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Strategies Used in the Biotechnology Industry to Develop and Continuously Improve Compliant Regulatory Processes to Meet the Food and Drug Administration Quality Federal Regulations

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This is to certify that the doctoral study by

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Walden University
2025

Abstract

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by

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MBA, Roosevelt University, 2004

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Research Project Submitted in Partial Fulfillment

of the Requirements for the Degree of

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Abstract

Failure to comply with the U.S. Food and Drug Administration (FDA) quality regulations can lead to enforcement actions for the biotechnology (biotech) industry. Noncompliant regulatory strategies have the potential for adverse medical outcomes for patients. As a result, managers in the biotech industry are concerned about ensuring compliance to avoid adverse medical outcomes for patients and sustain business operations. Grounded in Deming's total quality management concept, the purpose of this qualitative pragmatic inquiry project was to explore effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations. The participants were six biotech managers with five or more years of experience in the biotech industry from the central region of the United States. Data were collected using semistructured interviews and public data from the U.S. FDA data dashboard of enforcement actions. Through Braun and Clarke's thematic analysis, four major themes emerged: understanding U.S. FDA enforcement actions and the business consequences of poor regulatory compliance, fostering a quality culture, providing leadership support and engagement at all levels, and accelerating education and experience. A key recommendation is for biotech managers to create a company-specific risk-based compliance improvement plan. Implications for positive social change include the potential to reduce FDA enforcement actions, reduce market shortages, reduce treatment delays, and increase patient safety within the community.

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Dedication

I dedicate my DBA to my wife, Jennifer Sousa, and my sister-in-law, Emmarie Burger. You have taught me love, compassion, a passion for life, and above everything else, never to give up. Your love and support surround me, motivating me to climb mountains and achieve dreams.

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Section 1: Foundation of the Project

Background of the Problem

The U.S. Food and Drug Administration (FDA) regulatory framework has become broader and more complicated as biotechnology (biotech) products have become more technologically advanced. FDA enforcement actions do not benefit the biotech firm, employees, the patient's treatment, or drug availability. The biotech industry includes products such as medical devices, pharmaceuticals, combination devices, vaccines, and biologic market segments. The FDA (2023b) regulates the biotech industry. FDA regulations are enforced through investigations, which could result in multiple types of written deficiency notifications that indicate corrections are necessary (Mohite et al., 2021; Rathore et al., 2023). FDA enforcement actions can cause a poor reputation, financial penalties, and loss of profit (Almeter et al., 2022; Saini et al., 2022). From 2010 to 2020, 48% of FDA warning letter enforcement actions were issued to the drug and device biotech industry for noncompliance with current good manufacturing practices (cGMP; Rathore et al., 2023). Enforcement actions can lead to a manufacturing disruption while attention is focused on correcting the violations (Blankart & Felder, 2021). Product market shortages create poorer patient medical outcomes, affect patient access, force treatment substitutes, delay treatments, and reduce patient safety (Blankart & Felder, 2021; FDA, 2025; Fellows et al., 2022). Noncompliant regulatory strategies that do not meet the U.S. FDA quality federal regulations have the potential for adverse medical outcomes for patients.

Business Problem Focus and Project Purpose

The specific business problem was that some biotech managers do not have effective strategies to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations. Therefore, the purpose of this qualitative pragmatic inquiry was to explore effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations. The targeted sample population consisted of six biotech managers with five or more years of experience in the biotech industry, residing in the U.S. central region, who had successfully used effective quality management strategies to develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations. Data sources for this study consisted of semistructured interviews and public data from the U.S. FDA data dashboard of enforcement actions. Methods used to gain access to participants were professional contacts, word of mouth, and professional associations. Deming's (1986) total quality management (TQM) was the conceptual framework for this research project.

Research Question

What effective quality management strategies do biotech managers use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations?

Assumptions and Limitations

Assumptions

Ataro (2020) defined assumptions as claims researchers hold about the world without verification. I assumed the participants would answer the open-ended interview questions based on their truthful experiences and responses. I also assumed that the data collected in the project would be accurate because each participant was an expert who had been successful using effective quality management strategies within the biotech industry. Finally, I assumed participants would provide bias-free responses and accurately represent their experiences.

Limitations

Levitt (2021) defined limitations as an objective weakness and an uncontrollable threat to the project's validity. One limitation in the current study was that the subjects were volunteers and could withdraw from the project. The participants who finished the project could have provided a skewed representation of effective strategies. A second limitation was that this study was limited to a qualitative pragmatic inquiry project, so individual strategies identified and explored were unique to the participants' experiences. A third and final limitation was that I targeted midwestern biotech managers, which limited the research project to a small segment of biotech firms.

Transition

In Section 1, I discussed the focus of the business problem, project purpose, research question, and assumptions and limitations. The project was a qualitative pragmatic inquiry. Purposive sampling consisted of six biotech managers with five or more years of experience in the biotech industry, residing in the U.S. central region, who had successfully used effective quality management strategies to develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations. Deming's TQM was used as the conceptual framework. In Section 2, I provide a review of professional and academic literature, Deming's 14 points of TQM, the biotech market shortage, the history of the FDA and regulation development, and U.S. FDA public enforcement data on the biotech industry. In Section 3, I address the research project methodology, project ethics, the nature of the project, the population, sampling, participants, data collection activities, interview questions, data organization and analysis techniques, and reliability and validity. Finally, in Section 4, I present the findings and conclusions, business contributions, recommendations for professional practice, implications for social change, recommendations for further research, and the conclusion.

Section 2: The Literature Review

A Review of the Professional and Academic Literature

The purpose of the project was to explore effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations. Findings may help managers in the biotech industry develop and improve compliant regulatory strategies to prevent U.S. FDA enforcement actions. In the biotech industry, scholars have reported that quality management maturity positively correlates with decreased drug shortage and increased drug delivery performance (Fellows et al., 2022). Deming (1986) posited that the strategies of the TQM 14 points of top management transform an organization through continuous improvement, increased quality, and higher profitability. Ali and Johl (2022), Babatunde (2021), and Nienaber and Martins (2020) have found that applying the flexible framework of the TQM 14-point strategies in management commitment, organizational performance, customer focus, training/ learning, and on-the-job experience has led to continuous improvement and successful change management programs.

The literature review aligned with the project's research question, the problem, and purpose statement. The literature review was organized by (a) Deming's TQM strategies, (b) market shortage, (c) history of FDA and regulations, and (d) public U.S. FDA enforcement data. I used the Walden University online library. The databases used included EBSCO Discovery Service Research Starters, Emerald Management, Taylor & Francis Online, DOAJ Open Global and Trusted, Sage Journals, ProQuest Central, Gale Academic OneFile Select, EBSCO Open Access Journals, and Google Scholar. In addition, I used a collection of peer-reviewed journal articles, dissertations, and textbooks to strengthen the literature review. The keywords used when searching the databases included *quality*, *FDA*, *continuous improvement*, *FDA-compliant*, *Deming*, *TQM*, *quality management system*, *six sigma*, and *lean quality.* The literature review contains 118 references and 107 (91%) peer-reviewed journal articles. One hundred and three, or 87%, of referenced sources were published within five years of my expected research completion date.

Conceptual Framework

Deming developed TQM in 1986. Deming created a quality framework focused on continuous improvement, increased efficiency, and higher quality and profitability. The four major principles of TQM are (a) the 14 points of top management, (b) the seven deadly diseases that top management must cure, (c) the act model, and (d) the chain reaction quality implementation theories (Deming, 1986). The 14 points of top management are constancy of purpose, adopting the new philosophy, ceasing dependent inspections to achieve quality, working with one supplier to reduce costs, continuous improvement, on-the-job training, adopting and instituting leadership, driving out fear, breaking down silos, no slogans, no quotas, remove the annual rating system, institute education, and involve all workers in the transformation (Deming, 1986). Five of the 14 points were related to the current study: create a purpose for improving, adopt the new philosophy, continuous improvement, adopt and institute leadership, and involve all workers in the transformation.

Deming’s (1986) TQM provides a framework to continuously improve processes to meet customer needs. Deming’s 14-point model enables companies to engage in their work processes, meet customer expectations, and develop and maintain a competitive advantage (Ibegbulem, 2021). Deming’s 14-point framework transforms an organization through continuous improvement, higher quality, and minimizing non-value-added work (Wiwiek et al., 2020). Deming's 14-point framework supports the idea that quality is the critical control point for market differentiation and a primary factor in a company’s success (Deming, 1986; Ibegbulem, 2021). Deming's TQM concept was used in the current study.

Deming's 14 Points of Total Quality Management Strategies

Create a Purpose to Improve

One tenet of the TQM is to create a purpose for improving by engaging and empowering everyone in the company in the transformation. Boikanyo and Heyns (2019) indicated that higher employee engagement and empowerment in TQM-based companies lead to higher quality, higher customer satisfaction, and a sustained competitive advantage. For example, Tran et al. (2022) proposed a new engagement framework to create, maintain, and continuously improve work culture to meet customer needs, create a competitive advantage, and facilitate TQM principles. The framework consists of three categories: identify and plan, manage engagement, and sustain engagement (Tran et al., 2022). Similarly, in a quantitative study, Boikanyo and Heyns (2019) found that worker engagement positively correlates with a competitive advantage in TQM-based South African petrochemical companies. Similarly, Cucino et al. (2022) found increased individual and organizational performance because of increased employee engagement and empowerment programs in technology transfer professionals at Italian universities. In summary, research indicated that higher employee engagement and empowerment in TQM-based companies lead to higher quality, higher customer satisfaction, and a sustained competitive advantage (Boikanyo & Heyns, 2019; Cucino et al., 2022; Tran et al., 2022). Supporting TQM as a transformation framework, employee empowerment, and engagement practices can lead to higher quality, customer satisfaction, and competitive advantage.

Adopt a New Philosophy

TQM has been shown to have a positive relationship with continuous improvement and change initiatives in many industries. In three quantitative studies, TQM was shown to be significant in various aspects of the change initiative. Haffar et al. (2022) investigated the relationship between employee readiness, employee commitment to change, and TQM within industrial firms in Jordan. Haffar et al. found a strong relationship between employee readiness for change, employee commitment to change, and TQM success. In the sustainability space, Akanmu et al. (2023) studied the relationship between TQM and sustainability in Malaysian food and beverage companies. Akanmu et al. found a significant positive relationship between TQM and sustainability in continuous improvement, benchmarking, quality assurance, service design, and information/analysis. Finally, AlQershi et al. (2023) found a significant and positive effect on green sustainability, green creativity, and TQM when evaluating Malaysian manufacturing firms. TQM is relevant to change initiatives and continuous improvement strategies in multiple industries and regions worldwide.

Institute for on-the-Job Training

Training is essential for successful change within TQM. The TQM tenet of training is critical to continuous improvement, higher quality, and minimizing non-value-added work. In a systematic interpretive structural modeling study, Agrawal (2019) argued that training is a strategic element of TQM. Similarly, three studies highlighted the importance of training within TQM change programs. Budayan and Okudan (2022) researched moving 40 Turkish construction companies to continuous TQM improvement and found that employee training was the most significant strategic gap. Similarly, Puthanveettil et al. (2021) researched moving to TQM to improve patient health care in 40 hospitals in the Kollam district of India. Puthanveettil et al. found, among other principles, that training enhancements were needed to implement the change strategy. In the third study, Cavallone and Palumbo (2022) studied 15,958 European companies for employees' commitment to organizational excellence. Cavallone and Palumbo found that training and motivation were statistically significant, while employee involvement only marginally contributed. In conclusion, training is an essential strategy for successful change within TQM.

Institute Leadership

Institute leadership is one of the fourteen points of management outlined in TQM. Although leadership has been found to mediate TQM practices within an organization, the type of leadership differs between researchers (Bouranta, 2020; Sawaean & Ali, 2020;

Wagimin et al., 2019). Sawaean and Ali (2020) found that organizational performance and entrepreneurial leadership mediate TQM practices. Tawaean and Ali (2020) conducted a quantitative study that surveyed 384 small and medium enterprise business owners from Kuwait to understand the relationship between organizational performance and TQM practices. In contrast, Wagimin et al. (2019) found that transformational and transactional leadership mediates TQM practices and employee performance. Similarly, in a third research study, transformational leadership mediated TQM practices in a survey of Greek ISO 9000 (International Standard Organization)-certified manufacturing and service sector companies (Bouranta, 2020). Although Bouranta (2020), Sawaean & Ali (2020), Wagimin et al (2019) agree that leadership is a mediating component of TQM practices, the type of leadership required varies between entrepreneurial and transformational leadership.

Additionally, researchers have found that lower levels of management leaders mediate the success of TQM projects. In a quantitative study, Anh et al. (2021) studied the effect of floor-level leadership and the success of TQM change projects within 304 manufacturing plants from 13 countries. Ahn et al. (2021) found that floor leadership positively impacted the quality of information and performance, which moderated the success of TQM. Similarly, in a second quantitative study of 203 leaders from manufacturing and service firms in Ethiopia, Yadeta et al. (2022) found that servant and transactional leadership have a positive direct effect, while transformational leadership has a positive indirect effect on TQM project implementation. In a third study, Shokri (2019) studied the younger generation and expressed concerns about their ability to lead

TQM change projects. In a recent study of future early career operations leaders in the UK, Shokri (2019) opines that a lack of leadership confidence, a preferred participatory leadership style, and team-driven decision-making create a concern for TQM project failure. Leadership at multiple levels of management is essential to successful TQM change projects.

Deming (1986) posited that leaders improve performance, quality, and output while making employees proud. Global research from manufacturing, service, petroleum, and operational business sectors indicates that young leaders, floor leaders, managers, and top management leadership styles influence the success of TQM projects (Anh et al., 2021; Bouranta, 2020; Sawaean & Ali, 2020; Shokri, 2019; Wagimin et al., 2019; Yadeta et al., 2022). Leadership is a critical component of TQM success; the style of leadership and the management level of the leader are not as critical.

Involve all Workers in the Transformation

Another of the fourteen points of TQM is to involve all workers in the change, to increase employee engagement. Three quantitative studies from the Middle East, Asia, and South Africa studied employee engagement, and none agreed on the most significant influences of employee engagement. In the first study, Ababneh (2021) studied 153 senior hotel employees in Jordan and opined that a hierarchical leadership style and quality initiatives positively influence employee engagement. In a second study, Durairatnam et al. (2021) studied 100 export apparel manufacturers in Sri Lanka and posited that teamwork, training, and employee involvement were the most important to employee engagement. Finally, in a study evaluating 858 participants involved with industrial industries in South Africa, Nienaber and Martins (2020) found that organizational strategy and commitment are predictors of employee engagement. The findings were diverse, but all indicated a positive correlation between management style and employee engagement. Other factors, like cultural norms, may influence the management style. More research is needed to better understand the relationship between increased employee engagement and management style.

TQM

TQM is a flexible change framework with specific points to consider during planning. It is not a prescriptive equation for any change program. A criticism of TQM is that it is more of a mindset and less of an organizational quality improvement plan (Psarommatis et al., 2020). Similarly, Aquilani et al. (2017) opined that TQM does not have an established, shared, or standardized model. Many variables exist within the biotech industry, and a prescribed change equation may not be flexible enough to work in the industry. On the contrary, the criticisms and research have indicated that certain TQM practices benefit operational performance and change programs.

Four studies highlight the critical components of TQM in operational and change programs. In the first qualitative study, Babatunde (2021) mapped the complex technical and soft social TQM aspects of Industry 4.0 and employee learning. Working experience was the differentiator in developing a better appreciation for the social (soft) and technical (Hard) TQM aspects of work (Babatunde, 2021). In the second study, Acquah et al. (2023) found that the TQM practices of management leadership, knowledge management, training, customer focus, and strategic quality planning influence operational performance in 154 health facilities in Ghana (Acquah et al., 2023). Similarly, in the third study, top management commitment, customer focus, training and learning, technical expertise (big data and analysis), continuous improvement, and service are important categories in TQM literature (Ali & Johl, 2022). Finally, a fourth study indicates that leadership commitment, infrastructure, technical expertise, the application of test technology, employee motivation, and training were found to significantly impact a firm's green change initiatives (Azam et al., 2023). Although no correlation can be drawn from the research studies, management commitment, customer focus, training and learning, and technical expertise are common concepts throughout the research. Although there is no specified TQM equation, considering the 14 points of change within TQM creates a more flexible framework for continuous improvement.

Quality Management System

The quality management system (QMS) theory was also considered for this project, but was less beneficial. The QMS constructs certification to international standards through written processes, while the TQM framework is predicated on employee engagement, operational efficiencies, and increased quality. In a review of 263 quality management research papers from 2000 to 2017, Kumar, P. et al. (2018) opine that 90% of TQM research articles positively impacted a firm's bottom line compared to 70% of QMS research articles. A deeper look into recent quantitative research confirms that TQM improves organizational performance, and in some cases, an established QMS improves the TQM outcome. In a mixed-method study, Hassis et al. (2023) found that the TQM constructs significantly impacted corporate social responsibility (CSR) and corporate sustainability (CS) (Hassis et al., 2023). In a second study of 287 small to mid-sized Finnish firms, Lepistö et al. (2022) found that QMS certification of small and industrial firms improved the dimensions of TQM, while medium-sized firms and firms in the service sector did not improve TQM dimensions. Similarly, Benzaquen and Narro (2023) found that ISO 9001-certified companies scored higher in the TQM dimensions in 259 Peruvian goods companies certified to ISO 9001 and not certified to TQM for operational performance during the COVID-19 global pandemic. In conclusion, research indicates that the TQM concept overall is more advantageous to the bottom line, strongly supports CSR, and can be supported by the QMS theory. The TQM concept applies to this project.

Biotech Market Shortage

Non-compliant regulatory strategies that do not meet the FDA quality regulations can result in product shortages. The market shortage is often caused by multifaceted scenarios that are challenging to monitor. Product market shortages create poorer patient medical outcomes, affect patient access, force treatment substitutes, delay treatments, and reduce patient safety (Blankart & Felder, 2021; FDA, 2025; Fellows et al., 2022). In the first study, 27 interviews were conducted with pharmaceutical business and trade association professionals to examine how firms strategize to prevent drug disruption from the uncertainty of a geopolitical event (Roscoe et al., 2020). Roscoe et al. (2020) opine that case scenario planning in large multinational companies was the most prevalent strategy, while small and medium-sized companies deployed the wait-and-see strategy. In a second study, Ravela et al. (2022) reviewed Finland, Sweden, Norway, Spain, and the

U.S. drug shortage databases from January to September 2020 and found that the databases were inconsistent. Specifically, Ravela et al. (2022) found that of 5132 drug shortage reports, 52% occurred in a single country, and 1% occurred in all five countries. The strategy of monitoring and planning for biotech product shortages is risky and could be improved.

Biotech companies can improve and develop market shortage strategies. Three research studies evaluate the cause and improvement strategy of biotech shortages. In the first study, Musazzi et al. (2020) found that market shortages are caused by supply-related issues, such as manufacturing, regulatory, logistics, distribution, and demand-related issues. In the second study, Patel et al. (2023) found that supply chain improvements include better transparency and traceability, continuous manufacturing over batch manufacturing, strategic stockpiles, vertical supply chain integration, and risk management focus areas for improving resilience and decreasing drug costs. In the third study, Fellows et al. (2022) performed a quantitative benchmarking study of over 200 global pharmaceutical manufacturers. Fellows et al. (2022) found that quality management maturity (QMM) principles significantly and positively correlated with delivery performance. The five QMM scales include spare parts for bottleneck machines, statistical process control, quality risk management process, corrective and preventative action (CAPA) effectiveness, and 5S practices (sort, set in order, shine, standardize, sustain) procedures. Harmonizing biotech product shortage databases worldwide, decreasing manufacturing disruptions, regulatory actions, and supply chain concerns, and improving QMM could improve the current strategy and decrease the risk of biotech product shortages.

History of the FDA and Regulation Development

Biotech regulations in the U.S. evolved alongside public health crises. Four early examples are the 1902 Biologics Control Act, the 1906 Pure Foods and Drug Act, the 1906 Federal Food, Drug, and Cosmetics Act (FD&C), and the 1962 Keffauer-Harris Act (FDA, 2023a). In a historical analysis, Esparza et al. (2020) assert that two tetanus outbreaks among animal vaccine manufacturers of the smallpox vaccine in 1901 led to the passage of the Biologics Control Act of 1902. The Biologics Control Act required manufacturing licenses for vaccines. In a review of FDA history, there were several infant deaths and patient adverse reactions relating to unsubstantiated claims and a lack of ingredient declaration that led to the Pure Food and Drug Act of 1906 (Wesley et al., 2021). This regulation laid the pathway for modern FDA regulations and was the first to protect consumers directly by enforcing ingredient disclosure, labeling, and drug purity (Wesley et al., 2021).

There was a public health crisis with the elixir sulfanilamide disaster in 1937 (Swaters et al., 2022). A poisonous, undeclared, non-active ingredient chemical compound (diethylene glycol) killed more than 100 people in the U.S. and brought support to pass the FD&C (Coca et al., 2022). The FD&C Act required pre-approval, established drug identity and quality standards, toxicology testing, authorized FDA inspections of manufacturing facilities, and allowed court injunctions and seizures. In a historical review, Waggoner and Lyerly (2022) found that the early 1960s thalidomide drug scare led to the Kefauver-Harris Act of 1962. Swaters et al. (2022) agree that thalidomide was approved in many other countries for the prevention of nausea and morning sickness, given to pregnant patients, and later found to cause congenital disabilities. Although Thalidomide was not approved for distribution in the U.S., the manufacturing company distributed two million pills through investigational use, and the FDA recalled the drug. The Keffauer-Harris Act established development requirements, proof of effectiveness, modern clinical trial regulations, animal testing requirements, and cGMP regulations (Almeter et al., 2022; Lee, 2022; Swaters et al., 2022; Waggoner & Lyerly, 2022). The Keffauer-Harris Act of 1962 established the framework of the modern FDA regulations for developing new pharmaceutical, biological, and medical device products within the U.S. (Coca et al., 2022). Medical device classifications and cGMPs were established in 1976 by the Medical Device Amendments Act (Walker, 2018). Biotech regulations in the U.S. evolved alongside the public health crisis, setting the foundation for today's regulatory pathways.

This research project is focused on the biotech industry, specifically human drugs, biologics, and medical devices regulated by the FDA Centers for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH). The U.S. FDA protects public health in human and veterinary drugs, biologics, medical devices, food, cosmetics, radiation, and tobacco products (FDA, 2023b). The FDA is also responsible for advancing public health by increasing the speed of innovation, effectiveness of treatment, patient safety, and reducing the cost of treatment.

Modern Biotech Regulations

Protecting patient safety and preventing the next health crisis is challenging and imperfect. Global variations in disease classification, politics, and established precedents have led to regulations that do not always correlate with patient safety. In the 1960s, there were multiple global standards for disease classification during the global thalidomide disaster (Lee, 2022). Lee's (2022) research found that disease surveillance infrastructure varied among countries and influenced how disease outbreaks are determined. Specifically, various coding methods of similar thalidomide data led to different conclusions about patient safety. In a second example, politics, specifically the national debate over reproductive rights, have played a role in the regulation of the drug mifepristone within the U.S. Adashi et al. (2022) studied the history of mifepristone and found that there is political interference with the FDA as a regulatory authority, which has led to 38 congressional bills and 11 congressional hearings from 1989 to 2020 (Adashi et al., 2022). Although mifepristone is safe and effective for the termination of pregnancy, approval has been embedded in the national debate over reproductive rights. In a third example of FDA regulations not correlating to patient safety, Swaters et al. (2022) conducted a historical review of non-human animal testing to observe and reduce the toxicity risks of approved drugs in humans. Swaters et al. (2022) found correlation issues with extrapolating a risk reduction in humans from non-human animal studies. Science has evolved to understand that toxicity testing on animals during drug development does not correlate to toxicity in humans and may not lead to improved patient safety (Swaters et al., 2022). The U.S. FDA was created to protect patient safety, and global practices in disease classification, politics, and antiquated scientific precedence have led to some regulations that do not necessarily protect patient safety.

Biotech Product Development Regulations

The FDA regulates biotech product development. New product introductions (NPIs) are an essential source of revenue for medical devices and biotech products. U.S. FDA regulations challenge biotech product development strategies. Regulations limit innovation due to process development, design for manufacturability, process validation, design transfer, and supporting evidence required for regulatory submissions (Slattery et al., 2022). NPIs and changes to on-market biotech products often require additional FDA approvals. It is not very easy to establish compliant NPI quality strategies.

Three research groups evaluated compliant NPI strategies and found that engineering controls, lean methodology, and continuous manufacturing reduce cost and innovate NPI. Boylan et al. (2021) found that a subset of engineering design outputs is essential for the safety and efficacy of the biotech product in a medical device case study. The subset of design outputs is proprietary, needs additional reliable engineering controls, and must be documented and traced to the larger design during FDA inspections to maintain compliance. In the second study, Slattery et al. (2022) researched compliant product development strategies and lean methodology for the medical device NPI process. Slattery et al. (2022) found that concurrent engineering could solve the traditional end-to-end stage-gate NPI. Concurrent engineering reduces the time and cost of NPI while maintaining compliance with U.S. regulations. In a third study, Domokos et al. (2021) reviewed the NPI using continuous manufacturing over batch manufacturing.

Domokos et al. (2021) found that continuous manufacturing is cheaper, more flexible, has a higher level of quality, and requires a deep understanding of the end-to-end process during product development from small batch to market-scale production. U.S. FDA regulations can cause limited innovation opportunities for biotech firms. However, three continuous improvement-compliant NPI strategies to consider during development and NPI are engineering controls, lean methodologies, and continuous manufacturing techniques.

Biotech Clinical Trial Regulations

Clinical trials are often required before launching an NPI. Clinical trials demonstrate that biotech products are safe and effective in humans. Clinical trials and biotech approvals are becoming more technical and have more complicated regulatory approval pathways. Alzheimer's disease is an example. New drug approvals have targeted the accumulation of amyloid in the brain. New clinical studies are focused on therapy prevention before disease development (Huang et al., 2023). Mirasol (2020) reported on emerging trends in cell and gene therapy and the difficulty with the FDA regulatory pathway to clearance. New FDA guidance provides a cell and gene therapy framework but lacks cGMP recommendations or harmonization.

Responding to the complexities and slow review of new and innovative biotech products, the FDA increased the number of reviewers and decreased approval review times. To increase the speed of review within the U.S., the Prescription Drug User Fee Act of 1992 (PDUFA) was passed (Almeter et al., 2022). PDUFA established an industry payment for expedited drug application review. Shortly after, the FDA Safety

Information Act (FDASIA) expanded industry pay to expedite the review of medical devices. Biotech firms privately pay for the review and approval of new products. Wang and Wertheimer (2022) conducted a review of biotech products that were expedited because of manufacturing payment and found that it shifted resources at the FDA from post-market drug data reviews to new drug applications. In 1992, 53% of the FDA budget was pre-market review; in 2003, it was 79% (Wang & Wertheimer, 2022). There is concern that PDUFA and FDASIA negatively impact biotech product quality because the FDA focuses on industry payment for new product review and approval, not patient safety in the field.

Perhaps more important than the timing of the clinical trials and NPI approvals is the data and equality of participants within the clinical data. The FDA was formed to protect the public's health by ensuring safe and effective products and safeguarding patient safety (FDA, 2023b). Patients are diverse, and modern clinical trials have excluded pregnant women and diverse populations. Waggoner and Lyerly (2022) found that the origin of the exclusion of pregnant women in clinical trials originated from a protectionist cultural position after the 1960s thalidomide drug disaster. Waggoner and Lyerly (2022) indicated that pregnant women are less safe today because they have been excluded from clinical trials. In 2018, the FDA recognized the need to include pregnant women in clinical trials in draft guidance that has never been finalized (FDA, 2019). Salloum et al. (2023) researched 22 U.S. vaccine clinical trials between 2018 and 2023 and found that 6% of trials were designed to include pregnant women. None were sponsored by industry (Salloum et al., 2023). Although the U.S. FDA has provided a regulatory framework to include pregnant women in clinical trials, few are included.

Similarly, modern clinical trials have excluded diverse participants. Underrepresented populations in clinical trials may lead to drug safety or effectiveness concerns. In 2014, the FDA released guidance detailing expectations for race and ethnicity in clinical trials (FDA, 2024a). Nguyen et al. (2023) researched 12,334 clinical trial patients enrolled in breast cancer clinical trials from 2010 to 2020 and found that 73.8% of participants were Caucasian. Nguyen et al. (2023) determined that there was no significant change in enrollment diversity between 2010 and 2015 before the FDA guidance and from 2016 to 2020 after the FDA guidance (Nguyen et al., 2023). Similarly, Matthew-Onabanjo et al. (2023) researched clinical patient diversity from 2015 to 2020 in clinical trials and found that 80.8% of the 704 bladder cancer participants and 69.8% of the 5202 prostate cancer trial participants were Caucasian. In the U.S., black men are 70-80% more likely to be diagnosed with prostate cancer and 2.5% more likely to die from the diagnosis than Caucasian men (Matthew-Onabanjo et al., 2023). Studies indicate that clinical trial participation does not represent diversity within the patient population, and pregnant women are not represented. In conclusion, modern clinical trial regulations have changed: clinicals have become more technical, regulatory approval pathways are more complicated, firms can now pay for expedited review, and trials still lack patient diversity.

Biotech Product Realization Regulations

Biotech product realization, or manufacturing, is regulated by the FDA. Firms engage in strategies during product realization to improve U.S. FDA inspection outcomes. Three theories to improve U.S. FDA inspections of biotech manufacturing are: operational excellence (OPEX), strategies to reduce costs of poor quality, and certification to international standards. In the first strategy, Eich and Friedli (2021) researched connections between regulatory inspection outcomes and manufacturing operational excellence programs. Eich and Friedli (2021) found that OPEX programs focusing on TQM improvements are more likely to receive favorable inspection outcomes. In a second research study, Faciane et al. (2021) evaluated quality TQM strategies to reduce the cost of poor quality. In the qualitative study, Faciane et al. (2021) found that essential themes were TQM principles of continuous improvement, quality assurance, considering all employees as agents of quality, communication, accountability for quality, and training. Contrary to the first two studies, Casteleiro and Mendes (2022) studied 219 firms and the influence of quality with and without ISO-9001-based quality management systems certification. Casteleiro and Mendes (2022) found that the staff was significantly more engaged and empowered with an ISO-9001 QMS certification (Casteleiro & Mendes, 2022). TQM principles and QMS certification to the ISO standards are two strategies to improve U.S. FDA inspection outcomes.

Harmonizing and continuously improving cGMPs are two additional theories that can improve quality outcomes. cGMP requirements include contemporaneous signatures, documented standard work in standard operating procedures (SOPs), quality control procedures, training, and record retention. cGMP is a biotech regulatory requirement. In the first study, Kumar et al. (2023) compared the regulatory requirements for generic drug manufacturing in the U.S., Japan, and the EU. Kumar et al. (2023) found that each regulatory authority created cGMP requirements to protect patient safety, which are significantly different from each other; requirements for facilities, equipment, production processes, and record-keeping varied. Global harmonization of cGMPs would simplify and improve compliance. In a second study, Alparslan (2022) studied cGMP practices and adjustments during the COVID-19 pandemic. Alparslan (2022) found that biotech companies improved the quality system and provided additional protection for employees and product safety. Continuous improvement of cGMPs improved patient and employee safety during the COVID-19 pandemic. Global harmonization and continuous improvement of cGMPs are two critical concepts that can improve regulatory outcomes.

General continuous improvement strategies in product realization are another consideration for improving compliance with FDA regulations. Continuous improvement of quality planning, understanding barriers, and management opinion on the quality system are examples of general improvement strategies. Kaur and Kaushik (2022) studied quality planning in Indian pharmaceutical companies to examine how the companies plan, include continuous improvement goals, and implement TQM programs. Kaur and Kaushik (2022) found that pharmaceutical companies in India rely on traditional planning methods, not those driven by continuous quality improvement projects. In a second study, McDermott et al. (2021) studied barriers to quality continuous improvement. In a survey of 80 professionals within the Irish pharmaceutical industry, the main obstacles to continuous improvement were stringent regulations, fear of extra non-value-added compliance work, and risk-averse culture due to regulatory compliance (McDermott et al., 2021). Finally, Gremyr et al. (2021) conducted mixed-method research from eight organizations and twelve interviews to better understand management perceptions of quality management systems (QMS) regarding respect, cost, and strategic importance. Gremyr et al. (2021) identified three types of QMS orientation: business management, improvement, and compliance, and opine that a compliance-oriented QMS leads to higher costs and little respect. Further evaluation indicates that documentation negatively influences management perceptions, while standardization is perceived to add more value. Creating and planning quality continuous improvement projects focusing on business management and improving risk aversion and compliance could improve quality outcomes.

Some U.S. FDA regulations limit innovation within biotech manufacturing. In three research studies, higher-quality production was not pursued because of the regulatory burden. In the first study, Domokos et al. (2021) reviewed the pharmaceutical innovation of continuous manufacturing over batch manufacturing and found that continuous manufacturing is cheaper, more flexible, and has a higher level of quality. Domokos et al. (2021) also found that continuous manufacturing requires a significant regulatory burden, specifically a deep end-to-end process understanding from small batch to scale-up. Similarly, in a second study, Byrne et al. (2021) found that the proper fix to a problem is not always pursued due to regulations. Byrne et al. (2021) opined that a drug shortage of acetaminophen tablets was caused by pill breakage during production; the pills were too soft. The tablet fix, making the tablets harder, could not be executed because it would require years of regulatory studies and additional submissions. Due to the regulatory requirements, the team changed the manufacturing handling system to reduce tablet breakage stress. Finally, in a third study, the biotech digital transformation, quality 4.0, was challenging in the U.S. regulatory environment. Chen et al. (2020) conducted a literature review of quality 4.0 in the pharmaceutical biotech industry. Chen et al. (2020) found that building a digital twin simulation model has the promise of being accurate, but it is difficult to get regulatory approval in the U.S. FDA regulations limit innovation within biotech manufacturing.

In conclusion, focusing on the product realization processes and regulations can improve inspection outcomes. Strategies that focus on reducing the cost of poor quality, OPEX, and international standard adherence have been shown to have improved inspection outcomes (Casteleiro & Mendes, 2022; Eich & Friedli, 2021; Faciane et al., 2021). Harmonizing and continuously improving cGMPs improve quality outcomes (Alparslan, 2022; Kumar, J. et al., 2023). Understanding the regulatory approval pathway before undertaking large continuous improvement projects can inform innovation strategy and limit non-value-added work within product realization (Kaur & Kaushik, 2022; McDermott et al., 2021). Effective quality management strategies that meet the FDA quality federal regulations can improve inspection outcomes and create production efficiencies.

Biotech Postmarket Regulations

Post-market U.S. FDA Regulations require patient safety reports, complaint investigations, and field actions for defective biotech products. There are concerns from four research studies that the biotech products on the market are not safe and effective. In the first study, Almeter et al. (2022) reviewed post-market drug quality literature and found defects and safety concerns with the purity of FDA-approved drugs. In a second study, Veronin et al. (2020) found evidence of erroneous data impacting patient safety in the FDA adverse event reporting system (FAER). In a third study, drug names were evaluated for accuracy in the publicly available data from the FDA Adverse Event Reporting System (FAER) patient safety database, and 19 types of data integrity errors were categorized (Veronin et al., 2020). Errors originated from abbreviations, upper and lowercase letters, trailing or leading whitespace, misspellings, and name combinations. Veronin et al. (2020) found data integrity, inaccurate research, and patient safety concerns. In the final study, Watson et al. (2021) reviewed U.S. FDA patient harm reports from 2019-2020 and found 2155 reports identifying 63 compounding errors. The most frequent errors were cGMP errors for concentration and contamination errors in compounding (Watson et al., 2021). Four studies indicate that data integrity and errors lead to safety and effectiveness concerns for marketed biotech products.

Impurities have also been found in marketed pharmaceutical products. Two independent laboratories, the University of Kentucky Drug Quality Study (DQS) and Valisure LLC, have independently tested FDA-approved biotech products for patient safety concerns. In the first study, Sunscreen was evaluated by Valisure LLC and found to be contaminated with the carcinogenic benzene compound (Hudspeth et al., 2022). In the second study, Isaacs et al. (2023) found impurities in some measles, mumps, and rubella vaccines, suggesting that the manufacturing process may not be wholly controlled and that the vaccines contained unknown impurities. In both cases, the FDA was informed through a citizen's petition. U.S. post-market regulations and cGMP manufacturing requirements add layers of risk mitigation but may not ensure purity and that biotech products are safe and effective. In conclusion, errors in patient safety databases, summaries of patient harm events, and evidence of drug impurities are reasons to be concerned that biotech products are not all safe and effective.

U.S. FDA Enforcement of Public Data on the Biotech Industry

The FDA is authorized to conduct announced and unannounced quality inspections on biotech firms. Inspections begin with Form 482 and conclude with objectionable observations printed on Form 483 (FDA, 2025). From 483 observations, it can become a warning letter if the biotech firm does not address it acceptably. Enforcement actions include warning letters, untitled letters, product seizures, injunctions, and criminal prosecution (FDA, 2025). Understanding the trends of FDA observations is advantageous to developing or continually improving effective quality management strategies that meet the FDA quality federal regulations. Dmour (2023) reviewed 141 U.S. FDA compounding pharmacies' warning letters from 2017 to 2022 for cGMP violations and found that adulterated products and misbranded product violations were the most common. Dmour (2023) found that 78% of the warning letters resulted from a lack of sterilization, 73% from a lack of personnel qualifications, and 60% from a lack of cleaning.

In addition to research studies, the FDA publishes all inspection violations in a public database. The FDA keeps records of audit violations from 2008 to 2024. The public database was downloaded to evaluate biotech Form 483 observations on June 16, 2024 (FDA, 2024b), to better understand FDA biotech observations. Two hundred forty-nine thousand seven hundred seventy-seven were sorted into ten categories: 1) biologics, 2) bioresearch monitoring, 3) devices, 4) drugs, 5) food, 6) human tissue for transplant, 7) part 11 (computer system validation), 8) parts 1240 and 1250 (food microbiology), 9) radiological health, and 10) veterinary. Three categories: food, parts 1240 and 1250, and veterinary, were excluded because the data points do not reflect the biotech industry. Ninety-nine thousand, two hundred eighty-four FDA observations were made, of which 483 observations were written to the biotech industry between 2008 and June 28, 2024 (FDA, 2024b). The top five observations for each of the seven biotech categories are listed (see Table 1). Medical devices and drugs are the top two biotech categories. Twenty-five percent of FDA 483 observations are focused on 16 top categories (see Table 2). Medical device corrective and preventative action (CAPA) investigations and post-market complaint files comprise the highest number of observations at four percent each. Drug cGMP violations are four of the top five. Drug cGMP violations comprise five percent of the FDA's 483 observations between 2008 and June 2024 (see Table 2).

Table 1

Observations Given to the Biotech Industry Between 2008 and 2024

Number	Category	Number of citations	Top five observations per category	Number by observation
1	Biologics	4,397	21 CFR 606.100(b)	1,010
			21 CFR 606.160(a)(1)	497
			21 CFR 606.100(c)	368
			21 CFR 606.160(b)	212
			21 CFR 606.60(a)	204
2	Bio research monitoring	6,814	21 CFR 312.60	1,887
			21 CFR 312.62(b)	1.034
			21 CFR 312.62(a)	345
			21 CFR 56.115(a)(2)	283
			21 CFR 312.66	280
3	Devices	46,466	21 CFR 820.100(a)	3.905
			21 CFR 820.198(a)	3,522
			21 CFR 820.22	1,983
			21 CFR 820.30(g)	1,786
			21 CFR 820.75(a)	1,719
4	Drugs	36,667	21 CFR 211.192	2,343
			21 CFR 211.22(d)	1,968
			21 CFR 211.100(a)	1,475
			21 CFR 211.25(a)	1,280
			21 CFR 211.160(b)	1,194
5	Human tissue for transplant	4,178	21 CFR 1271.47(a)	483
			21 CFR 1271.75(a)(1)	299
			21 CFR 1271.50(a)	293
			21 CFR 1271.180(a)	183
			21 CFR 1271.260(e)	162
6	Part 11 (computer system validation)	221	n/a	194
			21 CFR 11	27
7	Radiological health	541	21 CFR 1002.13	92
			21 CFR 1002.10	43
			21 CFR 1010.2(c)	32
			21 CFR 1010.2(b)	28
			21 CFR 1002.30(a)(2)	21

Note. Adapted from the U.S. FDA data dashboard inspections public data (FDA, 2024b).

Table 2

Top 16 Categories of Observations Given to the Biotech Industry Between 2008 and 2024

Category	Top observations	Description	Number of observations	Percentage
Biologics	21 CFR 606.100(b)	General responsibilities of clinical investigators	1,010	1%
Bio research monitoring	21 CFR 312.60	General responsibilities of clinical investigators	1,887	2%
	21 CFR 312.62(b)	Required clinical trial patient case histories	1,034	1%
Devices	21 CFR 820.100(a)	Establish and maintain procedures for implementing corrective and preventative action (CAPA)	3,905	4%
	21 CFR 820.198(a)	Complaint file requirements	3,522	4%
	21 CFR 820.22	Quality audit requirements	1,983	2%
	21 CFR 820.30(g)	Design control: design validation requirements	1,786	2%
	21 CFR 820.75(a)	Production and process controls: validation	1,719	2%
Drugs	21 CFR 211.192	cGMP: records and reports: production and control record requirements	2,343	2%
	21 CFR 211.22(d)	cGMP: quality control unit responsible for written and controlled procedures	1,968	2%
	21 CFR 211.100(a)	cGMP: identity, strength, quality, and purity written procedure requirements	1,475	1%
	21 CFR 211.25(a)	Employee experience and training requirements	1,280	1%
	21 CFR 211.160(b)	cGMP: laboratory control requirements	1,194	1%

Note. Adapted from the U.S. FDA data dashboard inspections public data (FDA, 2024b).

Transition

I reviewed professional and academic literature, Deming's 14 points of total quality management, the biotech market shortage, the history of the FDA and regulation development, and U.S. FDA public enforcement data on the biotech industry. In Section 3, I describe ethics, the nature of the project, data collection, data analysis, reliability, and validity. I discuss research methodology, project ethics, the nature of the project, the population, sampling, and participants, data collection activities, interview questions, data organization and analysis techniques, and reliability and validity. Section four contains findings and conclusions, the presentation of the findings, business contributions, recommendations for professional practice, implications of social change, recommendations for further research, and the conclusion.

Section 3: Research Project Methodology

The research methodology is discussed in Section 3. There are seven subcategories within Section 3: project ethics; the nature of the project; population, sampling, and participants; data collection activities; interview questions; data organization and analysis techniques; and reliability and validity of the research project. Section three concludes with a summary highlighting the main points of the research project methodology.

Project Ethics

As the researcher, I managed all aspects of the research project and data collection process. In the thematic analysis, my role included collecting the data; familiarizing myself with the data; generating codes; searching for themes; and reviewing, defining, and presenting findings (see Braun & Clarke, 2006). As Yin (2018) posited, collecting the data is a complex first step critical to the research project. The researcher can influence the data collection process through reactions and experiences with the subject (Wilson & Kim, 2021). The researcher needs to have a critical discipline of avoiding researcher bias called the reflexive concept (Braun & Clarke, 2024). I was an internal researcher because I had over 30 years of experience as an employee and manager in the biotech industry. I developed and continually improved compliant regulatory strategies that met the FDA quality federal regulations. I am an experienced biotech executive who has led quality and regulatory teams of various sizes and management levels. As a result, my perceptions may have influenced my research. My role in the data collection process included soliciting my professional network, conducting semistructured interviews, reviewing public FDA compliance data, and leaning into reflexive discipline to understand researcher bias.

As a researcher, I respected the Belmont Report. I developed an ethically aligned research protocol that complied with the Belmont Report. The Belmont Report is meaningful because it established the basic principles of ethical responsibility in research conducted on human participants (Robinson, 2019). The principles of the Belmont Report include respect for persons, beneficence, and justice (Office for Human Research Protections, 2024). I ensured that participants were treated with respect and protection, their well-being was considered, and they were treated fairly. In my project, I received participant consent, allowed participant withdrawal, ensured participant privacy and confidentiality, and protected the identity of the participants.

All participants gave consent and could have withdrawn from the project at any time. Withdrawal was managed by email at any time in the process. There was no monetary payment for participating in my study. The benefit of this research project was that it provided data and insights that could be valuable to biotech professionals. The participants' identities were masked, and the data were coded to protect participants' identities. Participation was confidential. The data were stored on a password-protected hard drive for at least five years, as required by Walden University. The final research project documentation included the Walden University IRB approval number: 10-23-24-1164010. As the researcher conducting this research project, I ensured that my project adhered to the ethical standards set by the Belmont Report.

Nature of the Project

Quantitative, qualitative, and mixed research methods were considered for this project. I chose the qualitative method to understand the meaning behind the business problem. The quantitative method was unsuitable for my research project. Quantitative methodology includes testing hypotheses (Saunders et al., 2019). Research that requires context to understand complex experiences best suits qualitative methodology (Wilson & Kim, 2021). The mixed-methods approach was inappropriate because it includes qualitative and quantitative methods (Nooraie et al., 2020). Combining both methods in the current project was unnecessary because the qualitative method alone was appropriate to answer the research question.

Qualitative pragmatic inquiry was used for my project because it allowed me to identify and explore a phenomenon. Inductive pragmatic inquiry is used to identify strategies, develop potential best practices, and discover themes within the qualitative data (Ramanadhan et al., 2021). I chose a qualitative inductive pragmatic inquiry design because I sought to explore effective quality management strategies to develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations.

Population, Sampling, and Participants

The targeted population consisted of six biotech managers with five or more years of experience in the biotech industry, residing in the U.S. central region, who had successfully used effective quality management strategies to develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations.

These participants were ideal for this research project because they possessed the experience needed to answer the research question. I gained access to participants through professional contacts, word of mouth, and professional associations.

Recruiting participants from existing professional connections is called snowball sampling. When investigators know the participants through professional affiliation and they see the research as important, they are more likely to participate and volunteer for the study (Negrin et al., 2022). This outreach strategy creates a working and professional relationship between the researcher and the participant (Dooley et al., 2022). I reached out through professional networks. I shared information about the research project and the informed consent form and helped participants prepare for the interview by answering questions and explaining the interview process. I scheduled a voice-only Zoom meeting for interested participants who met the inclusion criteria, and I had them sign the informed consent form. This method established a working relationship with participants before the semistructured interviews.

Purposeful sampling involves selecting participants who can provide rich data and experiences and meet selection criteria for the study (Sanders et al., 2022). The characteristics of the participants and purposeful sampling aligned with the project's overarching purpose. Data saturation occurs when no new themes emerge from the data (Naeem et al., 2024). Data saturation is reached when a researcher determines correlations between data sets and sees no new patterns or connections (Naeem et al., 2024). I used three strategies to ensure data saturation. These included semistructured interviews, member checking, and reviewing FDA public compliance data. Iterative interviews allow the researcher to obtain multiple-time-point data analyses. Iterative data collection and expansion on preexisting themes is an established framework for data saturation in thematic analysis (Naeem et al., 2024). Another method I used to ensure data saturation was member checking. Member checking occurs when the researcher shares their interpretation of the data with the participants to ensure accuracy and authenticity (Subedi, 2023). In qualitative research, member checking creates a trusting and collaborative relationship between the researcher and participants (Subedi, 2023). In conclusion, I justified the number of participants by ensuring data saturation. I achieved data saturation by purposefully sampling six participants, conducting semistructured interviews followed by member checking data, and reviewing FDA public compliance data until no new themes were identified. I reached data saturation after the third interview.

Data Collection Activities

As a researcher, I was the primary data collection instrument in this qualitative research project. The researcher is a critical tool for collecting data in qualitative research (Harerimana et al., 2024). I collected data through semistructured interviews and a review of public data from the U.S. FDA dashboard of enforcement actions of the biotech industry. Semistructured interviews allow gathering rich data from the same practice area within different companies (Buys et al., 2022). Semistructured interviews require good pre-planning and protocol development. Semistructured interviews allow research participants to have a more natural conversation and express ideas because of pre-planned, open-ended questions (Elhami & Khoshnevisan, 2022). Semistructured interviews were the primary data collection method for collecting rich participant data and included open-ended questions. The interviews were completed and provided in a setting that allowed for a more natural conversation.

I used an interview protocol (see Appendix) to guide the semistructured interviews and to mitigate bias. Interviews were conducted using Zoom and specifically using the audio recording functionality. The interview protocol ensured consistency in my approach by ordering a list of open-ended and secondary probing questions.

A stepwise data collection process was systematically conducted to ensure rich data collection. After obtaining IRB approval, I recruited members of my professional network and discussed the opportunity to participate in my research project. The participants were six biotech managers with five or more years of experience in the biotech industry, residing in the U.S.' central region, who have successfully used effective quality management strategies to develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations. Potential participants received an information sheet with details of the research project. When a potential participant showed interest, a Consent Form was provided. I scheduled the interviews once the Consent Form was signed and returned.

Interviews were conducted on Zoom audio and recorded with participant consent. I used the interview protocol to guide the semistructured interview to facilitate a deep, meaningful, open-ended conversation to explore the research participants' insights, experiences, and strategies. The audio recordings were meticulously transcribed and later used for member checking. Participants were invited to review transcribed recordings using member-checking. I interpreted the interview responses and provided a transcribed summary to ensure their perspective was represented. Member checking is a validation technique that enhances credibility and mutual trust between the researcher and the participant (Subedi, 2023). The interview process facilitates meaningful, reliable, and valid qualitative research data.

Reliability and validity were enhanced by member checking and data saturation. After recording the semistructured interviews, I used member checking as a reliability technique. Member checking involves reviewing the interview transcripts with the research participants and creating an environment to solicit their feedback on your interpretation (Subedi, 2023). Once the researcher receives the participant feedback, the researcher decides to change or keep the data interpretation (de Loyola González-Salgado et al., 2024). As previously stated, data saturation and methodological triangulation were used to validate the data.

Interview Questions

What effective quality management strategies do biotech managers use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations?

1. When you needed to implement a new strategy to meet FDA compliance with regulations, how did you identify that you needed to improve or that a change was needed?
2. What strategies do you use to maintain a compliant culture or a culture of quality?

3. How have you integrated compliant strategies into planning? Can you describe the type of planning, the timing, and the scale of change?
4. What leadership traits are important when managing a change program to FDA regulatory compliance?
5. How did you or your organization identify critical continuous improvement opportunities to ensure compliance with FDA quality requirements?
6. Please think about improvement strategies that worked. Why did those strategies work? Were they sustainable over time?
7. Please think about improvement strategies that were not successful. Why did those strategies not work?

Data Organization and Analysis Techniques

An appropriately labeled, password-protected, external hard drive houses data and emerging interpretations of my research data. Data is securely kept for a minimum of five years. Data is organized and includes audio files, text files, a research notebook, research logs and tables, and a reflexive journal. Conceptually, data software may include, but is not limited to, Microsoft Word, Microsoft Excel, and Microsoft PowerPoint. Data were organized to include audio recordings, maps, diagrams, and coding displaying qualitative data to allow for data immersion, initial coding, theme generation, theme definition, revisions, and reports. There is a logical, disciplined, and sequential process for data analysis. I determined key themes that correlated with current literature and the conceptual framework.

Thematic analysis (TA) was the foundational method for qualitative data analysis in this research project. The data will be coded and analyzed using the six-phase TA method (Braun & Clarke, 2006). TA is a systematic method for coding and developing themes or patterns of meaning in qualitative data (Braun & Clarke, 2021). As the primary data collection instrument, reflexivity and transparency are important for effectively collecting qualitative data (Kirsop-Taylor & Esmene, 2021). Reflexivity is understanding how my knowledge shapes the research values and methods (Braun & Clarke, 2021). I used reflexive thematic data analysis to mitigate my influence and bias on the meaning of the research project. There are six phases of TA.

Phase 1

In phase one, I familiarized myself with the depth and breadth of the data. Qualitative data analyses begin with the researcher's deep understanding of the data. Reviewing the transcripts and member checking are critical steps for phase 1. I generated the initial list of interesting ideas in phase 1.

Phase 2

In phase two, I generated the initial codes using the most basic elements of the raw data in a meaningful way related to the research phenomenon. In this phase, I coded the data into meaningful groups (Braun & Clarke, 2006). Working systematically through the entire interview transcript, I manually color-coded repeated patterns. It was critical in this step to code for as many patterns as possible. Coding for as many patterns as possible was critical to the iterative approach when evaluating data saturation.

Phase 3

I searched for broader themes within the code patterns in phase three. Coding was subjective, and as a researcher, I developed a flexible approach as my understanding of the data deepened (Braun & Clarke, 2024). Evaluating broader themes within the coded patterns was the beginning of a deeper understanding of the data.

Phase 4

I reviewed and further refined the themes in phase four. The reflexive TA model creates an environment for the researcher to reflect on their assumptions and position and probe into how the researcher's understanding may restrict the data (Braun & Clarke, 2024). Researchers use reflexivity in TA to evaluate researcher-specific bias and ensure that the data has been evaluated from alternate perspectives contributing to the research objective (Naeem et al., 2024). Visual thematic maps will aid a deeper understanding of the data and allow the researcher to evaluate the data from different perspectives (Braun & Clarke, 2006). Coding and themes may evolve during phase four. In this phase, I developed a thematic map, and the research themes evolved.

Phase 5

Once I developed a stable thematic map of the data, I defined and named the themes in phase five. I wrote a detailed analysis and definition of each theme and understood how it fit into the broader data (Braun & Clarke, 2006). By the end of this phase, each theme was discussed and defined in a few sentences. Names were concise and conveyed the sense of the theme.

Phase 6

Finally, in phase six, I produced a final report that included fully defined themes, extracts from the dataset, and a clear connection to the research question. The goal was to tell a complicated story easily with merit and validity (Braun & Clarke, 2006). I completed the final report to provide a convincing analysis beyond the dataset.

Reliability and Validity

Reliability

Reliability is defined as the dependability and consistency of research data and analysis. Conveying how the researcher reached the theoretical understanding of their data and how their data fits to answer the research question increases reader reliability (Howard-Grenville et al., 2021). Janis (2022) asserted that there are two strategies to establish reliability: method, source, triangulation, and code and meaning saturation to identify similar meanings. I used an interview protocol to enhance dependability, conducted semistructured interviews, reviewed publicly available FDA compliance data, and transcribed interview transcripts to conduct member checking.

Each participant was interviewed, and data were transcribed. Qualitative reliability is more robust when researchers are transparent with participants and create procedural trustworthiness through audio recordings and complete transcriptions (Coleman, 2021). I used multiple scholarly sources to provide insight to support claims and decisions.

Validity

In qualitative research, validity can also be thought of as the accuracy of the research findings. Validity is the credibility, rigor, and trustworthiness of the findings (Kakar et al., 2023). Member checking with data that has been analyzed ensures that the participant's voice is represented (de Loyola González-Salgado et al., 2024). Methodological triangulation is achieved by collecting data from multiple sources to improve the rigor and trustworthiness of research by cross-checking for consistency of understanding (Shea, 2022). I ensured the credibility and validity of the data using member checking, which included data interpretation and methodological triangulation, which includes using multiple sources in data collection.

I addressed transferability and ensured confirmability and data saturation in my project. Transferability refers to contextualizing the data to other settings or a researcher's interpretation (Kakar et al., 2023). Purposeful sampling, the description of the research context, data collection methods, and the research phenomenon addressed the transferability of my research. Confirmability- termed neutrality or unbiasedness in qualitative research ensures that research findings reflect participant perspectives (Kakar et al., 2023). Including direct excerpts from participants' interviews in the final report, practicing reflexivity, documenting decisions, providing an audit trail, and transparency will ensure confirmability (de Loyola González-Salgado et al., 2024; Kakar et al., 2023). Data saturation is achieved when codes and themes emerge (Janis, 2022). I used multiple strategies to enhance validity in my research project, including concepts of member checking, methodological triangulation, transferability, confirmability, and data saturation.

Transition and Summary

In this research project, I explored effective quality management strategies to develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations. I collected data by conducting semistructured interviews with purposefully sampled participants. Data analysis was conducted using reflexive TA. I described the project ethics, the nature of the project, the population, sampling, participant category, the data collection activities, the interview questions, the data organization and analysis techniques, the reliability, and the validity of the research project. In Section 4, I will present the findings of my research project, the business contributions and recommendations, implications for social change, recommendations for further research, and the conclusion.

Section 4: Findings and Conclusions

The purpose of this qualitative pragmatic inquiry project was to explore effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations. The data to determine the strategies came from semistructured interviews with six biotech managers and public data from the U.S. FDA data dashboard of inspections. The findings revealed four strategies: understand U.S. FDA enforcement actions and the business consequences of poor regulatory compliance, foster a quality culture, engage leadership support and engagement at all levels, and accelerate education and experiences.

Presentation of the Findings

The research question was the following: What quality management strategies do managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations? The data analysis of the interview transcripts resulted in 47 initial codes, 10 broader themes, and four emerging themes. Data were dependable because each theme/strategy and broader theme appeared in the six semistructured interviews (see Table 3).

Table 3

Occurrence of Themes/Strategies and Broader Themes Within Each Semistructured Interview

Theme/strategy	Broader theme	IP1	IP2	IP3	IP4	IP5	IP6
Understand U.S. FDA enforcement actions and the business consequences of poor regulatory compliance	Common FDA findings from public data	X	X	X	X	X	X
	Business consequences of noncompliance	X	X	X	X	X	X
Foster quality culture	Constancy of purpose	X	X	X	X	X	X
	Adopt a new philosophy	X	X	X	X	X	X
	Continuous improvement and process management	X	X	X	X	X	X
Engage leadership support and engagement at all levels of the organization	Leadership support	X	X	X	X	X	X
	Involve all workers	X	X	X	X	X	X
	Break down silos	X	X	X	X	X	X
Accelerate education and experience	On-the-job training	X	X	X	X	X	X
	Education/experience	X	X	X	X	X	X

Emergent Theme 1: Understand U.S. FDA Enforcement Actions and the Business Consequences of Poor Regulatory Compliance

The first emerging theme for effective quality management strategies was understand U.S. FDA enforcement actions and the business consequences of poor regulatory compliance. Understanding FDA objectionable observations is an advantage to developing or continually improving compliant regulatory strategies that meet the FDA quality federal regulations. Knowledge of potential consequences of noncompliance helps inform decisions to protect the business and keep biotech products safe for patients and on the market.

The U.S. FDA was created to protect patient safety. Historically, the U.S. FDA regulatory requirements were established in response to public health crises. For example, the 1902 Biologics Control Act established manufacturing licenses. The law came about because of a tetanus outbreak in vaccines (Esparza et al., 2020). The thalidomide drug scare led to the Kefauver-Harris Act of 1962, which created clinical trial requirements, evidence of effectiveness, animal testing requirements, and cGMPs (Swaters et al., 2022). The U.S. FDA regulations have become broader and more complicated over time.

U.S. FDA enforcement actions can cause business consequences. Researchers posited poor company reputation, financial penalties, and loss of profit among the business consequences of quality regulation noncompliance (Almeter et al., 2022; Saini et al., 2022). The public database from the U.S. FDA dashboard of enforcement actions provided real-world evidence of specific noncompliant strategies. Between 2008 and 2024, the top five most cited FDA observations were CAPA and complaint investigations, cGMPs, validations, design control, and clinical records (FDA, 2024b). A high level of dependability was achieved when I compared the publicly available data and the semistructured interview transcripts. Each of the top five most cited FDA observations from the publicly available enforcement database was mentioned in the semistructured interviews (see Table 4). Understanding U.S. FDA regulation enforcement actions and the business consequences of poor regulatory compliance were confirmed throughout the six interviews.

Table 4

Understanding the U.S. FDA Regulation Enforcement and Business Consequences From Publicly Available Data and Semistructured FDA Interviews

Interview participant	CAPA/complaints investigations	cGMP/GxP	Validation	Design control	Clinical record
IP1	X	X	X	-	X
IP2	X	X	X	X	X
IP3	-	-	-	X	X
IP4	X	-	-	-	-
IP5	X	X	X	X	-
IP6	X	-	X	X	-

Six participants discussed the negative financial impact and loss of company resources as business consequences of noncompliance. The five most common FDA regulatory enforcement actions identified in the public data corroborated participant semistructured interviews. IP6 asserted that CAPA FDA observation is high risk because it is one of the first things FDA evaluates during an inspection. IP6 stated "CAPA is a pretty risky 483, because that's one of the first things [*sic*] the FDA would look at [*sic*]." IP2 mentioned a warning letter with 15 observations noting design controls, validation, and complaint handling deficiencies:

> The warning letter had 15 observations on it, and [*sic*] the quality manager didn't know where to start … They had never done any design control. They had never done any validation. They didn't have a complaint-handling program. It was, it was bad.

The research data confirmed the most common FDA enforcement actions in publicly available data.

In the biotech industry, the FDA approves and removes biotech products for use in the market. Raguri et al. (2024) studied the approval rate of new antiretroviral drugs in recent research. Raguri et al. (2024) found that FDA rejections were caused by not following FDA guidelines and not effectively communicating with the FDA. Bahizi et al. (2024) reviewed biotech market withdrawals from the Rwandan FDA between 2019 and 2023 and found 35.8% were antibiotics and 26.4% were taken off the market due to contamination. Dmour (2023) reviewed 141 U.S. FDA compounding pharmacies' warning letters from 2017 to 2022 for cGMP violations and found that adulterated products and misbranded product violations were the most common. Understanding FDA regulatory enforcement actions and the business consequences of noncompliance can create a competitive advantage to better focus and understand the internal customer.

Emergent Theme 2: Foster Quality Culture

The second theme that emerged from the research was fostering a quality culture. Creating a purpose for improving, adopting a new change philosophy, and continually improving process management are principles of TQM and broader themes of the current research project. Multiple researchers found the TQM concept relevant to change initiatives and continuous improvement strategies (Akanmu et al., 2023; AlQershi et al., 2023; Haffar et al., 2022). More recently, Tajouri et al. (2025) conducted a literature review on TQM and organizational learning and found that both shared a common and complementary focus with improvement, employee engagement, and training. In recent studies, multiple researchers found TQM to increase customer orientation and satisfaction within multiple industries (Issifu & Kano, 2024; Klarić et al., 2024; Makinde et al., 2024). Multiple researchers also found customer focus to be a familiar concept of TQM (Acquah et al., 2023; Ali & Johl, 2022). Fostering quality culture is supported by independent research and was an emerging theme in the research data.

All six interviews supported quality culture. Constancy of purpose, adopting a new philosophy, and continual improvement process management were broader themes within the six interviews. IP6 discussed the reluctance to change as a cause of long-term failure, indicating that compliance will fail if you are not keeping up with continuous improvement or new regulations:

> I think the largest [*sic*] thing is that a lot of times people fail because there is a reluctance to change. But if you're not changing and keeping up with continuous improvement projects or regulations that have changed, you're destined to fail. So, you [*sic*] must always be open to change and open to the ideas that your stakeholders and or collaborators have.

IP2 indicated that the long-term compliance failure was caused by people who did not want to change. “There were personalities, people, some people don't want to change, or some people want to own changes the way they want to own them.” Fostering a quality culture focused on continuous improvement and process management, adopting a new philosophy, and focusing on a constancy of purpose creates a culture of improvement.

Emergent Theme 3: Leadership Support and Engagement at All Levels

The third theme to emerge was the importance of leadership support and engagement at all levels of the organization. Employee engagement and empowerment lead to higher quality, better customer satisfaction, and a sustained competitive advantage

(Boikanyo & Heyns, 2019). Leadership influences continuous improvement and operational excellence programs. Leadership support of regulatory compliance initiatives, cross-functional teamwork, strong communications with stakeholders, and the engagement of all employees are important broader themes coded from the research project.

Leadership is one of the 14 principles of TQM. Deming (1986) posited that leaders improve performance, quality, and output while making employees proud. Research from the literature review indicated that young leaders, floor leaders, managers, and top management leadership styles were shown to influence the success of continuous improvement and operational excellence programs (Anh et al., 2021; Bouranta, 2020; Sawaean & Ali, 2020; Shokri, 2019; Wagimin et al., 2019; Yadeta et al., 2022). Most recently, Wiyatno et al. (2024) opine that product quality improvement requires leadership, direction, communication, decision-making, and motivation. The institution of leadership is an important theme for developing and continuously improving compliant regulatory strategies to meet the FDA quality federal regulations. Senior management support, leadership, cross-functional communication to break down silos, and worker engagement were all second-level themes in the project that supported the institution of leadership.

All six research participants discussed the importance of leadership support and engagement at all levels during the interview. IP2 indicated that the CEO supported making the changes once he understood what must be done:

> A bad quality system is just like an illness. There's a lot of finger-pointing. There's a lot of ill will, and probably correctly, the CEO was blamed for the quality problems. For not knowing what the [*sic*] quality problems were. But he was actually really on board with making the changes, once he understood what needed to be done.

IP5 indicated that the CEO engaged in monthly calls and ensured the organization was aligned. In addition, IP5 specifically focused on communication strategies to increase stakeholder engagement and whole team participation:

> Having the CEO engaged on [*sic*] monthly calls you know, was, you know, extremely helpful from a tactical standpoint. To make sure that that individual was kind of playing their part to make sure that the whole organization, rather than it just being kind of one department or a couple of individuals, kind of synced up working to the same cause. I think, in projects of this scale and complexity, [*sic*] you kind of need, the whole organization to be aligned.

Leadership support and engagement at all levels were identified as an emerging theme.

Emergent Theme 4: Accelerating Education and Experience

The fourth theme that emerged was accelerating education and experience. TQM emphasizes employee engagement through employee experience and training (Psarommatis & Azamfirei, 2024). Education and experience were defined as business acumen, outside training, experience, regulatory acumen, mentoring, and on-the-job training. In the literature review, training was found to be the most significant gap to continuous improvement, training enhancements were needed to support the change strategy, and training was significant to organizational excellence programs (Budayan & Okudan, 2022; Cavallone & Palumbo, 2022; Puthanveettil et al., 2021). Researchers found that training is essential for successful change in the TQM conceptual framework (Agrawal, 2019). Training, education, and experience are essential to successful TQM change strategies.

The need to accelerate education and experience was also an emerging theme in the research data. All six participants discussed the need for on-the-job training, education, and experience. IP3 discussed the need to look at new regulatory guidance documents to communicate to the company, management, and corporate management and to see why these new things need to be done. "It was just a lot of education, and you know, discussions with the FDA, and then ultimately bringing those back to that management, too." IP4 opined that people need to be trained and educated about the meaning and application of the regulations:

> But the more important part was the training [*sic*]. I documented the training and [*sic*] I'm going to call it more than training. The re-education to everyone who was involved in the process from top to bottom … The reason I'm bringing this one up and talking through it is because sometimes, in order to stay compliant or create a compliance strategy, you need to train people and educate people exactly what those regulations are actually for [*sic*].

Accelerating education and experience is the fourth identified emerging theme.

Business Contributions and Recommendations for Professional Practice

The current project adds to the existing body of knowledge for practitioners, specifically managers in the biotech industry, who are responsible for effective quality management strategies that develop and continuously improve compliant regulatory processes to meet the FDA quality regulations. The research addresses a gap in the practice of successful business strategies. Four emerging themes developed from the interviews of biotech managers: understanding U.S. FDA enforcement actions and business consequences of poor regulatory compliance, fostering a quality culture, instituting leadership at all levels, and accelerating engagement through education and training.

FDA enforcement actions can cause a poor reputation, financial penalties, and loss of profit for biotech companies (Almeter et al., 2022; Saini et al., 2022). Enforcement actions can lead to manufacturing disruptions and shortages (Blankart & Felder, 2021). Product market shortages create poorer patient medical outcomes, affect patient access, force treatment substitutes, delay treatments, and reduce patient safety (Blankart & Felder, 2021; FDA, 2025; Fellows et al., 2022). The current biotech strategies for planning disruptions are risky, including scenario planning and the wait-and-see strategy (Roscoe et al., 2020). Improving compliant regulatory strategies to meet the FDA quality federal regulations can create competitive advantages for biotech firms.

Change can be difficult. U.S. FDA regulatory violations bring change and a high-pressure business crisis. Waiting to establish strategies after receiving U.S. FDA enforcement actions is not efficient. Biotech managers can improve compliance strategies by understanding and explaining the U.S. FDA regulatory enforcement actions and business consequences of non-compliance. Managers could create company-specific risk-based plans. These plans could include business strategies and goals to bolster quality culture, engage leadership support and employees at all levels, and accelerate the education and experience of all employees. These are emerging themes from this research project. This information can be further disseminated at conferences and training within the biotech industry.

Implications for Social Change

The findings of this research project could help biotech managers develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations. The findings could aid in reducing FDA enforcement actions, disruptions in manufacturing, and product shortages. Higher product quality and continuous improvement projects could mitigate manufacturing issues and increase operational efficiency. The findings could create customer satisfaction, better patient outcomes, and more employment opportunities for the biotech industry.

In four recent research studies, operational efficiencies have increased with a focus on TQM principles. Psarommatis and Azamfirei (2024) found that Deming’s 14 points of top management helped companies increase production efficiencies and product quality. In a second study, Issifu and Kano (2024) researched the effect of TQM on operational efficiency. Issifu and Kano (2024) found a significant positive statistical relationship in the health sector in the Upper East Region of Ghana. In a third study, TQM was found to significantly affect the performance of Nigeria's food and beverage industry (Makinde et al., 2024). In the fourth and final research study, TQM principles were shown to enhance the business performance of Croatian furniture companies (Klarić et al., 2024). In recent research, TQM has been shown to create operational efficiencies and better financial performance.

This project may lead to increased compliance with FDA federal regulations by biotech managers, which could reduce the number of drug shortages and increase patient safety within the community. The literature search noted that FDA enforcement actions can lead to manufacturing disruptions while attention is focused on correcting the violations (Blankart & Felder, 2021). Product market shortages create poorer patient medical outcomes, affect patient access, force treatment substitutes, delay treatments, and reduce patient safety (Blankart & Felder, 2021; FDA, 2025; Fellows et al., 2022). Compliant strategies to meet the FDA quality federal regulations can help community medical practitioners deliver the proper medical treatment, at the right time, positively affecting patient treatment.

In recent research studies, drug and biotech market shortages have been found to negatively impact patient outcomes, decrease patient safety, and increase the cost of treatment and time in the hospital. Pandey et al. (2024) found that shortages of antibiotics caused treatment failure and antimicrobial resistance. Adak (2024) found that market shortages caused treatment delays, higher hospitalization rates, and mortality in patients affected by drug shortages. Additionally, the research has indicated that, among other things, market shortages are caused by manufacturing problems and quality and regulatory non-compliance (Adak, 2024; Pandey et al., 2024). Drug and biotech shortages have been shown to adversely affect patient safety.

Recommendations for Further Research

The purpose of my research project was to explore effective quality management strategies to develop and continuously improve compliant regulatory processes that meet the FDA quality federal regulations. One limitation of my research project was geography; I targeted midwestern biotech firms, which limited the project to a small segment of biotech firms. Future researchers could consider quantitative or mixed-method research studies and research designs with larger sample sizes from additional regions, including surveys. Researchers could also study U.S. FDA regulations outside the biotech industry.

Conclusion

The purpose of my project was to explore effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations. In my literature review, I provided research content on the TQM conceptual framework, biotech market shortages, modern biotech regulations, the history of U.S. FDA regulations, new product development, clinical trials, product realization, post-market regulations, and public U.S. FDA enforcement data. The findings revealed four strategies: understanding the U.S. FDA enforcement actions and the business consequences of poor regulatory compliance, fostering a quality culture, engaging leadership support at all levels of the organization, and accelerating education and experiences. The current project adds to the existing body of knowledge for practitioners. The research addresses a gap in the practice of successful business strategies. The findings could aid in reducing FDA enforcement actions, disruptions in manufacturing, and biotech product shortages. The findings could lead to increased compliance with FDA federal regulations by biotech managers, which could reduce the number of drug shortages and increase patient safety within the community.

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Appendix: Interview Protocol

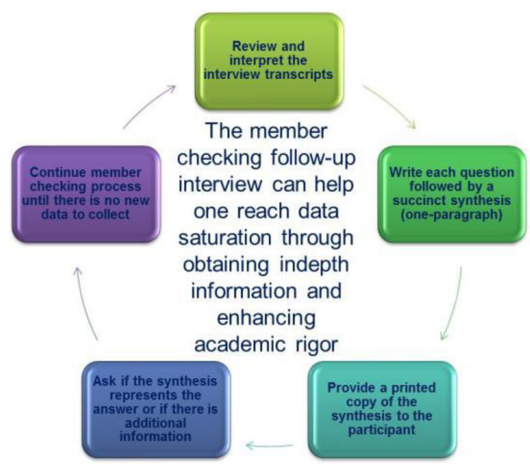
<table>
<tr><th colspan="2">Interview Protocol</th></tr>
<tr><th>What you will do</th><th>What you will say—script</th></tr>
<tr><td>Introduce the interview and set the stage— over Zoom audio

Therefore, the purpose of this proposed qualitative, pragmatic inquiry is to explore the effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations. The purposive sampled target population consisted of six biotech managers with five or more years of experience in the biotech industry residing in the United States' central region who have adopted and successfully implemented FDA-compliant quality strategies.</td><td>Script

1. Hello (name of participant).
2. Thank you for participating in my research project.
3. Today, we will spend an hour or so discussing the effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations.
4. I will ask you a series of open-ended questions, and I would like to talk about your experiences.
5. At no time do I want to talk about proprietary detailed biotech information or company-specific information. Please broadly discuss the situation and be more detailed about your experiences.
6. Everything will be recorded and transcribed. Before using the information in my research, I will set up more time to review the transcript with you.
7. Do you have any questions before we start?
8. Let me start by asking you about your professional experience and what state you live in.
a. How many years have you worked in the biotech industry?
b. Which part of the United States do you live in? Western, Central, or Eastern?
c. Thinking about all the strategies that you have implemented, have you adopted and successfully implemented a strategy to become FDA compliant?</td></tr>
</table>

• Ask open-ended questions • Paraphrase as needed. • Ask follow-up probing questions to get more in-depth.	Script: 1. Thinking back to a time when you needed to implement a new strategy to meet FDA compliance to regulations, How did you identify that you needed to improve or that there was change needed? 2. What strategies do you use to maintain a compliant culture or a culture of quality? 3. How have you integrated compliant strategies into planning? Can you describe the type of planning, the timing, and scale of change? 4. What leadership traits are important when managing a change program to FDA regulatory compliance? 5. How did you or your organization identify critical opportunities for continuous quality improvement to ensure compliance with FDA quality requirements? 6. Please think about improvement strategies that worked. Why did those strategies work? Were they sustainable over time? 7. Please think about improvement strategies that were not successful. Why did those strategies not work? 8. What strategies are used by your organization to monitor quality compliance to meet FDA regulations? 9. What total quality management (TQM) processes tool(s) do(es) you use to implement compliant quality strategies? The fourteen points of top management are constancy of purpose, adopting the new philosophy, ceasing dependent inspections to achieve quality, working with one

<table>
<tr><td></td><td>supplier to reduce costs, continuous improvement, on-the-job training, adopting and instituting leadership, driving out fear, breaking down silos, no slogans, no quotas, remove the annual rating system, institute education, and involve all workers in the transformation (Deming, 1986).

10. What additional experiences have you had that you would like to talk about?</td></tr>
<tr><td>Wrap up interview, thanking the participant.</td><td>Script:
This was an amazing, rich, deep conversation. Thank you for talking to me and sharing your experiences.</td></tr>
<tr><td>Schedule a follow-up member checking interview.</td><td>Can we schedule a follow-up meeting for member checking?</td></tr>
<tr><td colspan="2">Follow–up Member Checking Interview


Graphic by Gene E. Fusch, Ph.D., not needed in proposal or research project —just a visual reminder during proposal stage when creating interview protocol.</td></tr>
<tr><td>Introduce a follow-up interview and set the stage</td><td>Script:
1. Hello (name of participant).
2. Thank you for participating in my research project.
3. Today, we will spend time member checking the interview we had when we discussed the effective quality management strategies that managers in the biotech industry use to develop and continuously improve compliant regulatory processes to meet the FDA quality federal regulations.</td></tr>
</table>

	4. I have transcribed the interview and summarized each question. 5. I would like to know if the synthesis represents your answer or if there is additional or different information that you would like me to know. 6. Any questions before we get started?