regulatory agencies may disagree with what the company provided leading to delays and collateral impact on other activities about the manufacturing and other business operations.

The company addressed such challenges through persistent dialogs with the regulatory officers assigned to the company.

With the experience of the company on regulatory matters, P1, P2, and P4 asserted that the company always conducted a diligent review of (a) sample, (b) submission timeline, and (c) "compliance directives" issues, to prevent questions and deficiencies before approaching regulators for product registration, annual renewals, or facility inspection. Lack of adequate preparations, revisions of documents, and effective planning often resulted in delays of other activities because of logistical issues and potentially repeating the entire process. Adequate preparation before indicating to the authorities that the company had a product requiring registration was a key determinant of the successes achieved in regulatory compliance.

All participants (P1, P2, P3, and P4) explained that multiplicity and duplication of government agencies roles and lack of definitive differences in the functions of some regulatory agencies was an obstacle to regulatory compliance. Participants' assertion about the duplication of functions by government agencies and the general public-sector inefficiency buttressed Adanri's (2016) observation that that public-sector incompetence was a contributory hindrance to business operations in Nigeria. P4 stated,

> Talking of government, the challenge is mainly related to the bureaucracy. One must move from one office to the other to have files processed, but recently we have noticed some changes because one of the agencies has introduced online submission of applications to overcome the burden of physically moving files from one table and office to another. This challenge with bureaucratic obstacle also involved having us traveling hours away from our location the main offices of the agencies. On reaching these government offices, we ended up waiting in

> the office for hours certain activities that could be executed online. However, after persistent dialogs with regulators, we observed that some of the regulatory impediments were addressed by the regulatory authorities' resulting in a lower rate of delays from regulatory authorities. As a result, many companies are complying, and particularly, companies like us that are always interested in compliance in every area of our processes both quality control, engineering, production, and documentation.

P1 and P4 attributed the proactive approach to regulatory issues that involve frequent interactions with key government agencies with direct impact on product imports, manufacturing, and distribution helped managers and employees to meet the expectations of each regulatory agency. The regulatory affairs unit respond to the issue of duplication by customizing their responses to each agency to meet their specific needs in the format required by the agency. The regulatory affairs unit liaises with each regulatory agency by identifying what the regulations are, which is foremost especially when dealing with the respective agencies (P2). Understanding the role of each regulatory agency in the pharmaceutical product value chain is essential to ensure that every product destined for distribution undergoes the required regulatory approval from product development through final consumption. The company maintained a checklist and additional follow up on the checklist generated for each regulatory agency with direct impact on the company business operations. Employing a system that leads to improving the compliance, built on a mutual working relationship between the organization and the

regulatory agencies, and helped mitigate the negative impact of the uncertainties in regulatory policies.

Critical factors. P1, P2, P3, and P4 all expressed that critical factors influenced compliance with regulatory requirements. All participants indicated that critical factors included (a) culture of the people and their way of life, (b) finance, (c) infrastructural development, and (d) availability of resources. P2 and P3 particularly noted that business operations in Africa were challenging given the hurdles pharmaceuticals companies must contend with. P3 stressed that the cost of complying with standards was high because guidelines required that a number tests be conducted but the costs and availability of the materials made compliance almost impossible. P3 said, "The way that we conduct businesses in the African environment, where we do not have the types of resources available to companies in the West made regulatory compliance almost impossible." Financial constraints on procuring equipment and materials increased the cost of compliance for products with the required quality standard, making these products expensive by Africa standards. Access to critical materials required for production is significant because local companies import most of the materials used in production thereby creating difficulty in product manufacturing chain.

In addition, P1, P2, and P3 identified cultural constraints resulting from the mindset and attitude of the people. The people do not necessarily consider adherence to standards and compliance with regulations, guidelines, and code a priority. Using various campaigns to explain the importance of quality products that result from regulatory compliance influenced the noncompliance mindset of the people. Cultural influence

reinforced Bourke and Roper's (2014) assertion that critical factors, including employees, organizational characteristics, and culture, influence decisions within an organization. Influencing the mindset of the general populace has an impact on overall compliance with regulatory requirements.

All participants considered critical factors as extraneous barriers that company must work around by formulating strategies to enhance compliance with regulation. According to P3,

> If you have an infrastructural deficit, which is beyond your control, the company must provide alternatives. For instance, where you do not have electricity, you provide your generator, where you do not have low-interest rates loans; you must find other ways of bringing either equity for your business or raise debt.

The company worked with business advocacy groups such as the Manufacturer Association of Nigeria (MAN) and the Pharmaceutical Manufacturer Association of Nigeria (PMAN). These advocacy groups engaged with the government and regulatory agencies in discussions to work on the constraints identified by business operators. The advocacy groups also mounted pressure on the government and society by organizing public discussions, press conferences, and press releases. Individual companies cannot assert the kind of influences that the advocacy groups bring to bear. The advocacy groups attempt to collaborate with similar organizations to shape or influence, agencies responsible for creating and enforcing mandates and to advocate for the provision of a conducive business environment.

NAFDAC and *PCN* (D5 and D6) are documents I obtained from statutory agencies that detailed the statutory responsibilities of the regulatory agencies indicating that different regulatory agencies have varied requirements. A review of D5 and D6 revealed that each organization has a specific regulatory oversight function in the manufacture, distribution, and practice of pharmaceuticals in Nigeria. Regulatory agencies developed various guidelines for the registration and distribution of pharmaceutical products in Nigeria. D5 indicated that NAFDAC is the agency mandated to regulate and control the importation, exportation, manufacture, advertisement, distribution, sale, and use of pharmaceutical products in Nigeria. NAFDAC performs its functions by issuing guidelines on the requirements for registration of pharmaceutical products, including distribution, marketing, and storage of the products for safety and efficacy.

D6 indicated that PCN functions in the issuance of establishment licenses to companies involved in the importation, manufacturing, and retail pharmacy. In addition, PCN is responsible for granting licenses for practicing pharmacy in the country. The pharmacist for each facility, company, pharmacy, or establishment must be the superintendent pharmacist who oversees the pharmaceutical organization. PCN grants license for establishments or pharmacists who will run or oversee the pharmaceutical processes that occur in that establishment and ensure that they are accountable for these pharmaceutical processes.

Correlation to the conceptual framework. Theme 3 aligns with complexity leadership theory. In CLT, leadership is attained through the interaction of three

functions: (a) administrative, (b) adaptive, and (c) enabling Mendes et al. (2016). As it relates to this study, administrative function entails managerial activities of the company including coordination and planning of tasks. To navigate through barriers to ensure regulatory compliance, the company engaged in the formal planning of tasks such as a diligent review of (a) sample, (b) submission timeline, and (c) compliance directives issues. This allowed the company to prevent deficiencies before approaching regulators. The adaptive component of CLT related to this study emerged from complex interactions between the company, regulators, and other stakeholders with regard to conflicts, ideas, and preferences. Navigating through barriers requires adaptability in response to challenges and opportunities that enhance performance and innovation (Arena & Marion, 2016). The interactions between agents, including government agencies, advocacy groups, and the company lead to adaptive change. In this study, the company, regulators, and advocacy groups engaged in interactive exchanges to solve challenges that they faced, which is an adaptive function.

Applications to Professional Practice

I conducted a qualitative single case study to explore the strategies used by pharmaceutical company managers to ensure compliance with regulatory requirements. Data obtained from interviews with four functional managers and company and public documents provided insight into the organization's compliance with regulation in the pharmaceutical industry. Companies who comply with regulatory requirements have a higher chance of being successful (Rolling, 2017). Using strategies that encourage

regulatory compliance can eliminate or reduce unnecessary enforcement and compliance costs associated with legal actions between companies and regulatory agencies.

Noncompliance with guidelines, codes, standards, and laws significantly affects organizations' image and profitability (Mulinari, 2016). The findings in this study might provide managers and organization leaders with information relevant to the running of pharmaceutical businesses in a highly regulated business environment. Understanding what strategies led one organization to successful regulatory compliance could allow other organizations to identify and mitigate issues that may lead to noncompliance of their organizations as well. When organizations imperfectly comply with regulations, company operational costs increase because of the cost implications of fines and corrective actions.

Another contribution to professional practice relates to the influence of senior leadership in ensuring compliance with regulatory requirements. This study findings revealed that leaders' involvement and engagement in compliance strategies helped facilitate a compliance culture in the company. Increased engagement among senior leaders in ensuring regulatory compliance can lead to a solid reputation with regulators and customers, ultimately affecting company revenue and overall business performance.

Implications for Social Change

This study has implications for social change. The pharmaceutical companies play a significant role in driving social change in the community. The core of pharmaceutical business outputs is designed to improve and save people's lives, which is consistent with the position of Konda et al. (2015) and Ney et al. (2015) that social change includes

generating good deeds critical to human welfare development and availability of pharmaceutical products. The availability of pharmaceutical products as a contribution to social change reinforces Muzaka's (2013) position that the availability of pharmaceutical products was a social function that represents bargaining among government, business, and society. Availability of pharmaceutical products has implication on the overall health of communities. Compliance with regulatory requirements ensures that pharmaceutical companies develop high quality and safe products, which are critical in healthcare leading to the prevention, alleviation, and cure of diseases. Lack of access to quality medicine remains a vital issue in many communities, hence having strategies that lead to the development of pharmaceutical products through regulatory compliance will help combat drug shortage.

Effective compliance regulatory strategies yield considerable social benefits, particularly in cost reduction. The inability of organizations to comply with regulatory requirements can be costly resulting in costs that companies transmit into the overall cost of the pharmaceutical products. Anyakora et al. (2017) noted that regulatory compliance can influence the availability, affordability, and plays an important role in cost reduction of pharmaceutical products. Niessen and Khan (2016) noted that having strategies to improve regulatory compliance might result in the pharmaceutical products that are affordable in most markets. Disruption of products supply may lead to societal ills, death, and public health hazard.

Recommendations for Action

Pharmaceutical companies in Nigeria and sub-Saharan region of Africa can use the information in this study to develop strategies to ensure compliance with regulatory requirements. The findings signaled that pharmaceutical company managers might improve the level of regulatory compliance as a way to avoid the negative impact of noncompliance such as fines, company image, and reduced profitability. The strategies shared in this study might contribute to the success of company leaders and managers who lack the knowledge and strategies to ensure regulatory compliance. An increase in the level of regulatory compliance might result in increased productivity, profitability, and company success.

The first recommendation is for pharmaceutical companies to establish a regulatory affairs unit with responsibility for handling all regulatory and compliance issues in the pharmaceutical product value chain. The regulatory affairs unit will serve as the coordinating center for the implementation of regulatory requirements. Tanwar et al. (2015) conducted a study on regulatory affairs unit in pharmaceutical companies and found that the regulatory affairs unit provided the strategic and operational skills required to address regulatory requirements effectively. Second, implementing a comprehensive recruitment strategy, which leads to the recruitment of only qualified employees to perform specific tasks. Mehralian et al. (2014) found that intellectual capital was critical to the success of the business organization. Third, I recommend that pharmaceutical company functional managers and leaders review the findings of this study on training and continuous learning because implementing a strategy that fosters knowledge acquired

through training and continuous learning facilitates employees' ability to perform their tasks. Lastly, company leaders should formulate a comprehensive strategy that includes senior leadership member's direct involvement with representatives of regulatory agencies.

Researchers have many ways to disseminate their research findings including, (a) by presenting the findings as a policy brief to a non-specialized audience, (b) publication in a peer-reviewed journal, signaling the acceptance of the research within the community, and (c) writing a book from based on the research findings. I will disseminate the result of this study via scholarly journals, training, conference presentations, and developing the study into a book. I will provide a summary of the findings to the research establishment and specialized trade groups involved in both the pharmaceutical industry and in general regulatory compliance. I hope to disseminate my findings widely.

Recommendations for Further Research

This study was an exploratory study to understand the strategies used by managers to ensure regulatory compliance using complexity leadership theory as a theoretical guide. In this qualitative case study, I explored strategies used for compliance with regulatory requirements. In evaluating findings from the research, it is pertinent to note the limitations and context of this study while suggesting areas for future research. The first recommendation for further research is to extend the study to multiple pharmaceutical companies in the country to obtain results with wider reach given that this study was limited geographically to Nigeria and one organization. Yin (2014) noted that

with multiple cases, researchers have the possibility of direct replication, or might offer contrasting situations. In addition, the study was limited to functional managers, thereby limiting the number of participants; future research may increase the pool of participants to include senior leadership, employees, and nonsupervisory managers. I recommend increasing the pool of participants by conducting a multiple case study to investigate compliance strategies.

The second recommendation is to perform a quantitative or mixed method study. Researchers use the quantitative method for data collection to test hypothesis or analyze data using statistical forms, and the results are generalizable (Brockington, 2014). Researchers can investigate relationships between financial indicators, and how the indicators influence regulatory compliance and to examine the impact of regulatory compliance on revenue or other financial indicators. The current study is an exploratory study providing only in-depth information about the lived experience. Conducting a quantitative study could generate results that might lead to the generalization findings. Future research in these areas might increase existing literature in regulatory compliance, especially among African countries.

Reflections

During the DBA study, I learned the importance of steadfastness and resolved to complete a task in the face of huge challenges from across the board. The program enhanced my confidence in the handling life-changing situations because the research phase of the program built my inner strength and tenacity to accomplish a goal. The challenges include issues relating to proposal development, finding the right research

establishment, and managing access to research participants. Within this period, I relied on networking to secure the research establishment and access to research participants; I fully appreciate the importance of networking to achieve desired goals. Owing to the nature of the topic and the location of the research establishment, it was a burden to gain access to the establishment and participants and use of networking made this study possible.

Upon selecting the research establishment and research participants, I strived to minimize bias and personal errors right from the design of the research question and interview questions to obtain as much lived information from research participants. The in-depth review of the literature honed my skills in the development of the appropriate interview questions. In addition, I minimized bias by adhering to the interview protocol.

Before this research study, my research was science-based; as such, I had no experience about research in management or conducting research interviews and was not involved in the interaction with the leadership of a corporate organization. The experience that I gained in this study provided me a new academic vista and prism due to the opportunity of interacting with professionals in the field and learning their lived experiences with the research topic. This study exposed me to successful business practices relative to regulatory compliance with the chosen location. Gaining insight into the strategies used for compliance offered me the opportunity to compare what I learned from the study with my experience about the topic in developed nations. I am now more attuned and have the requisite knowledge to discuss and contribute topics relating to regulatory compliance in the pharmaceutical industry in Nigeria, including their

regulatory framework, regulatory agencies, and stakeholders in the pharmaceutical industry in Nigeria. I will publish the findings of this study in the related or related professional and academic journals and publications as a contribution to the body of knowledge.

Conclusion

Ding et al. (2015) argued that compliance with regulation is critical to business performance, while Page et al. (2015) argued that noncompliance with regulation has become a challenge to managers. However, only a few studies exist on pharmaceutical companies' compliance with regulatory requirements in the Sub-Saharan region (Olugbenga, 2013). Business Monitor International (2016) reported that Nigeria has a poor pharmaceutical regulatory environment; as such having insight into the strategies used by successful companies under such regulatory environment is an important contribution to knowledge and pharmaceutical business performance. Evaluation of business compliance under unstable business conditions such as the dynamic regulatory environment using complexity leadership theory is a plausible approach to understand how leaders adapt to the changes in the regulatory environment.

The research question addressed the strategies that managers used to ensure compliance with regulatory requirements. Using CLT, I explored the strategies used by managers to ensure compliance with regulations. Based on participants' responses and data analysis, I found that the establishment of a regulatory affairs unit and engaged leadership enhanced regulatory compliance. Similarly, the hiring of qualified employees and their compliance training learning improved compliance with regulatory

requirements. Furthermore, having strategies to navigate through barriers to enhance regulatory compliance. All participants emphasized the importance of compliance with regulatory requirements as part of the availability of products and business success. The results of this study underscore the critical importance effective regulatory compliance strategies to the overall success of a pharmaceutical company.

References

Akomea, S. Y., Sørensen, O. J., & Amponsah-Efah, K. (2014). Export drivers and barriers: Evidence from Ghanaian pharmaceutical manufacturing firms. *Global Journal of Business Research, 8*, 81-96. Retrieved from http://www.theibfr.com/gjbr.htm

Albert, D., Kreutzer, M., & Lechner, C. (2015). Resolving the paradox of interdependency and strategic renewal in activity systems. *Academy of Management Review, 40*, 210-234. doi:10.5465/amr.2012.0177

Almashat, S., Wolfe, S. M., & Carome, M. (2016). *Twenty-five years of pharmaceutical industry criminal and civil penalties: 1991 through 2015*. Retrieved from Public Citizen website: https://www.citizen.org/sites/default/files/2311.pdf

Almici, A. (2015). Does EU anti-corruption regulation work: The case of the pharmaceutical industry. *Journal of Business & Economics Policy, 2*(4), 126-140. Retrieved from http://jbepnet.com/

Amadi, L., & Amadi, M. (2014). Sustainable drug consumption, regulatory dynamics and fake drug repositioning in Nigeria: A case of NAFDAC. *Sci-Afric Journal of Scientific Issues, Research and Essays, 2*, 412-419. Retrieved from http://www.sci-africpublishers.org/

Amis, J. M. (2018). Understanding organization change and innovation: A conversation with Mike Tushman. *Journal of Change Management, 18*, 23-34. doi:10.1080/14697017.2017.1378697

Anderson, R. A., Bailey Jr, D. E., Wu, B., Corazzini, K., McConnell, E. S., Thygeson, N.

M., & Docherty, S. L. (2015). Adaptive leadership framework for chronic illness: Framing a research agenda for transforming care delivery. *ANS. Advances in Nursing Science, 38*, 83-95. doi:10.1097/ANS.0000000000000063

Andrighetti, H. J., Semaka, A., & Austin, J. C. (2017). Women's experiences of participating in a prospective, longitudinal postpartum depression study: Insights for perinatal mental health researchers. *Archives of Women's Mental Health, 20*, 547-559. doi:10.1007/s00737-017-0744-7

Anuruang, S., Davidson, P. M., Jackson, D., & Hickman, L. (2015). Strategies to enhance recruitment of rural-dwelling older people into community-based trials. *Nurse Researcher, 23*(1), 40-43. doi:10.7748/nr.23.1.40.e1345

Anyakora, C., Ekwunife, O., Alozie, F., Esuga, M., Ukwuru, J., Onya, S., & Nwokike, J. (2017). Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre-and post-certification of a Nigerian pharmaceutical manufacturer. *BMC Health Services Research, 17*, 1-9. doi:10.1186/s12913-017-2610

Argote, L. (2013). Organization learning: A theoretical framework. In *Organizational Learning* (pp. 31-56). New York, NY: Springer

Arora, S., Christman, T. J., Mays, A. N., & Schmidt, A. (2013). The interplay between FDA and patent law: Infusing organizational knowledge for medical device companies. *William Mitchell Law Review, 39*, 1176-1206. Retrieved from http://open.wmitchell.edu/wmlr/vol39/iss4/5

Bailey Jr, D. E., Docherty, S. L., Adams, J. A., Carthron, D. L., Corazzini, K., Day, J. R.,

... & Anderson, R. A. (2012). Studying the clinical encounter with the adaptive leadership framework. *Journal of Healthcare Leadership, 4*, 83-91. doi:10.2147/JHL.S32686

Balasubramanian, J., Muthukumaran, T., Hariram, S., Nandhini, G. A., & Saisugathri, K. (2016). A procession at the EU regulatory guidelines. *Indo-Americas Journal of Pharmaceutical Sciences, 3*(1), 5-17. Retrieved from www.iajps.com

Baldwin, R., Cave, M., & Lodge, M. (2012). *Understanding regulation: Theory, strategy, and practice.* Oxford, England: Oxford University Press.

Baltaci, A., & Balcı, A. (2017). Complexity leadership: A theoretical perspective. *International Journal of Educational Leadership and Management, 5*(1), 30-58. doi:10.17583/ijelm.2017.2435

Baskarada, S. (2014). Qualitative case study guidelines. *The Qualitative Report, 19*(40), 1-25. Retrieved from http://nsuworks.nova.edu/tqr/

Battiston, S., Farmer, J. D., Flache, A., Garlaschelli, D., Haldane, A. G., Heesterbeek, H., ... & Scheffer, M. (2016). Complexity theory and financial regulation. *Science, 351*, 818-819. doi:10.1126/science.aad0299

Baumann, O., & Siggelkow, N. (2013). Dealing with complexity: Integrated vs. chunky search processes. *Organization Science, 24*, 116-132. doi:10.1287/orsc.1110.0729

Baxter, P., & Jack, S. (2008). Qualitative case study methodology: Study design and implementation for novice researchers. *The Qualitative Report, 13*, 544-559. Retrieved from http://nsuworks.nova.edu/tqr/

Beauregard, N., Lemyre, L., & Barrette, J. (2015). The domains of organizational

learning practices: An agency-structure perspective. *Societies, 5,* 713-733. doi:10.3390/soc5040713

Bedi, O., Krishan, P., & Singh, G. (2017). Regulatory requirements for medical devices: An insight. *Applied Clinical Research, Clinical Trials and Regulatory Affairs, 4,* 16-25. Retrieved from http://benthamscience.com/journals/applied-clinical-research-clinical-trials-and-regulatory-affairs/

Belias, D., & Koustelios, A. (2014). The impact of leadership and change management strategy on organizational culture. *European Scientific Journal, 10,* 451-470. Retrieved from http://eujournal.org/index.php/esj

Bernard, H. (2013). *Social research method: Qualitative and quantitative approaches* (2nd ed.). Thousand Oaks, CA: Sage.

Bernauer, J. A., Lichtman, M., Jacobs, C., & Robinson, S. (2013). Blending the old and the new: Qualitative data analysis as critical thinking and using Nvivo with a generic approach. *The Qualitative Report, 18*(31), 1-10. Retrieved from http://nsuworks.nova.edu/tqr/

Berson, Y., Da'as, R., & Waldman, D. A. (2015). How do leaders and their teams bring about organizational learning and outcomes?. *Personnel Psychology, 68,* 79-108. doi:10.1111/peps.12071

Birt, L., Scott, S. E., Cavers, D., Campbell, C., & Walter, F. M. (2016). Member checking: A tool to enhance trustworthiness or merely a nod to validation? *Qualitative Health Research, 26,* 1802-1811. doi:10.1177/1049732316654870

Blomme, R. J., Kodden, B., & Beasley-Suffolk, A. (2015). Leadership theories and the concept of work engagement: Creating a conceptual framework for management implications and research. *Journal of Management & Organization, 21*, 125-144. doi:10.1017/jmo.2014.71

Bone, C. (2016). A complex adaptive systems perspective of forest policy in China. *Technological Forecasting and Social Change, 112*, 138-144. doi:10.1016/j.techfore.2016.08.024

Bradley, E. H., Curry, L. A., & Devers, K. J. (2007). Qualitative data analysis for health services research: developing taxonomy, themes, and theory. *Health Services Research, 42*, 1758-1772. doi:10.1111/j.1475-6773.2006.00684.x

Bristol, S. T., & Hicks, R. W. (2014). Protecting boundaries of consent in clinical research: Implications for improvement. *Nursing Ethics, 21*(1), 16-27. doi:10.1177/0969733013487190

Brockington, D. (2014). Q-squared. Combining qualitative and quantitative approaches in poverty analysis. *Journal of Development Studies, 50,* 1735-1736. doi:10.1080/00220388.2014.978987

Brodszky, V., Baji, P., Balogh, O., & Péntek, M. (2014). Budget impact analysis of biosimilar infliximab (CT-P13) for the treatment of rheumatoid arthritis in six Central and Eastern European countries. *The European Journal of Health Economics, 15*(1), 65-71. doi:10.1007/s10198-014-0595-3

Broekhuizen, H., Groothuis-Oudshoorn, C. G., van Til, J. A., Hummel, J. M., & IJzerman, M. J. (2015). A review and classification of approaches for dealing with uncertainty in multi-criteria decision analysis for healthcare decisions. *PharmacoEconomics*, *33*, 445-455. doi:10.1007/s40273-014-0251-x

Bourke, J., & Roper, S. (2014). The influence of experiential learning on medical equipment adoption in general practices. *Health Policy*, *118*, 37-47. doi:10.1016/j.healthpol.2014.05.004

Bujar, M., McAuslane, N., Walker, S. R., & Salek, S. (2017). Evaluating quality of decision-making processes in medicines' development, regulatory review, and health technology assessment: A systematic review of the literature. *Frontiers in Pharmacology*, *8*(189), 1-20. doi:10.3389/fphar.2017.00189

Business Monitor International. (2016). *Nigeria Pharmaceuticals & Healthcare Report* (Q3 2016). Retrieved from www.bmiresearch.com

Byrne, D. (2013). Evaluating complex social interventions in a complex world. *Evaluation*, *19*, 217-228. doi:10.1177/1356389013495617

Caldwell, R. (2012). Leadership and learning: A critical reexamination of Senge's learning organization. *Systemic Practice and Action Research*, *25*, 39-55. doi:10.1007/s11213-011-9201-0

Caffrey, L., & Munro, E. (2017). A systems approach to policy evaluation. *Evaluation*, *23*,463-478. doi:10.1177/1356389017730727

Caffrey, L., Wolfe, C., & McKevitt, C. (2016). Embedding research in health systems: Lessons from complexity theory. *Health Research Policy and Systems*, *14*(54), 1-

9. doi:10.1186/s12961-016-0128-x

Cassell, C. (2017). “Pushed beyond my comfort zone": MBA student experiences of conducting qualitative research. *Academy of Management Learning & Education.* Advance online publication. doi:10.5465/amle.2015.0016

Chadwick, I. C., & Raver, J. L. (2015). Motivating organizations to learn: Goal orientation and its influence on organizational learning. *Journal of Management, 41*, 957-986. doi:10.1177/0149206312443558

Chandler, J., Rycroft-Malone, J., Hawkes, C., & Noyes, J. (2016). Application of simplified complexity theory concepts for healthcare social systems to explain the implementation of evidence into practice. *Journal of Advanced Nursing, 72,* 461-480. doi:10.1111/jan.12815

Che-Ha, N., Mavondo, F. T., & Mohd-Said, S. (2014). Performance or learning goal orientation: Implications for business performance. *Journal of Business Research, 67,* 2811-2820. doi:10.1016/j.jbusres.2012.08.002

Childers, S. M. (2014). Promiscuous analysis in qualitative research. Qualitative Inquiry, 20, 819-826. doi:10.1177/1077800414530266

Chiva, R., Ghauri, P., & Alegre, J. (2014). Organizational learning, innovation and internationalization: A complex system model. *British Journal of Management, 25,* 687-705. doi:10.1111/1467-8551.12026

Cirella, S., Canterino, F., Guerci, M., & Shani, A. B. R. (2016). Organizational learning mechanisms and creative climate: Insights from an Italian fashion design company. *Creativity and Innovation Management, 25,* 211-222.

doi:10.1111/caim.12161

Clancy, T. R. (2015). Complexity, flow, and antifragile healthcare systems: Implications for nurse executives. *Journal of Nursing Administration, 45*, 188-191. doi:10.1097/NNA.0000000000000182

Clarke, N. (2013). Model of complexity leadership development. *Human Resource Development International*, *16*, 135-150. doi:10.1080/13678868.2012.756155

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

Cordon, C. P. (2013). System theories: An overview of various system theories and its application in healthcare. *American Journal of Systems Science, 2*(1), 13-22. doi:10.5923/j.ajss.20130201.03

Corrigan, S., & Curtis, E. A. (2017). Facilitating informal learning in nursing. *British Journal of Healthcare Management, 23*, 22-27. doi:10.12968/bjhc.2017.23.1.22

Counsell, A., Cribbie, R. A., & Harlow, L. L. (2016). Increasing literacy in quantitative methods: The key to the future of Canadian psychology. *Canadian Psychology/Psychologie canadienne*, *57*, 193-201. doi:10.1037/cap0000056

Cronin, C. (2014). Using case study research as a rigorous form of inquiry. *Nurse Researcher, 21*(5), 19-27. doi:10.7748/nr.21.5.19.e1240

Dasgupta, M. (2015). Exploring the relevance of case study research. *The Journal of Business Perspective*, *19*, 147-160. doi:10.1177/0972262915575661

Day, G. S., & Schoemaker, P. J. (2016). Adapting to fast-changing markets and technologies. *California Management Review, 58*, 59-77.

doi:10.1525/cmr.2016.58.4.59

Dechezleprêtre, A., & Sato, M. (2017). The impacts of environmental regulations on competitiveness. *Review of Environmental Economics and Policy, 11*, 183-206. doi:10.1093/reep/rex013

De Massis, A., & Kotlar, J. (2014). The case study method in family business research: Guidelines for qualitative scholarship. *Journal of Family Business Strategy, 5*, 15-29. doi:10.1016/j.jfbs.2014.01.007

Ding, M., Eliashberg, J., & Stremersch, S. (2014). The pharmaceutical industry: specificity, challenges, and what you can learn from this book. In *Innovation and Marketing in the Pharmaceutical Industry* (pp. 1-18). New York, NY: Springer.

Dinh, J. E., Lord, R. G., Gardner, W. L., Meuser, J. D., Liden, R. C., & Hu, J. (2014). Leadership theory and research in the new millennium: Current theoretical trends and changing perspectives. *The Leadership Quarterly*, *25*(1), 36-62. doi:10.1016/j.leaqua.2013.11.005

Docherty, M. A. (2014). Change leadership during hospital mergers: A case study of the formation of Alberta Health Services. *South Asian Journal of Business and Management Cases, 3*(1), 77-87. doi:10.1177/2277977914525285

Doody, O., & Noonan, M. (2013). Preparing and conducting interviews to collect data. *Nurse Researcher*, *20*(5), 28-32. doi.10.7748/nr2013.05.20.5.28.e327

Duggal, E., Kashyap, P., Singh, R., & Kakar, S. (2014) Fast track approaches for drug approval across the globe. *Asian Pacific Journal of Health Science, 1*, 2-12. Retrieved from http://www.apjhs.com/

Dumbili, E. W. (2014). Use of mixed methods designs in substance research: A methodological necessity in Nigeria. *Quality & Quantity, 48*, 2841-2857. doi:10.1007/s11135-013-9928-z

Dunlap, D., Marion, T., & Friar, J. (2014). The role of cross-national knowledge on organizational ambidexterity: A case of the global pharmaceutical industry. *Management Learning, 45*, 458-476. doi:10.1177/1350507613480099

Dworkin, S. L. (2012). Sample size policy for qualitative studies using in-depth interviews. *Archives of Sexual Behavior, 41,* 1319-1320. doi:10.1007/s105080120016-6

Earp, M., Mitchell, M., McCarthy, J., & Kreuter, F. (2014). Modeling nonresponse in establishment surveys: Using an ensemble tree model to create nonresponse propensity scores and detect potential bias in an agricultural survey. *Journal of Official Statistics, 30*, 701-719 doi:10.2478/jos-2014-0044

Eger, S., & Mahlich, J. C. (2014). Pharmaceutical regulation in Europe and its impact on corporate R&D. *Health Economics Review, 4*(1), 1-9. doi:10.1186/s13561-014-0023-5

Elo, S., Kaariainen, M., Kanste, O., Polkki, T., Utriainen, K., & Kyngas, H. (2014). Qualitative content analysis: A focus on trustworthiness. *Sage Open, 4*(1), 1-10. doi:10.1177/2158244014522633

Epitropaki, O., Kark, R., Mainemelis, C., & Lord, R. G. (2017). Leadership and followership identity processes: A multilevel review. *The Leadership Quarterly, 28*, 104-129. doi:10.1016/j.leaqua.2016.10.003

Evers, S. M., Hiligsmann, M., & Adarkwah, C. C. (2015). Risk of bias in trial-based economic evaluations: Identification of sources and bias-reducing strategies. *Psychology & Health, 30,* 52-71. doi:10.1080/08870446.2014.953532

Ferguson, H. (2016). Researching social work practice close up: Using ethnographic and mobile methods to understand encounters between social workers, children, and families. *British Journal of Social Work, 46,* 153-168. doi:10.1093/bjsw/bcu120

Fitzgerald, L., Ferlie, E., McGivern, G., & Buchanan, D. (2013). Distributed leadership patterns and service improvement: Evidence and argument from English healthcare. *The Leadership Quarterly, 24,* 227-239. doi:10.1016/j.leaqua.2012.10.012

Fusch, P. I., & Ness, L. R. (2015). Are we there yet? Data saturation in qualitative research. *The Qualitative Report, 20,* 1408-1416. Retrieved from http://nsuworks.nova.edu/tqr/

Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology, 13*(1), 1-8. doi:10.1186/1471-2288-13-117

Galvin, R. (2015). How many interviews are enough? Do qualitative interviews in building energy consumption research produce reliable knowledge? *Journal of Building Engineering, 1,* 2-12. doi:10.1016/j.jobe.2014.12.001

Galuska, L. (2014). Enabling leadership: Unleashing creativity, adaptation, and learning in an organization. *Nurse Leader, 12*(2), 34-38. doi:10.1016/j.mnl.2014.01.011

Gerrits, L., & Verweij, S. (2015). Taking stock of complexity in evaluation: A discussion of three recent publications. *Evaluation, 21*, 481-491. doi:10.1177/1356389015605204

Gill, M. J. (2014). The possibilities of phenomenology for organizational research. *Organizational Research Methods*, *17*, 118-137. doi:10.1177/1094428113518348

Giorgi, S., Lockwood, C., & Glynn, M. A. (2015). The many faces of culture: Making sense of 30 years of research on culture in organization studies. *The Academy of Management Annals, 9*, 1-54. doi:10.1080/19416520.2015.1007645

Gioia, D. (2014). Reflections on teaching ethnographic fieldwork: Building community participatory practices. *Qualitative Social Work*, *13*, 144-153. doi:10.1177/1473325013509301

Goodman-Deane, J., Mieczakowski, A., Patmore, J., & Clarkson, J. (2015). Effective teleconferencing: An international investigation of the factors influencing the effectiveness of distributed meetings. *International Journal of Business Research and Development, 4*(4), 1-18. Retrieved from www.sciencetarget.com

Gropp, M., & Takes, P. A. (2016). *Global medical device regulatory strategy*. Rockville, MD: RAPS.

Grosse, E. H., Dixon, S. M., Neumann, W. P., & Glock, C. H. (2016). Using qualitative interviewing to examine human factors in warehouse order picking. *International Journal of Logistics Systems and Management*, *23*, 499-518. doi:10.1504/IJLSM.2016.075211

Haahr, A., Norlyk, A., & Hall, E. O. (2014). Ethical challenges embedded in qualitative research interviews with close relatives. *Nursing Ethics, 21,* 6-15. doi:10.1177/0969733013486370

Handoo, S., Arora, V., Khera, D., Nandi, P. K., & Sahu, S. K. (2012). A comprehensive study on regulatory requirements for development and filing of generic drugs globally. *International Journal of Pharmaceutical Investigation, 2*(3), 99-105. doi:10.4103/2230-973X.104392

Hanisch, B., & Wald, A. (2014). Effects of complexity on the success of temporary organizations: Relationship quality and transparency as substitutes for formal coordination mechanisms. *Scandinavian Journal of Management, 30,* 197-213. doi:10.1016/j.scaman.2013.08.005

Harper, C. L., & Leicht, K. T. (2015). *Exploring social change: America and the world.* (6th) New York, NY: Routledge.

Harraf, A., Wanasika, I., Tate, K., & Talbott, K. (2015). Organizational agility. *Journal of Applied Business Research, 31,* 675-686. doi:10.19030/jabr.v31i2.9160

Haslam, S. A., Steffens, N. K., Peters, K., Boyce, R. A., Mallett, C. J., & Fransen, K. (2017). A social identity approach to leadership development. *Journal of Personnel Psychology, 16,* 113-124. doi:10.1027/1866-5888/a000176

Hassali, M. A., Alrasheedy, A. A., McLachlan, A., Nguyen, T. A., AL-Tamimi, S. K., Ibrahim, M. I. M., & Aljadhey, H. (2014). The experiences of implementing generic medicine policy in eight countries: A review and recommendations for a successful promotion of generic medicine use. *Saudi Pharmaceutical Journal, 22,*

491-503. doi:10.1016/j.jsps.2013.12.017

Hazy, J. K. (2014). 'Is this "thermodynamic inquiry" metaphor or more?', *Journal of Consulting Psychology, 66*, 200-305. doi:10.1037/cpb0000020

Hazy, J. K., & Uhl-Bien, M. (2015). Towards operationalizing complexity leadership: How generative, administrative and community-building leadership practices enact organizational outcomes. *Leadership, 11*, 79-104. doi:10.1177/1742715013511483

Hennink, M. M., Kaiser, B. N., & Marconi, V. C. (2016). Code saturation versus meaning saturation how many interviews are enough? *Qualitative Health Research, 27*, 591-590. doi:10.1177/1049732316665344

Heracleous, L., Papachroni, A., Andriopoulos, C., & Gotsi, M. (2017). Structural ambidexterity and competency traps: Insights from Xerox PARC. *Technological Forecasting & Social Change, 117,* 327-338. doi:10.1016/j.techfore.2016.11.014

Herzberg, F. (2015). Motivation-hygiene theory In J. Miner, *Organizational behavior I: Essential theories of motivation and leadership* (pp. 61-74), New York, NY: Routledge.

Herwig, C., Garcia-Aponte, O. F., Golabgir, A., & Rathore, A. S. (2015). Knowledge management in the QbD paradigm: Manufacturing of biotech therapeutics. *Trends in Biotechnology*, *33*, 381-387. doi:10.1016/j.tibtech.2015.04.004

Horvat, A., & Filipovic, J. (2017). Service quality and maturity of health care organizations through the lens of complexity leadership theory. *Journal of Evaluation in Clinical Practice*. Advance online. doi:10.1111/jep.12789

Houghton, C., Casey, D., Shaw, D., & Murphy, K. (2013). Rigor in qualitative case-study research. *Nurse Researcher*, *20*(4), 12-17. doi:10.7748/nr2013.03.20.4.12.e326

Hsiao, C. C., & Chiou, J. S. (2017). The social influence of online collaborative community: The moderating effect of achievement. *Behaviour & Information Technology, 36*, 269-280. doi:10.1080/0144929X.2016.1221463

Hu, Q., Found, P., Williams, S., & Mason, R. (2014). The role of consultants in organizational learning. *Journal of Management Policy & Practice*, *15*(4), 29-39. Retrieved from http://m.www.na-businesspress.com/jmppopen.html

Hyett, N., Kenny, A., & Dickson-Swift, V. (2014). Methodology or method? A critical review of qualitative case study reports. *International journal of Qualitative Studies on Health and Well-Being*, *9*(1), 1-12. doi:10.3402/qhw.v9.23606

Ingold, T. (2014). That's enough about ethnography! *Journal of Ethnographic Theory*, *4*, 383-395. doi:10.14318/hau4.1.021

Jekunen, A. (2014). Decision-making in product portfolios of pharmaceutical research and development–managing streams of innovation in highly regulated markets. *Drug Design, Development and Therapy*, *8*, 2009-2016. doi:10.2147/DDDT.S68579

Johnson, M., O'Hara, R., Hirst, E., Weyman, A., Turner, J., Mason, S., ... & Siriwardena, A. N. (2017). Multiple triangulation and collaborative research using qualitative methods to explore decision making in pre-hospital emergency care. *BMC Medical Research Methodology*, *17*(1), 1-11. doi:10.1186/s12874-017-0290-z

Junni, P., Sarala, R. M., Taras, V., & Tarba, S. Y. (2013). Organizational ambidexterity

and performance: A meta-analysis. *The Academy of Management Perspectives, 27,* 299-312. doi:10.5465/amp.2012.0015

Kawar, L. N., Pugh, D. M., & Scruth, E. A. (2016). Understanding the role and legal requirements of the institutional review board. *Clinical Nurse Specialist, 30,* 137-140. doi:10.1097/NUR.0000000000000197

Kennedy, J. M., & Ouimet, J. A. (2014). The effect of incentives on internet surveys: Response rate changes after the introduction of incentives. *Asian Journal for Public Opinion Research, 1,* 128-146. doi:10.15206/ajpor.2014.1.2.128

Ketokivi, M., & Choi, T. (2014). Renaissance of case research as a scientific method. *Journal of Operations Management, 32,* 232-240. doi:10.1016/j.jom.2014.03.004

Keshavarz, E., Ftahikenari, M., Rohani, A., & Bagheri, S. M. (2014). Performance evaluation of banks using balanced scorecard. *International Journal of Business Excellence, 7,* 371-393. doi:10.1504/IJBEX.2014.060781

Konda, I., Starc, J., & Rodica, B. (2015). Social challenges are opportunities for sustainable development: Tracing impacts of social entrepreneurship through innovations and value creation. *Economic Themes, 53,* 211-229. doi:10.1515/ethemes-2015-0012

Krause, R., Semadeni, M., & Cannella, A. A. (2013). External COO/presidents as expert directors: A new look at the service role of boards. *Strategic Management Journal, 34,* 1628-1641. doi:10.1002/smj.2081

Kroll, A., & Moynihan, D. P. (2015). Does training matter? Evidence from performance management reforms. *Public Administration Review, 75*, 411-420. doi:10.1111/puar.12331

Lemmens, T., & Gibson, S. (2014). Decreasing the data deficit: Improving post-market surveillance in pharmaceutical regulation. *McGill Law Journal; 59*, 943-988. doi:10.7202/1026134ar

Liberti, L., Breckenridge, A., Hoekman, J., Leufkens, H., Lumpkin, M., McAuslane, N., . . . & Rägo, L. (2016). Accelerating access to new medicines: Current status of facilitated regulatory pathways used by emerging regulatory authorities. *Journal of Public Health Policy, 37*, 315-333. doi:10.1057/jphp.2016.8

Liden, R. C., Wayne, S. J., Liao, C., & Meuser, J. D. (2014). Servant leadership and serving culture: Influence on individual and unit performance. *Academy of Management Journal, 57*, 1434-1452. doi:10.5465/amj.2013.0034

Lishner, D. A. (2015). A concise set of core recommendations to improve the dependability of psychological research. *Review of General Psychology*, *19*, 52-68. doi:10.1037/gpr0000028

Lu, U. (2014). Biologics price competition and innovation act: Striking a delicate balance between innovation and accessibility. *Minnesota Journal of Law, Science & Technology, 15*, 613-649. Retrieved from http://mjlst.umn.edu/

Lucas, S. R. (2014). Beyond the existence proof: Ontological conditions, epistemological implications, and in-depth interview research. *Quality & Quantity, 48*, 387-408. doi:10.1007/s11135-012-9775-

Lynch-Wood, G., & Williamson, D. (2014). Understanding SME responses to environmental regulation. *Journal of Environmental Planning and Management, 57,* 1220-1239. doi:10.1080/09640568.2013.793174

Macdonald, J. C., Hartman, H., & Jacobs, I. A. (2015). Regulatory considerations in oncologic biosimilar drug development. *MAbs, 7,* 653-661. doi:10.1080/19420862.2015.1040973

Malerba, F., & Orsenigo, L. (2015). The evolution of the pharmaceutical industry. *Business History*, *57*, 664-687. doi:10.1080/00076791.2014.975119

Malone, H., Nicholl, H., & Tracey, C. (2014). Awareness and minimization of systematic bias in research. *British Journal of Nursing*, *23*, 279-282. doi:10.12968/bjon.2014.23.5.279

Malterud, K., Siersma, V. D., & Guassora, A. D. (2015). Sample size in qualitative interview studies guided by information power. *Qualitative Health Research, 26,* 1753-1760. doi:10.1177/1049732315617444

Marino, A., Aversa, P., Mesquita, L., & Anand, J. (2015). Driving performance via exploration in changing environments: Evidence from Formula One racing. *Organization Science*, *26,* 1079-1100. doi:10.1287/orsc.2015.0984

Marion, R., & Uhl-Bien, M. (2001). Leadership in complex organizations. *The Leadership Quarterly*, *12*, 389-418. doi:10.1016/S1048-9843(01)00092-3

Marion, R., Christiansen, J., Klar, H. W., Schreiber, C., & Erdener, M. A. (2016). Informal leadership, interaction, cliques and productive capacity in organizations: A collectivist analysis. *The Leadership Quarterly*, *27*, 242-260.

doi:10.1016/j.leaqua.2016.01.003

Marshall, C., & Rossman, G. B. (2016). *Designing qualitative research.* (6th ed.). Thousand Oaks, CA: Sage.

Maynard, A., & Bloor, K. (2015). Regulation of the pharmaceutical industry: Promoting health or protecting wealth? *Journal of the Royal Society of Medicine, 108,* 220-222. doi:10.1177/0141076814568299

Mazzei, M. J., Ketchen, D. J., & Shook, C. L. (2017). Understanding strategic entrepreneurship: A "theoretical toolbox" approach. *International Entrepreneurship and Management Journal*, *13,* 631-663. doi:10.1007/s11365-016-0419-2

Mehralian, G., A. Nazari, J., Akhavan, P., & Reza Rasekh, H. (2014). Exploring the relationship between the knowledge creation process and intellectual capital in the pharmaceutical industry. *The Learning Organization*, *21,* 258-273. doi:10.1108/TLO-07-2013-0032

Melton, E. K. (2017). Testing turbulence: Exploring the determinants of managerial networking. *Public Organization Review*, *17,* 19-37. doi:0.1007/s11115-015-0324-0

Mendes, M., Gomes, C., Marques-Quinteiro, P., Lind, P., & Curral, L. (2016). Promoting learning and innovation in organizations through complexity leadership theory. *Team Performance Management*, *22*, 301-309. doi:10.1108/TPM-02-2016-0004

Mendoza, J. P., Dekker, H. C., & Wielhouwer, J. L. (2016). Firms' compliance with

complex regulations. *Law and Human Behavior, 40*, 721-733. doi:10.1037/lhb0000215

Mintz, C. S. (2015). Cannabis-derived pharmaceuticals. *Journal of Commercial Biotechnology, 21*(3), 16-31. doi:10.5912/jcb709

Miracle, V. A. (2016). The Belmont Report: The triple crown of research ethics. *Dimensions of Critical Care Nursing, 35,* 223-228. doi:10.1097/DCC.0000000000000186

Morgan, S. J., Pullon, S. R., Macdonald, L. M., McKinlay, E. M., & Gray, B. V. (2017). Case study observational research: A framework for conducting case study research where observation data are the focus. *Qualitative Health Research, 27*, 1060-1068. doi:10.1177/1049732316649160

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

Mourlon-Druol, E. (2016). Banking union in historical perspective: The initiative of the European Commission in the 1960s–1970s. *JCMS: Journal of Common Market Studies, 54*, 913-927. doi:10.1111/jcms.12348.

Mthuli, S., Bodhanya, S., & Sobratee, N. (2017). How should strategy prevail if organizations are seen as having the properties of complex adaptive systems? *Journal of Business and Retail Management Research*, *11*(4), 140-149. Retrieved from http://www.jbrmr.com/

Mulinari, S. (2016). Regulating pharmaceutical industry marketing: Development,

enforcement, and outcome of marketing rules. *Sociology Compass, 10,* 74-86. doi:10.1111/soc4.12335

Murphy, J., Rhodes, M. L., Meek, J. W., & Denyer, D. (2017). Managing the entanglement: Complexity leadership in public sector systems. *Public Administration Review, 77,* 692-704. doi:10.1111/puar.12698

Murray, J. (2017). Complexity leadership and collective action in the age of networks. *College English, 79,* 512-525. Retrieved from http://www.ncte.org/journals/ce

Muzaka, V. (2013). Prizes for pharmaceuticals? Mitigating the social ineffectiveness of the current pharmaceutical patent arrangement. *Third World Quarterly, 34*(1), 151-169. doi:10.1080/01436597.2012.755009

Nadler, D. A., & Tushman, M. L. (1980). A model for diagnosing organizational behavior. *Organizational Dynamics, 9*(2), 35-51. doi:10.1016/0090-2616(80)90039-X

Naghshineh, N., Brown, S., Cederna, P. S., Levi, B., Lisiecki, J., D'Amico, R. A., . . . & Rubin, J. P. (2014). Demystifying the U.S. Food and Drug Administration: Understanding regulatory pathways. *Plastic and Reconstructive Surgery, 134,* 559-569. doi:10.1097/PRS.0000000000000477

Naqvi, A., Khan, I., & Butt, I., (2015). The impact of motivational factors on organizational learning: A study on educational sector of Pakistan. *Pakistan Business Review, 17, 303-324.* Retrieved from journals.iobmresearch.com/index.php/PBR/index

Ney, S., Beckmann, M., Gräbnitz, D., & Mirkovic, R. (2014). Social entrepreneurs and social change: Tracing impacts of social entrepreneurship through ideas, structures and practices. *International Journal of Entrepreneurial Venturing, 6(*1), 51-68. doi:10.1504/IJEV.2014.059405

Nielsen, V. L., & Parker, C. (2012). Mixed motives: Economic, social, and normative motivations in business compliance. *Law & Policy, 34, 4*28–462. doi:10.1111/j.1467-9930.2012.00369.x

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

Nooteboom, S. G., & Termeer, C. J. (2013). Strategies of complexity leadership in governance systems. *International Review of Public Administration*, *18*, 25-40. doi:10.1080/12294659.2013.10805238

Ofuani, A. B., Kuye, O. L., & Ogundele, O. J. K. (2015). An assessment of the efficiency of government regulatory agencies in Nigeria. Case of the National Agency for Food and Drugs Administration and Control. *Academic Journal of Economic Studies*, *1*(3), 9-26. Retrieved from http://www.ajes.ro/

Ogaji, J. I., Alawode, A. O., & Iranloye, T. A. (2014). Pharmaceutical industry capacity utilization in Nigeria. *African Journal of Pharmacy and Pharmacology, 8*, 579-585. Retrieved from http://www.academicjournals.org/AJPP

Ogbonna, B. O., Ilika, A. L., & Nwabueze, S. A. (2015). National drug policy in Nigeria. *World Journal of Pharmaceutical Research, 4*, 248-264. Retrieved from http://www.wjpr.net/

O'Keefe, C. M., & Rubin, D. B. (2015). Individual privacy versus public good: Protecting confidentiality in health research. *Statistics in Medicine, 34,* 3081-3103. doi:10.1002/sim.6543

O'Keeffe, J., Buytaert, W., Mijic, A., Brozovic, N., & Sinha, R. (2016). The use of semistructured interviews for the characterization of farmer irrigation practices. *Hydrology & Earth System Sciences, 20,* 1911-1924. doi:10.5194/hess-20-1911-2016

Olugbenga, E. O. (2013). The politics of pharmaceutical regulation in Nigeria: Policy options for third world countries. *Politics, 3*(8), 89-100. Retrieved from www.iiste.org

Onyema, E. O. (2014). Effects of entrepreneurial orientations on organizational learning in a manufacturing firm in Nigeria. *International Journal of Business Administration, 5*(2), 94-106. doi:10.5430/ijba.v5n2p94

O'Reilly, M., & Parker, N. (2013). 'Unsatisfactory Saturation': A critical exploration of the notion of saturated sample sizes in qualitative research. *Qualitative Research, 13,* 190-197. doi:10.1177/1468794112446106

O'Reilly, C. A., & Tushman, M. L. (2013). Organizational ambidexterity: Past, present, and future. *The Academy of Management Perspectives, 27,* 324-338. doi:10.5465/amp.2013.0025

Pace, J., Pearson, S. A., & Lipworth, W. (2015). Improving the legitimacy of medicines funding decisions: A critical literature review. *Therapeutic Innovation & Regulatory Science*. Advance online publication. doi:10.1177/2168479015579519

Page, R. A., Cyr, D. M., & Richardson, A. S. (2015). Sustainability and stratified noncompliance in the pharmaceutical industry. *Journal of International Business Disciplines, 10*(1), 18-40. Retrieved from http://www.jibd.org/

Palinkas, L. A., Horwitz, S. M., Green, C. A., Wisdom, J. P., Duan, N., & Hoagwood, K. (2015). Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Administration and Policy in Mental Health and Mental Health Services Research, 42,* 533-544. doi:10.1007/s10488-013-0528-y

Pallett, H., & Chilvers, J. (2015). Organizations in the making: Learning and intervening at the science-policy interface. *Progress in Human Geography, 39,* 146-166. doi:10.1177/0309132513518831

Palos, R., & Stancovici Veres, V. (2016). Learning in organization. *The Learning Organization, 23*, 2-22. doi:10.1108/TLO-01-2015-0001

Palumbo, F. B., Rosebush, L. H., & Zeta, L. M. (2015). Navigating through a complex and inconsistent regulatory framework section 503B of the federal food drug and cosmetic act outsourcing facilities engaged in clinical investigation. *Therapeutic Innovation & Regulatory Science, 50,* 270-278. doi:10.1177/2168479015618695

Papaioannou, T., Watkins, A., Mugwagwa, J., & Kale, D. (2016). To lobby or to partner? Investigating the shifting political strategies of biopharmaceutical industry associations in innovation systems of South Africa and India. *World Development, 78*, 66-79. doi:10.1016/j.worlddev.2015.10.017

Parvizi, N., & Woods, K. (2014). Regulation of medicines and medical devices: Contrasts and similarities. *Clinical Medicine, 14,* 6-12. doi:10.7861/clinmedicine.14-1-6

Patton, D. U., Hong, J. S., Patel, S., & Kral, M. J. (2017). A systematic review of research strategies used in qualitative studies on school bullying and victimization. *Trauma, Violence, & Abuse*, *18*(1), 3-16. doi:10.1177/1524838015588502

Peticca-Harris, A., deGama, N., & Elias, S. R. (2016). A dynamic process model for finding informants and gaining access in qualitative research. *Organizational Research Methods*, *19*, 376-401. doi:10.1177/1094428116629218

Pilbeam, C., Doherty, N., Davidson, R., & Denyer, D. (2016). Safety leadership practices for organizational safety compliance: Developing a research agenda from a review of the literature. *Safety Science*, *86*, 110-121. doi:10.1016/j.ssci.2016.02.015

Pisani, A. R., Wyman, P. A., Mohr, D. C., Perrino, T., Gallo, C., Villamar, J., ... & Brown, C. H. (2016). Human subjects protection and technology in prevention science: Selected opportunities and challenges. *Prevention Science*, *17*, 765-778. doi:10.1007/s11121-016-0664-1

Polacsek, M., Boardman, G., & McCann, T. V. (2017). Paying patient and caregiver research participants: Putting theory into practice. *Journal of Advanced Nursing*, *73*, 847-856. doi:10.1111/jan.13222

Popova-Nowak, I. V., & Cseh, M. (2015). The meaning of organizational learning: A meta-paradigm perspective. *Human Resource Development Review*, *14*, 299-331. doi:10.1177/1534484315596856

Poutanen, P., Siira, K., & Aula, P. (2016). Complexity and organizational communication

a quest for common ground. *Human Resource Development Review, 15*, 182-207. doi:10.1177/1534484316639713

Proches, C. G., & Bodhanya, S. (2015). Exploring stakeholder interactions through the lens of complexity theory: Lessons from the sugar industry. *Quality & Quantity, 49*, 2507-2525. doi:10.1007/s11135-014-0124-6

Raina, R., & Roebuck, D. B. (2016). Exploring cultural influence on managerial communication in relationship to job satisfaction, organizational commitment, and the employees' propensity to leave in the insurance sector of India. *International Journal of Business Communication, 53,* 97-130. doi:10.1177/2329488414525453

Reddy, A. V. J., & Rao, B. M. (2017). Opportunities and challenges for Indian pharmaceutical companies in overseas markets and need of digital tools for sustainable success. *Indian Journal of Pharmaceutical Education and Research, 51,* 226-238. doi:10.5530/ijper.51.2.28

Redlich-Amirav, D., & Higginbottom, G. (2014). New emerging technologies in qualitative research. *The Qualitative Report, 19*(26), 1-14. Retrieved from http://nsuworks.nova.edu/tqr/

Rengerink, K. O., Kalkman, S., Collier, S., Ciaglia, A., Worsley, S. D., Lightbourne, A., ... & Irving, E. A. (2017). Participant eligibility, recruitment and retention in pragmatic trials. *Journal of Clinical Epidemiology*. Online. doi:10.1016/j.jclinepi.2016.12.021

Riggs, J. F., Widmier, S., & Plank, R. E. (2016). The impact of pharmaceutical industry

salesperson regulations, guidance statements, and laws on their sales behaviours: A taxonomy with managerial insights. *International Journal of Pharmaceutical and Healthcare Marketing, 10,* 161-191. doi:10.1108/IJPHM-05-2015-0019

Ritchie, J., Lewis, J., Nicholls, C. M., & Ormston, R. (Eds.). (2014). *Qualitative research practice: A guide for social science students and researchers*. London: Sage.

Rodwin, M. A. (2015). Do we need stronger sanctions to ensure legal compliance by pharmaceutical firms? *Food and Drug Law Journal, 70,* 435-452. Retrieved from https://www.fdli.org/resources/food-drug-law-journal

Rollings, N. (2017). Babcock and Wilcox Ltd, the 'Babcock Family'and regulation 17/62: A business response to new competition policy in the early1960s. *Business History*. Advance online publication. doi:10.1080/00076791.2017.1310197

Roulston, K., & Shelton, S. A. (2015). Reconceptualizing bias in teaching qualitative research methods. *Qualitative Inquiry, 21,* 332-342. doi:10.1177/1077800414563803

Roy, K., Zvonkovic, A., Goldberg, A., Sharp, E., & LaRossa, R. (2015). Sampling richness and qualitative integrity: Challenges for research with families. *Journal of Marriage and Family, 77,* 243-260. doi:10.1111/jomf.12147

Rubinstein, Y. R., Karp, B., Lockhart, N., Grady, C., & Groft, S. C. (2014). Informed consent template for patient participation in rare disease registries linked to biorepositories. *Rare Diseases and Orphan Drugs, 1*(2), 69-74. Retrieved from http://rarejournal.org/

Sabel, C., Herrigel, G., & Kristensen, P. H. (2017). Regulation under uncertainty: The

coevolution of industry and regulation. *Regulation & Governance*. Advanced online. doi:10.1111/rego.12146

Santos-Vijande, M. L., López-Sánchez, J. Á., & Trespalacios, J. A. (2012). How organizational learning affects a firm's flexibility, competitive strategy, and performance. *Journal of Business Research, 65,* 1079-1089. doi:10.1016/j.jbusres.2011.09.002

Schramm, M., L. Herbst, J., & Mattie, A. (2014). The False Claims Act: A review and policy recommendations. *International Journal of Pharmaceutical and Healthcare Marketing*, *8*, 295-313. doi:10.1108/IJPHM-04-2014-0020

Seidel, R. (2015). Organizational learning sequences in technological innovation: Evidence from the biopharmaceutical and medical device sectors. *International Journal of Innovation Management. 19*(3), 1-21. doi:10.1142/S1363919615400071

Seidman, I. (2012). *Interviewing as qualitative research: A guide for researchers in education and the social sciences.* (3rd ed.). Columbia University, NY: Teachers college press.

Seong, S., Kim, Y., & Szulanski, G. (2015). Leadership, innovation, and strategic change: A conversation with Michael Tushman. *Journal of Management Inquiry, 24*, 370-381. doi:10.1177/105649261557238

Shahzad, F., Luqman, R. A., Khan, A. R., & Shabbir, L. (2012). Impact of organizational culture on organizational performance: An overview. *Interdisciplinary Journal of Contemporary Research in Business, 3*, 975-985. Retrieved from

http://www.ijcrb.com/

Sieweke, J., & Zhao, B. (2015). The impact of team familiarity and team leader experience on team coordination errors: A panel analysis of professional basketball teams. *Journal of Organizational Behavior, 36*, 382-402. doi:10.1002/job.1993

Silva, T. P., Silva, I. R., & Leite, J. L. (2016). Interaction in the management of nursing care to hospitalized children with chronic conditions: Showing intervening conditions. *Texto & Contexto-Enfermagem, 25*(2), 1-9. doi:10.1590/0104-07072016001980015

Smits, S. J., & Bowden, D. E. (2015). A perspective on leading and managing organizational change. *Economics & Business Review*, *15*(2), 3-21. doi:10.18559/ebr.2015.2.1

Sorenson, C., & Drummond, M. (2014). Improving medical device regulation: The United States and Europe in perspective. *Milbank Quarterly, 92*, 114-150. doi:10.1111/1468-0009.12043

Sotiriadou, P., Brouwers, J., & Le, T. A. (2014). Choosing a qualitative data analysis tool: A comparison of NVivo and Leximancer. *Annals of Leisure Research, 17*, 218-234. doi:10.1080/11745398.2014.902292

Sravika, S., Bhavana, R., Sharmila, V., Anusha, S., Mounica, N. V. N., Reddy, D. N., & Nagabhushanam, M. V. (2017). A comprehensive study on regulatory requirements for development and filing of generic drugs globally. *The Pharma Innovation Journal*, *6*(4), 153-158. Retrieved from

http://www.thepharmajournal.com/

Stake, R. E. (2013). *Multiple case study analysis.* New York, NY: Guilford Press.

Starman, A. B. (2013). The case study as a type of qualitative research. *Journal of Contemporary Educational Studies, 64*(1), 28-43. Retrieved from http://www.sodobna-pedagogika.net/

Stettina, C. J., & Hörz, J. (2015). Agile portfolio management: An empirical perspective on the practice in use. *International Journal of Project Management*, *33*, 140-152. doi:10.1016/j.ijproman.2014.03.008

Suen, L. J., Huang, H. M., & Lee, H. H. (2014). A comparison of convenience sampling and purposive sampling. *The Journal of Nursing, 61*, 105-111. doi:10.6224/JN.61.3.105

Tan, F. Z. (2015). Definition and conceptual separation learning, organizational learning, and learning organizations terms. *Business & Management Studies: An International Journal*, *2*, 188-217. doi:10.15295/bmij.v2i2.71

Tang, L. L., & Yeh, Y. L. (2015). Effect of organizational culture, leadership style, and organizational learning on organizational innovation in the public sector. *Journal of Quality*, *22*, 461-481. doi:10.6220/joq.2015.22(5).06

Thach, S. V. (2015). High regulation and low certainty: Marketing strategy challenges for the pharmaceutical industry in China. *Journal International Business & Economy*, *16*(1), 1-12. Retrieved from http://www.i-jibe.org

Thakor, A. V. (2015). The financial crisis of 2007–2009: Why did it happen and what did we learn? *The Review of Corporate Finance Studies*, *4*, 155-205.

doi:10.1093/rcfs/cfv001

Thompson, D. S., Fazio, X., Kustra, E., Patrick, L., & Stanley, D. (2016). Scoping review of complexity theory in health services research. *BMC Health Services Research*, *16*(1), 1-16. doi:10.1186/s12913-016-1343-4

Tijjani, G. M. (2014). *An empirical investigation of the regulatory governance practice of Nigeria's downstream petroleum sector* (Doctoral dissertation). Retrieved from https://openair.rgu.ac.uk/

Tong, Y. K., & Arvey, R. D. (2015). Managing complexity via the competing values framework. *Journal of Management Development*, *34*, 653-673. doi:10.1108/JMD-04-2014-0029

Tsai, K. C. (2013). A journey to the qualitative wonderland: Lessons learned for novice qualitative researchers. *Anadolu Journal of Educational Sciences International, 3,* 95-102. Retrieved from http://www.ajesi.anadolu.edu.tr/

Turner, S. F., Cardinal, L. B., & Burton, R. M. (2017). Research design for mixed methods: A triangulation-based framework and roadmap. *Organizational Research Methods*, *20*, 243-267. doi:10.1177/1094428115610808

Tushman, M. L., & O'Reilly III, C. A. (1996). Ambidextrous organizations: Managing evolutionary and revolutionary change. *California Management Review*, *38*(4), 8-29. doi:10.2307/41165852

Uhl-Bien, M., & Arena, M. (2017). Complexity leadership: Enabling people and organizations for adaptability. *Organizational Dynamics, 46,* 9-20. doi:10.1016/j.orgdyn.2016.12.001

Uhl-Bien, M., Marion, R., & McKelvey, B. (2007). Complexity leadership theory: Shifting leadership from the industrial age to the knowledge era. *The Leadership Quarterly, 18*, 298-318. doi:10.1016/j.leaqua.2007.04.002

van Hoof, B. (2014). Organizational learning in cleaner production among Mexican supply networks. *Journal of Cleaner Production, 64*, 115-124. doi:10.1016/j.jclepro.2013.07.041

Van Norman, G. A. (2016). Drugs and devices: Comparison of European and US approval processes. *JACC: Basic to Translational Science, 1*, 399-412. doi:10.1016/j.jacbts.2016.06.003

Venkatesh, V., Brown, S. A., & Sullivan, Y. W. (2016). Guidelines for conducting mixed-methods research: An extension and illustration. *Journal of the Association for Information Systems, 17*, 435-494. Retrieved from http://aisel.aisnet.org/jais/

Waddell, A., & Pio, E. (2015). The influence of senior leaders on organizational learning: Insights from the employees' perspective. *Management Learning, 46*, 461-478. doi:10.1177/1350507614541201

Wadongo, B., & Abdel-Kader, M. (2014). Contingency theory, performance management and organizational effectiveness in the third sector: A theoretical framework. *International Journal of Productivity and Performance Management, 63*, 680-703. doi:10.1108/IJPPM-09-2013-0161

Waldman, D. A., & Bowen, D. E. (2016). Learning to be a paradox-savvy leader. *The Academy of Management Perspectives, 30*, 316-327. doi:10.1109/EMR.2016.7792412

Walton, M. (2014). Applying complexity theory: A review to inform evaluation design. *Evaluation and Program Planning, 45*, 119-126. doi:10.1016/j.evalprogplan.2014.04.002

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

Ward, K., Gott, M., & Hoare, K. (2015). Participants' views of telephone interviews within a grounded theory study. *Journal of Advanced Nursing, 71*, 2775-2785. doi:10.1111/jan.12748

Warier, N., & Mehta, P. (2016). Comparative study of generic drug registration requirements for dossier submission in African Region-Kenya, Ghana, Nigeria, and Botswana. *Applied Clinical Research, Clinical Trials and Regulatory Affairs, 3*, 71-81. http://benthamscience.com/journals/applied-clinical-research-clinical-trials-and-regulatory-affairs/

Weberg, D. (2012). Complexity leadership: A healthcare imperative. *Nursing Forum, 47,* 268-277. doi:10.1111/j.1744-6198.2012.00276.x.

Wilson, A. D., Onwuegbuzie, A. J., & Manning, L. P. (2016). Using paired depth interviews to collect qualitative data. *The Qualitative Report, 21*, 1549-1573. Retrieved from http://nsuworks.nova.edu/tqr/

Wolfe, N., Gotzsche, P. C., & Bero, L. (2013). Strategies for obtaining unpublished drug trial data: A qualitative interview study. *Systematic Reviews, 2*(3), 1-11.

doi:10.1186/2046-4053-2-31

Yin, R. K. (2013). Validity and generalization in future case study evaluations. *Evaluation, 19,* 321-332. doi:10.1177/1356389013497081

Yin, R. K. (2014). *Case study research: Design and methods*. (5th ed.). Thousand Oaks, CA: Sage.

Yukl, G. (2012). Effective leadership behavior: What we know and what questions need more attention. *The Academy of Management Perspectives, 26*(4), 66-85. doi:10.5465/amp.2012.0088

Yousefi, N., Mehralian, G., Rasekh, H., & Yousefi, M. (2017). New product development in the pharmaceutical industry: Evidence from Iran. *Iranian Journal of Pharmaceutical Research, 16,* 831-843. Retrieved from http://ijpr.sbmu.ac.ir/

Appendix A: Interview Protocol

Interview Protocol	
What I will do	**script**
Introduce the interview and set the stage	I am a student at Walden University pursuing my Doctor of Business Administration degree specializing in Technology Entrepreneurship. I am conducting a research study for my dissertation entitled “Strategies for Compliance with Government Regulations in a Pharmaceutical Company ". The purpose of this qualitative single case study is to explore the strategies used by leaders in pharmaceutical companies to adapt to regulatory requirements. Management approval for data collection will be sought, and your participation in this study is entirely voluntary, you can withdraw from participating at any point of the data collection process.
• Watch for non-verbal queues • Paraphrase as needed	1. What is your role in ensuring compliance with government regulations in your company?

• Ask follow-up probing questions to get more in-depth	2. What strategies do you use to prevent noncompliance with government regulations? 3. How do you communicate regulatory requirements within your company? 4. What specific strategies do you use to ensure regulatory compliance? 5. What challenges do you encounter in implementing strategies for compliance with regulatory requirements? 6. How do you address the challenges to the implementation of strategies for noncompliance to government regulations? 7. How do you assess the effectiveness of your strategies to prevent noncompliance 8. What other relevant information about compliance with regulatory requirements can you provide?

Wrap up interview thanking participant	Thank you for your time and consideration, do you have any additional questions or comments?
Inform participants about transcript review	I would like to send you the transcript of this recorded interview; can you provide two dates and times you are available next week?

Follow–up Transcript Review

Introduce follow-up interview	1. I prepared verbatim transcripts of recorded interviews 2. Verbatim transcript sent by email to each participant to review 3. Confirmation/correction of verbatim transcript by participants

Appendix B: Invitation Letter

Date:

Re: Doctoral Research Study Invitation

Dear ……..,

I am a student at Walden University pursuing my Doctor of Business Administration degree specializing in Technology Entrepreneurship. I am conducting a research study for my dissertation entitled “Strategies for Compliance with Government Regulations in a Pharmaceutical Company”.

The purpose of this qualitative single case study is to explore strategies that managers in pharmaceutical companies use to ensure compliance with regulatory requirements. Management approval for data collection will be sought, and your participation in this study is entirely voluntary, you can withdraw from participating at any point of the data collection process.

Participants in this study are not likely to benefit personally or financially by participating, but participation has the potential for improved abilities of managers to ensure compliance in a regulated environment, which might lead to increased access, availability, and affordability of pharmaceutical products by individuals with limited access to good healthcare.

The research will be conducted in by accordance with Walden University and HHS guidelines on ethical research. All participants and organizations will be kept confidential. Interested companies will be credited if they so desire in the final report.

Please review the consent form attached and if you accept this invitation to participate in the data collection phase of this study, please

Please do not hesitate to contact me if you have any question or concerns.

Kind regards,

Charles Jagun, Doctoral Research Student

Walden University

Appendix C: NIH Certificate