BEST PRACTICES ASSOCIATED WITH MEDICAL DEVICE REGULATORY STRATEGY SUCCESS: A CASE STUDY

by

Jonathan P. Ward

Dissertation

Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Business Administration

Liberty University, School of Business

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Abstract

In the evolving medical device industry, understanding how to achieve effective regulatory strategies is crucial. This study explored the foundations of regulatory strategy success in the United States, using qualitative insights from regulatory affairs professionals and industry investors. It identified operational, leadership, product design, and external factors essential for developing and implementing successful regulatory strategies. Key findings highlighted the importance of financial planning, agile regulatory process management, strategic knowledge integration, and proactive engagement with regulatory authorities. The study also pointed to the role of business ecosystems in supporting regulatory outcomes, suggesting a strategic planning approach that aligns product design with quality and business goals. This research contributed to the academic and practical discussion on regulatory strategy in the medical device sector, providing insights for stakeholders from entrepreneurs to investors. It sheds light on the complexity of regulatory pathways in the United States and its influence on market access, encouraging further research on the impact of technological advancements and global regulatory changes on strategy effectiveness.

Key words: medical device, regulatory strategy, strategic planning, FDA, market access

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Approvals

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Dr. Dalton Mathis, Committee Member	Date
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Alexander Averin, PhD, MBA Chair, Doctoral Programs	Date

Dedication

This dissertation is lovingly dedicated to my family, whose support and love have been the foundations of my strength and determination. To my wife, for her endless patience, encouragement, and faith in me, even when the path seemed insurmountable. Your strength and kindness have been my anchor, pushing me forward toward the completion of this endeavor. To my children, who bring light and laughter into every day, reminding me of the joy and wonder in the world. Your enthusiasm for life and learning has inspired me to persist, to strive, and to succeed. This achievement is not just mine but ours, a reflection of our collective journey through the ups and downs, a symbol of what we can overcome with love and support. May this work stand as a tribute to our resilience, the pursuit of knowledge, and the enduring power of God in our family.

Acknowledgments

I am profoundly grateful to a host of individuals whose support and guidance have been instrumental in the completion of this dissertation. The journey to this point has been one of immense growth, challenge, and fulfillment, made possible by the collective encouragement and wisdom of many. Firstly, I extend my deepest gratitude to my family. To my wife, for her unwavering patience and support; her belief in my potential has been a constant source of motivation. To my children, for their understanding and joy, which have brightened my days and reminded me of the bigger picture. Your sacrifices have not gone unnoticed, and this achievement is as much yours as it is mine.

I would also like to acknowledge my team at our business. Your flexibility, support, and encouragement have been crucial in allowing me the space and time needed to pursue this academic endeavor. Working alongside such dedicated individuals has been both a privilege and a source of inspiration.

Special thanks are due to my dissertation chair, Dr. Jonathan Wilson. Dr. Wilson, your guidance, patience, and academic rigor have been pivotal in shaping not only this research but also my growth as a scholar. Your constructive feedback and encouragement have pushed me to exceed my own expectations. I am also indebted to the other members of my committee for their insightful reviews and feedback throughout this process. Your collective wisdom, expertise, and support have been invaluable in refining my research and guiding me towards this significant milestone.

To all those who have contributed to this journey in various capacities, your roles have been instrumental in reaching this achievement. I am deeply thankful for the opportunity to learn from each of you and for the part you have played in making this dissertation possible.

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Section 1: Foundation of the Study

Managing regulatory compliance can have a significant impact on achieving successful market access for new medical technologies (C. O'Dwyer & Cormican, 2017). According to Schueler and Ostler (2016), most investors (89%) participating in a survey believed that regulatory intelligence or due diligence are vital aspects of the startup investment decision-making process; in fact, venture capitalists expect to see a regulatory strategy or plan at "first contact" (p. 13) with startups or project sponsors. This qualitative study addressed the personal experiences of regulatory affairs professionals and other medical device industry stakeholders to understand their perception of the various factors involved in developing and implementing a successful regulatory strategy. Although a number of variables influence how a strategy is developed and implemented, this study focused on operational, leadership, and product design, as well as external factors relative to the regulatory uncertainty involved in bringing a new medical device to the marketplace in the United States. The researcher sought to identify best practices in this arena as they relate to developing and implementing regulatory strategies for new product development (NPD) projects and investment opportunities in the medical device industry.

Background of the Problem

Life science sectors include developing industries such as biotechnology, biologics, and in vitro diagnostics, as well as more mature industries like pharmaceuticals and medical devices. Historical records date the practice of medicine and use of medical devices back to ancient Egyptian and Greek practitioners (Tebala, 2015). From women in the 15th century B.C. using papyrus leaves as tampons (Weissfeld, 2010) to "do-it-yourself" (DIY) tech-savvy engineers utilizing additive manufacturing to produce their own medical devices (Greene, 2016);

entrepreneurs and inventors continue to reshape and advance medical technology (medtech), mainly in the university and academic startup sphere (Manbachi et al., 2018). Yet many of these technologies fail to reach successful commercialization (Grose, 2016); as such, caretakers and patients cannot access innovative remedies.

Among numerous commercialization constraints, regulatory burdens, such as approvals and market clearance from domestic and international authorities, require technical qualifications that most medtech startups lack (Bergsland et al., 2014). The successful marketability of new medtech innovations relies heavily on sound regulatory strategies established early in the product lifecycle (Schueler & Ostler, 2016). Such strategies reduce the uncertainty inventors factor into decisions to proceed with NPD opportunities (Russell, 2015). According to Hoerr (2011), investors cite regulatory uncertainty as one of the most contributory factors in deciding the most appropriate industries to focus capital investments. Russell (2015) suggested that an innovation's speed-to-market significantly influences investor commitments to fund startup product lifecycle launches. Although traditional investment evaluation tools such as net present value (NPV) and internal rate of return (IRR) aid venture capitalists in measuring the impact of risks related to regulatory delays (Sisodia et al., 2016), due to the uncertain nature of the regulated environment, regulatory strategy success is difficult to quantify (Hoerr, 2011). Isasi et al. (2016) conducted a qualitative study of stakeholder perceptions associated with regulatory uncertainty and product commercialization in the Cell-based Therapies and Products (CTP) industry in Canada, among several emergent themes. The authors identified the management of regulatory uncertainty as a barrier to innovation and new product availability.

Problem Statement

The general problem to be addressed was that entrepreneurs operating in regulated industries face challenges raising sufficient investment capital to start a new business and comply with the regulatory requirements necessary to achieve commercialization and sustainability as venture capitalists focus investments towards industries that offer greater and higher returns than those facing less regulatory risk (Russell, 2015; Yonk et al., 2017). Regulatory intelligence and strategy represent risk management instruments venture capitalists evaluate when considering startup capital investments (Schueler & Ostler, 2016). NPD teams in the medical device industry face time, money, and uncertainty risks that stem from regulatory burdens, which lead to investor discouragement (Russell, 2015). Jarvis (2010) surmised that regulatory risk increases the risk premium and creates an inflated cost environment for investors. However, there is no standardized benchmark for evaluating investment risk from conception through regulatory market access clearance and approval in the United States. Traditional project evaluation methods such as real options (RO), NPV, discounted cash flow, and payback period focus on financial risk (Johal et al., 2008). Although these methods include factors related to the costs associated with regulatory compliance, they do not comprehensively address regulatory risk (the probability of successful outcomes). The specific problem addressed in this research was that the lack of generally accepted best practices to mitigate regulatory risk is a significant barrier to generating internal or external development capital.

Purpose Statement

The purpose of this case study was to explore the variables that contribute to medical device regulatory uncertainty and regulatory strategy best practices based on the experiences of industry professionals and investors. Sisodia et al. (2016) conducted a study to demonstrate the

impact of regulatory uncertainty on potential investments using NPV and RO values at a macro level. The authors evaluated uncertainty within the context of delayed marketability in the energy sector. While the study demonstrated NPV and RO as viable investment tools to predict financial outcomes associated with project delays, these assessment instruments do not offer investors or innovators a benchmark of regulatory strategy best practices to be employed during the NPD process. This study built on this gap by striving to discover the factors industry professionals perceive as contributory to both regulatory strategy success and regulatory uncertainty in the U.S. medical device industry.

Startups and new market entrants typically lack the infrastructure and experience to adequately demonstrate regulatory proficiency simply due to the lack of experience (Chatterji, 2009) when presenting investment opportunities to potential financial partners, a fact that venture capitalists weigh heavily when considering market entry options (Schueler & Ostler, 2016). At the same time, both entrepreneurs and investors lack objective analysis tools for evaluating regulatory strategy success early in the product life cycle, yet investors expect a sound, comprehensive regulatory strategy at the first meeting (Schueler & Ostler, 2016). The primary objectives of this study included the following: (a) To identify operational factors that reoccur across interviews and appear important to examples of successful regulatory outcomes; (b) To identify operational factors that reoccur across interviews and appear important to examples of unsuccessful regulatory outcomes; (c) To identify prerequisites to the formation of successful/unsuccessful operational factors; (d) To identify factors that emerge and define successful regulatory outcomes; and (e) To identify, operational variables that generate regulatory uncertainty. The researcher believed that a study of regulatory strategy best practices

would provide a benchmark for both innovators and investors to evaluate regulatory strategies associated with new medical device market entry projects for the U.S. marketplace.

Nature of the Study

The nature of this study focused on gaining a better understanding of the variables that medical device industry professionals perceive as essential to regulatory strategy success. The objective of this research was to identify factors that appear to be important for successful regulatory strategy outcomes, including prerequisites to the formation of such factors and associated regulatory uncertainty.

Discussion of Method

According to Stake (2010), qualitative research is interpretive, experiential, situational, and personalistic. Numerous studies utilized qualitative research methods while investigating perceptions on the topics of regulatory processes and strategies. Buckley (2015) utilized qualitative methods to examine interactions between U.S. Food and Drug Administration (FDA) regulators and small food processing organizations through interviews and field observations. Buckley found that collaborative interactions between small businesses and inspectors appear to play a role in improved regulatory compliance; however, the study was limited to food establishments and compliance inspections in the state of Michigan. Kesselheim et al. (2017) chose qualitative methods to assess individuals' knowledge and perception of FDA regulatory processes. de Vries et al. (2017) employed qualitative research to understand the influential factors of reporting adverse events to the FDA in healthcare environments. This study aimed to better understand the variables regulatory professionals perceive as crucial to regulatory strategy success in the medical device industry. The study required the interpretation of subjective

personal narratives based on experiences within a particular context (FDA-regulated environment).

Discussion of Design

This study utilized a qualitative case study design, an appropriate approach to gathering the necessary data to address and answer the research questions. Regulatory strategy success factors are an understudied topic, with most scientific journal articles reporting individual examples or generalized stepwise methods to fulfill regulatory requirements (Fisher et al., 2015; Johnson et al., 2014; King, 2015; Kwon & Lee, 2017). J. W. Creswell (2007) indicated that case study designs offer awareness and insight into how particular cases answer research questions associated with unique issues. Interviewing is an acceptable qualitative method of collecting insights on underexplored issues (Crowther et al., 2017).

Qualitative Design. The qualitative data in this study was collected by way of semistructured interviews to determine what variables industry professionals and investors perceived as essential to regulatory strategy success. Semistructured interviews allow improvised questions in follow-up discussions to gain deeper knowledge from the interviewee's narrative (Kallio et al., 2016). Interviews are also appropriate for this study because they facilitate interaction between the researcher and participant, which improves contextual understanding (Buckley, 2015). The interviews were transcribed, codified, and analyzed to identify themes and variables that emerged.

Case study designs are intended to explore real-life contexts over time or through a historical examination of an event (Runfola et al., 2017). Qualitative data collection through a case study is appropriate because one of the goals of this study was to understand subjective perceptions of how certain inputs may influence regulatory strategy outcomes. These outcomes

were observable in a case study context, as regulatory strategy success is typically achieved based on notification letters from the regulatory authorities (historical examination of an event). Ethnographic data collection is not appropriate for the proposed study because researchers must rely on embedded contextual observation to explore a particular cultural phenomenon (Reeves et al., 2008). This study did not address particular cultural experiences; as such, ethnographic research design will not be used. Narrative inquiry generates new knowledge through longitudinal experiential narrative and biographical stories (Bruce et al., 2016). The researcher was not concerned with embedded or biographical experiences; rather, the proposed study is intended to collect information to identify themes and variables related to individual cases associated with successful regulatory strategy implementation. As such, a case study was deemed the most appropriate approach to this study.

Summary of the Nature of the Study

The study explored the topic of the best practices of regulatory strategy success in the U.S. medical device industry. Regulatory intelligence and strategy are imperative to securing startup investment funds and achieving sustainable commercialization of medical technology (Schueler & Ostler, 2016), yet it is an underexplored issue of concern (Crowther et al., 2017). Through the use of semistructured interviews with industry professionals and investors, the researcher aimed to qualitatively identify and analyze themes related to the factors that appear to be critical in realizing desired strategic regulatory outcomes. Semistructured interviews facilitate improvised questions in follow-up discussions to gain deeper knowledge from the interviewee's narrative (Kallio et al., 2016). The interviews were transcribed and analyzed to identify themes and variables that emerged.

Research Questions

The research questions for this study provided guidance for the researcher to uncover variables that contribute to regulatory strategy success, a major milestone in the medical device commercialization process.

RQ1. What process variables do industry professionals perceive as the most important to regulatory strategy success in the U.S. medical device industry?

RQ2. How do industry professionals describe the operational factors that lead to regulatory strategy success in the U.S. medical device industry?

RQ3. What product variables do industry professionals perceive as factors that generate regulatory uncertainty in the U.S. medical device industry?

RQ4. How do industry professionals describe the leadership factors that lead to regulatory strategy success in the U.S. medical device industry?

RQ5. What external variables do industry professionals perceive as factors that generate regulatory uncertainty in the U.S. medical device industry?

Conceptual Framework

Regulatory strategies supported by corporate strategies contribute to successful medical device NPD (C. O'Dwyer & Cormican, 2017). While numerous authors have highlighted the importance of regulatory strategy in relation to successful medical technology commercialization (Ringel et al., 2013; Schueler & Ostler, 2016), few, if any, have concentrated on the variables believed important to successful regulatory strategy outcomes. This study was based on the convergence of several theories that focused on these variables from medical device regulatory professionals' and investors' perspectives and sought to gain a greater understanding of the regulatory strategic process and risk factors.

Institutional Theory

Institutional theorists distinguish institutions as agencies that compel organizations to employ normative behaviors and levels of conformity by limiting certain liberties and actions (Turner & Angulo, 2018). In the context of medical device regulatory strategy, the FDA is an institution governing the development and commercialization of medical technologies in the United States (Martins et al., 2015). The requirements imposed by regulatory authorities are often viewed as detrimental to small businesses (Buckley, 2015) and stifling to the innovation process (Stern, 2017). Due to legal constraints, organizations tend to establish standardized approaches to ensure compliance and viability, often by imitating competition operating in the same market sector (Turner & Angulo, 2018). This study examined the complex nature of the risk factors and strategic regulatory decision-making in the medical device industry relative to an innovator's ability to access internal or external product development capital.

Systems Theory

Proponents of systems theory suggest that the function of a system is organic in nature, such that each element of the system is coordinated and interacts with the other elements, so none operate in isolation (Yang, 2016). The performance of the system as a whole is dependent on the individual elemental performances (Yang). At the same time, bottlenecks in the system constrain and limit process effectiveness (Strobach et al., 2015). Systems exist across all disciplines, including natural science, social science, law, economics, and business (Mele et al., 2010). Interactive systems, including quality system operational process factors, play a pivotal role in the development of safe and effective medical devices (Martins et al., 2015). Such systems are mandated by international regulatory authorities, including the FDA (T. Li et al., 2015), and numerous process outputs from quality management systems become inputs to

regulatory applications and documentation (Peck et al., 2017). As risk classification and device complexity increase, the quality management system requirements imposed by regulatory authorities increase as well (T. Li et al., 2015). This study included an exploration of process variables and potential bottleneck constraints within the context of medical device regulatory strategy.

Chaos Theory

According to Hung and Lai (2016), chaos theory asserts that unpredictable consequences arise from "modest beginnings" (p. 31). The business environment is (and will remain) uncertain and chaotic (Collins & Hansen, 2011). The medical technology business is associated with high development costs, long market access timelines, and a high risk of failure (Schueler & Ostler, 2016). It is also an industry struggling to secure funding for next-generation technologies due, in part, to regulatory uncertainty (Russell, 2015). Venture capitalists acknowledge that sound regulatory strategy is imperative to investment decisions (Schueler & Ostler, 2016). From a strategic perspective, numerous variables introduce uncertainty to medical device development and regulatory applications that may result in chaotic results due to the asymmetrical nature of elemental risk profiles. For example, device complexity and marketing claims dictate the regulatory risk classification, which, in turn, dictates the FDA premarket pathway for a new or modified medical device. These pathways, while well-defined in the regulations, are not always clearly understood by the industry (C. O'Dwyer & Cormican, 2017) and are inconsistently interpreted by regulatory authorities, leading to regulatory application failures, delays, or even compliance and safety concerns (Palumbo et al., 2016). In other words, a poorly defined and executed regulatory strategy may lead to catastrophic results, failed business investments, and breakdowns in NPD launches.

Discussion of Relationships Between Concepts

Due to the importance of regulatory strategy success in the commercial viability of new medical technology, this study investigated the variables perceived as influential in achieving successful regulatory strategic outcomes. Figure 1, below, provides a diagrammatic visualization of the conceptual framework upon which this study was designed.

Summary of the Conceptual Framework

The conceptual framework of this study was rooted in the examination of regulatory strategies and their pivotal role in the successful commercialization of medical technologies. Central to this investigation was the interplay between institutional theory, systems theory, and chaos theory as they relate to the medical device industry's regulatory landscape. Although extensive research exists covering project and business valuation, there is a lack of research on the variables influential in regulatory strategy success. This qualitative study was designed to bridge the research gap to provide investors and innovators with actionable best practices to apply in project evaluations and investment due diligence opportunities.

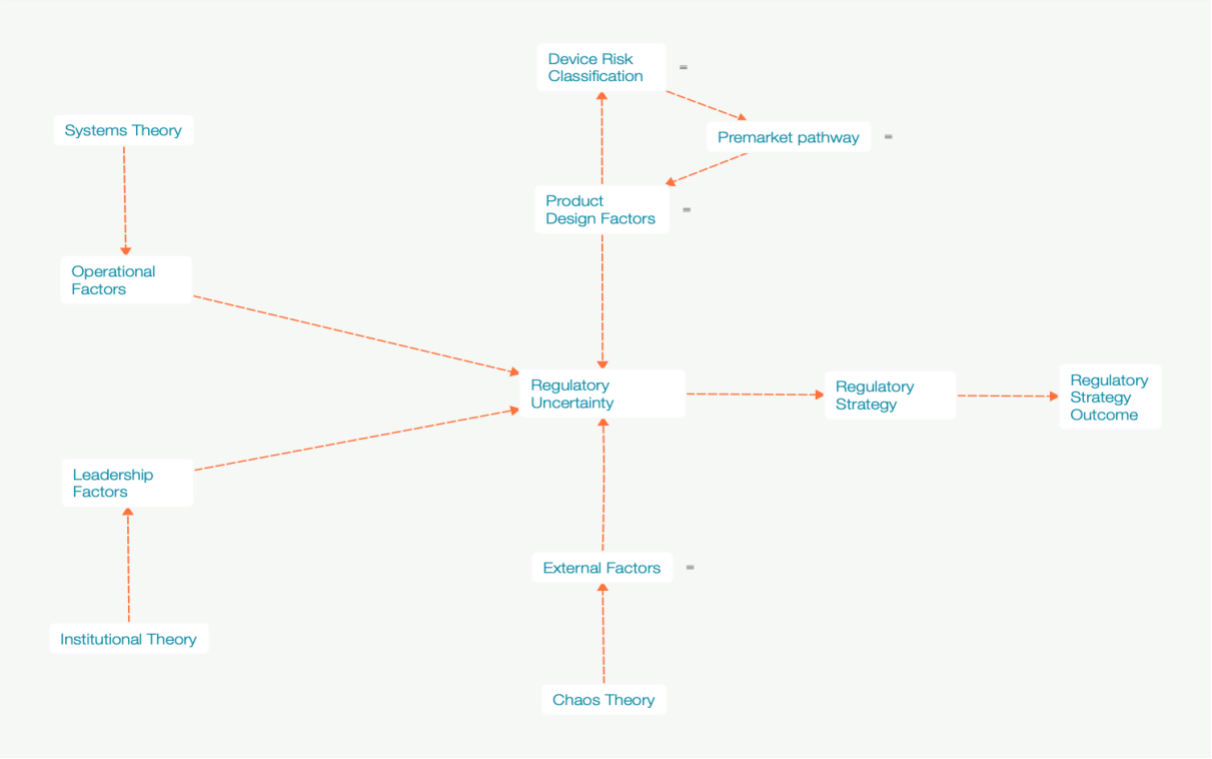

Figure 1. Conceptual Framework.

Definition of Terms

The following terms have been defined within the context of this study to provide clarity to the reader:

Current Good Manufacturing Practices (cGMP) - the regulatory requirements set forth by the U.S. Food and Drug Administration (FDA) in relation to medical device quality management systems (T. Li et al., 2015).

Innovation –a product that "fills a critical need for which no existing product or equipment is serving" (Krantz et al., 2017, p. 475).

Investment – capital utilized to fund innovative medical device development (Smith, 2017).

Medical device - “A device is: ‘an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: (a) recognized in the official National Formulary, or U.S. Pharmacopoeia, or any supplement to them, (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c). intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)” (Food and Drug Administration, 2018a).

Medical device manufacturer - according to 21 CFR Part 820.3, a manufacturer means “any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturers include but are not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions” (Food and Drug Administration, 2017a).

Regulatory compliance - achievement of legal requirements “mandated by the regulatory agencies to ensure public health and safety” (Saini et al., 2014).

Regulatory strategy - a strategic plan to achieve regulatory compliance within the context of NPD and commercialization (Saini et al., 2014; Schueler & Ostler, 2016).

Regulatory strategy success – achieving regulatory approval, market clearance, or exemption based on a particular regulatory strategy (Marcus et al., 2016).

Assumptions, Limitations, and Delimitations

Assumptions

This study assumed that the participants were knowledgeable with regard to their experiences in regulatory affairs and regulatory strategy. To mitigate the risk of recruiting inexperienced individuals, the study primarily targeted mid- to senior-level managers and directors. Another assumption was that the participants interviewed were actually responsible for the planning or implementation of regulatory strategies within their respective organizations. In order to provide triangulation of the results, the study included interviews from the perspective of investors, entrepreneurs, and other venture capital professionals involved in medical device innovation commercialization. To address the risk of researcher bias and jeopardizing the identification of thematic data, the interview questions were purposefully designed to elicit the personal experience of the participants (Salter & McGuire, 2015) based on prior studies, interviews, and surveys identified in the literature.

Limitations

One limitation of this study was the qualitative methodology employed, which, as Stake (2010) notes, is inherently subjective and interpretive, potentially affecting its broad applicability across different contexts. Furthermore, restrictions on accessing targeted individuals within organizations limited the study's findings. To counter this, interviews were conducted with a diverse range of subjects, including regulatory affairs professionals who are directly involved in the implementation of regulatory strategies and investors engaged in medical device projects. Despite the study being confined to participants within the U.S. medical device regulatory

experience, the principles of data saturation were diligently applied. The repetition of emergent themes indicated that no new data was forthcoming, suggesting that the research findings offer a comprehensive insight into the topics explored. Thus, while the number of interviews was finite, the depth and consistency of the information collected affirm the achievement of data saturation. Given the universal nature of the U.S. regulatory requirements applicable to both foreign and domestic manufacturers, the results and conclusions drawn from this study hold potential relevance for a global audience.

Delimitations

This study was limited to the application of regulatory strategies in relation to the medical device industry in the United States. While many companies and individuals have valuable experience with successful regulatory outcomes in the United States, the participants were limited to individuals representing medical device developers, manufacturers, and consultants representing such organizations. The study did not explore aspects of NPD such as product life cycle development, postmarket surveillance, marketing strategy, or commercial/financial viability, but rather, the study focused on aspects of NPD specifically related to regulatory strategy and associated outcomes.

Significance of the Study

The significance of successful regulatory strategy implementation in the medical device industry is vital to product commercialization and sustainable business operations (Russell, 2015). Venture capitalists agree that a sound regulatory strategy is an essential element in the investment due diligence and funding decision-making processes (C. O'Dwyer & Cormican, 2017). Yet, a 2016 study shows that a significant percentage (approximately 67.5%) of investors in biotechnology ventures have little to no experience in the field and, as a result, bring minimal

expertise and value to the regulatory process (Bains et al., 2016). Entrepreneurs developing new medical technologies are expected to present their regulatory strategy early in the due diligence period (Schueler & Ostler, 2016); however, many of the investors reviewing the regulatory strategies have no basis for judging the strategy's validity (Bains et al., 2016). This study is beneficial to entrepreneurs, investors, and project champions. Understanding the variables of strategic regulatory planning and implementation will help organizations and individuals to (a) identify systemic and leadership organizational gaps associated with successful or unsuccessful regulatory strategies, (b) identify and address important risk factors related to product characteristics prior to strategy implementation, (c) compare proposed projects and investment opportunities against best practices to judge potential regulatory strategy performance, and (d) reduce the regulatory uncertainty capitalists associate with unpredictable returns on investment.

Reduction of Gaps

The current state of knowledge regarding the evaluation of regulatory strategy success factors is quite limited in that most studies related to medical device NPD or commercialization projects are focused on traditional financial risk analysis tools (Johal et al., 2008) that do not include considerations for regulatory strategy. This study helped close the gap in the literature that is lacking scientific data regarding regulatory strategy challenges associated with successful implementation activities in the U.S. medical device industry. The strategic adoption and integration of processes, leadership, and risk factors early in the development process are essential to securing investment funds (Schueler & Ostler, 2016) and successful regulatory application outcomes (C. O'Dwyer & Cormican, 2017). Regulatory uncertainty is difficult to measure (Hoerr, 2011). The results of this study provided insight into the variables perceived as essential to the success of a regulatory strategy. Project stakeholders are able to utilize the data

and results from this study to plan and evaluate projects, investment opportunities, and related regulatory strategies. Prior to this study, screening criteria did not include factors and variables associated with regulatory strategy success.

Implications for Biblical Integration

Government regulation and oversight include numerous industries, from automotive, aerospace, and accounting to food, pharmaceuticals, and medical technology ("Rethinking closely regulated industries," 2016). These compliance requirements add cost, time, and uncertainty to the commercialization process and tend to discourage investors from funding opportunities in regulated industries (Russell, 2015). Since venture capitalists, investor groups, and individual entrepreneurs expect a positive return on investment, various assessment tools are utilized to evaluate the financial viability of potential projects (Johal et al., 2008). However, these traditional financial models do not incorporate methods to evaluate a project or organization in relation to the strategic approaches implemented to address regulations and federal governance. This study aimed to improve understanding of the factors vital to regulatory strategy success in the medical device industry. While several biblical principles relate to the implications of this study, the primary focus will include strategic planning from the innovator-entrepreneur's perspective and stewardship of resources from the investor's perspective.

Numerous scriptures closely associate wisdom with strategy. For example, the author of Proverbs 24 states that wisdom is better than strength, and strategic planning and good counsel are keys to success (Proverbs 24:5-6, The Message). While the scriptural context of strategic thinking typically relates to military activity, there are several biblical truths of historical relevance in which well-executed strategic plans lead to practical victories. Consider Nehemiah's strategic process and approach to rebuilding the walls of Jerusalem. First, he sought God's favor

(Nehemiah 1:4-11), then he sought permission, a project sponsor, and resources from the King (Nehemiah 2:1-9). From that stage, he examined the walls to understand the scope of work (Nehemiah 2:11-18) and recruited workers to rebuild the sections of the wall nearest their homes (Nehemiah 2:1-32). Throughout the project, Nehemiah sought godly counsel and dealt with opposition, all while keeping the objective in mind.

Other examples of strategic planning include Paul's approach to church building. While the missionary did speak publicly on occasion (Acts 17:1-33), nearly all of the church plants began in the homes of individual Christians (Atkinson & Comiskey, 2014) and has become one of the most effective strategic approaches to spreading the gospel throughout the world (Grant & Niemandt, 2015). Also, consider the innate strategic tendencies God designed into his creation. "Go to the ant...consider its ways and be wise! It has no commander, no overseer or ruler, yet it stores its provisions in summer and gathers its food at harvest." (Proverbs 6:6-8, New International Version). Interestingly, ants have no leader dictating their activities, yet the still plan strategically without encouragement or oversight. In the case of man, however, God mandates planning and encourages counsel (Proverbs 15:22; Proverbs 21:5). This study aimed to provide innovators and entrepreneurs with insight into the variables perceived as influential to regulatory strategy success and to aid in the development of such strategies and supporting processes.

Venture capitalists expect to achieve a positive return on investment, yet they operate in a highly volatile space (Achleitner et al., 2014). Positive returns on investment align with the biblical principle and mandates of stewardship and resource management (Matthew 25:14-30). Jesus bridged the gap between strategic planning and stewardship in his description of the cost of discipleship. While the example is related to building a tower, planning, and resource

management (Luke 14: 28-30), the deeper truth is that there is a significant cost to following Jesus, and potential followers must weigh the cost themselves to determine whether they are willing to pay such a price. Jesus' statement relays the importance of estimating the resources required to complete a project prior to its commencement and presents an argument that one that builds a foundation yet lacks the resources to finish may be considered foolish or subject to ridicule.

Due to the increased risk involved in commercializing products in regulated industries, investors demand even higher returns than otherwise unregulated products (Jarvis, 2010). Although numerous tools are available to evaluate the financial feasibility of NPD projects (Ignatova et al., 2016; Johal et al., 2008), these tools do not analyze the nonfinancial aspect of the regulatory strategy itself. Venture capitalists and investment groups may use the results of this study as they perform due diligence activities for funding opportunities in the high-regulated medical device industry, thus promoting new levels of stewardship as well as risk and resource management.

Relationship to Field of Study

This research is related to the field of international business in several respects. Innovation is at the heart of the American economy, specifically in the realm of small businesses (Yan & Yan, 2016). Yet, medical device manufacturers in the United States struggle to attain and maintain competitive advantage with other developed nations due to the perceived unpredictable nature of the FDA regulatory process (Krucoff et al., 2012; Sorenson & Drummond, 2014). Krucoff et al. (2012) suggested that the United States has entered a medical "device lag" (p. 790) due, in part, to a regulatory environmental crisis, and as a result, fewer innovations are available at points of care where they are needed most. Access to innovative medical technology is a

global struggle and is not limited to developing nations (Bergsland et al., 2014). While there is a domestic investor drought in the medical technology space (Russell, 2015), foreign direct investment is on the rise, with a focus on innovative technologies for use in the healthcare environment (Walcott, 2014).

Summary of the Significance of the Study

While this study was not intended to address all aspects of competitive advantage, investor reluctance, and regulatory uncertainty, the results of this research may aid investors and innovators in planning, risk and resource management, and project evaluation through the lens of regulatory strategy success in the US. medical device industry. Investor and board of director benefits include project screening criteria and ranking against industry best practices for investment opportunities under consideration. Innovators and project champions will also benefit from the knowledge of factors leading to regulatory success or failure that can be applied or enhanced within their respective medical device development projects and business operations. Additionally, understanding the potential pitfalls of projects in advance will benefit both internal project champions and sponsors prior to approving project funds.

A Review of the Professional and Academic Literature

The general problem addressed by this study is that entrepreneurs operating in regulated industries face challenges raising sufficient investment capital to start up a new business and comply with the regulatory requirements necessary to achieve commercialization and sustainability as venture capitalists focus investments towards industries that offer greater and higher returns than those facing less regulatory risk. The specific problem addressed in this research is that the lack of generally accepted best practices to mitigate regulatory risk is a significant barrier to generating internal or external development capital. This study examined

the complex nature of the risk factors and strategic regulatory decision-making in the medical device industry relative to an innovator's ability to access and secure internal or external product development capital. This literature review included an overview of the U.S. medical device regulatory environment and governance of the Food and Drug Administration. Additionally, it consisted of a review of the strategy process, specifically regulatory strategy, as it relates to influential factors associated with regulatory uncertainty as well as best practices for success. The purpose of this review was to provide a foundation for a comparison of the business practice themes identified during the interview analysis process and the results of previous professional and academic studies. Table 1 below provides a summary of the literature search strategy and results.

Literature Review Search Strategy

Table 1

Literature Search Criteria and Results

Terms	Results	Included
Liberty University, Jerry Falwell Library, Advanced Database Search Tool Filters activated:		
Filters activated: ● Publication date 30 July 2014 to 30 July 2018 ● Language – English ● Content type –Full text, scholarly and peer-reviewed journal articles ● Content exclusions - Newspaper articles, book reviews, dissertation/thesis		
Medical device AND FDA ● Disciplines - Business ● Subject terms - Medical device ● Exclusions: ○ Full Article not available: N=1 ○ Not related to the topic under research: N=1	13	11
Regulatory strategy AND medical device ● Disciplines - Business ● Subject terms - Medical device, Medical device industry ● Exclusions: ○ Not related to the topic under research: N=1 ○ Duplicate article from prior search: N=6	11	4

FDA AND quality system ● Disciplines - Business ● Subject terms - Medical device, Medical device industry ● Exclusions: ○ Not related to the topic under research: N=1 ○ Duplicate article from prior search: N=10	15	4
Regulatory strategy AND FDA AND medical device ● Disciplines - Business ● Subject terms - Medical devices, Medical technology, strategies ● Exclusions: ○ Not related to the topic under research: N=2 ○ Duplicate article from prior search: N=8	17	7
Regulatory strategy AND corporate infrastructure AND FDA • Disciplines - Business • Subject terms – Planning & development, strategy, policies, operations management, compliance, medical technology, organizational behavior, success, business models, medical equipment, business process management • Exclusions: ○ Not related to the topic under research: N=8 ○ Duplicate article from prior search: N=2 ○ Full article not available: N=1	28	17
FDA AND regulatory success • Disciplines – Business • Subject terms – Decision making • Exclusions: ○ Not related to the topic under research: N=2	8	6
Total	92	49
Citations from scholarly journals retrieved using unstructured literature searches or prior research	-	42
Citations industry websites or other sources	-	13
Total Citations Included	-	104

Medical Device Innovation Landscape

There is a common belief that the most innovative products develop in small and startup businesses. However, Ringel et al. (2013) suggested there is little empirical evidence exists to support this idea. Conversely, Kalcheva et al. (2018) asserted that small businesses with fewer

than 50 employees make up the bulk (>80%) of the medical device industry. The authors also noted the importance of young, privately held small businesses in the development of new products and serve as the "drivers of groundbreaking innovation" (Kalcheva et al., 2018, p. 441). Grose (2016) stated that startups develop nearly all healthcare innovations because most large device manufacturers are not interested in the extensive R&D required to bring new technologies to the market. Instead, mature companies tend to make slight modifications or incremental design changes to existing products because they have established institutional knowledge that economizes the development and regulatory processes for similar products (Maslach, 2016; Ray et al., 2017). However, several studies comparing research and development (R&D) productivity in biotechnology and pharmaceutical firms found that the size of the company does not necessarily correlate to R&D success (Ringel et al., 2013).

C. O'Dwyer and Cormican (2017) stated that while risky, expensive, and time-consuming, regulatory obligations are an essential element of the medical device development process. Achieving and maintaining compliance with applicable regulatory requirements is "synonymous with market access and ongoing trade viability" (C. O'Dwyer & Cormican, 2017, p. 26). Based on the results of a recent survey, C. O'Dwyer and Cormican (2017) found that medium-sized companies (51-249 employees) have the smallest teams of regulatory professionals participating in the product development process when compared to small (zero to 50 employees) and large (250+ employees) companies. The authors surmised that the bulk of regulatory affairs and compliance activities fall to individuals in quality assurance departments, thus creating an overburdened team, which may lead to misalignments between project stakeholders.

Medical Device Development Process

Medical device designs vary from simple tongue depressors to complex life-sustaining implantable defibrillators (Maak & Wylie, 2016). According to Altenstetter (2013), a medical device is:

> Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: Diagnosis, prevention, monitoring, treatment or alleviation of disease; Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; Investigation, replacement or modification of the anatomy or of a physiological process; or Control of conception. (p. 454)

Although the design and development effort may be different depending on device complexity, product development generally follows similar life cycles. Krucoff, et al. (2012) identified the stages of the medical device total product lifecycle as concept, prototype, preclinical, clinical, manufacturing, marketing, commercial use, and obsolescence. Similarly, C. O'Dwyer and Cormican (2017) identified six different phases in the medical device development process, including (a) concept development, (b) design, (c) manufacture, (d) packaging, labeling, and advertising, (e) commercialization, and (f) postmarketing vigilance and surveillance.

Medical device development is an iterative process, even for truly novel innovations that are unlike other currently marketable products (Maslach, 2016). However, as device complexity and interoperable risk increase, the FDA imposes more stringent regulatory controls (Morrison et al., 2015). The FDA has mandated design control elements under 21 CFR Part 820.30 for some

class I devices (including those containing software) and all class II and III devices (Coelho et al., 2015; Food and Drug Administration, 2017b). According to Morrison et al. (2015), the design control process involves identifying user needs, translating those needs into design inputs, which are then developed into outputs such as drawings, specifications, and prototypes to be verified against the established inputs, then finally the design is validated under clinical or simulated clinical use scenarios. Chatterji and Fabrizio (2014) encouraged design organizations to incorporate user collaboration during the development process to ensure user needs are clearly defined. Anderson, Liu et al. (2017) offered additional details about each phase of the design process, as depicted in Table 2 below.

Table 2

Design Control Considerations

Design Control Element	Technical Considerations
Design Planning	All design and development activities must be planned and the plan must be documented.
Design Input	Design inputs are documented and analyzed according to identify user needs and the device intended use, including an analysis of the risks.
Design Output	Based on the established design inputs, design outputs including labeling, risk mitigations and controls, drawings, specifications, and procedures are developed.
Design Transfer	During design the design transfer phase, the outputs are finalized and transitioned into manufacturing to produce production equivalent devices for subsequent testing.
Design Verification	Design verification confirms that the design outputs (including the final device design) meet the established design inputs and related requirements. Design verification may include bench testing, animal testing, testing product stability, shelf life studies, biological evaluations, and electrical safety testing. This phase typically includes initial process validation to ensure manufacturing activities are controlled and consistently produce the device according to specifications.
Design Validation	Design validation follows successful design verification and test the finished device design under clinical or simulated use controls in an effort to ensure the device intended use and user needs have been met.
Design Review	Design reviews are conducted throughout the development lifecycle to assess design adequacy and completion of respective design tasks.
Design History File	The design history file (DHF) is a compilation of records demonstrating that all

	the design control activities have been accomplished according to the established design and development planning. The DHF may contain or reference the location of the design records.
Risk Management	Risk management activities apply throughout the product development lifecycle and include risk management planning, risk analysis, hazard analysis, application of risk controls, residual risk evaluation, and risk management reporting.

Adapted from Anderson et al. (2017)

Product Design Factors Associated With Medical Device Commercialization

The medical practice is becoming more connected and software-driven with mobile technology and home-health monitoring through telemedicine in an effort to reduce the cost of healthcare (Aungst et al., 2014). The FDA took particular interest in the software development process after the agency discovered the majority of medical device adverse events and safety recalls stemmed from software failures (Ronquillo & Zuckerman, 2017). Such failures introduce significant risk to the patients and users of software-controlled devices, and the regulatory authorities now require adherence to internationally recognized standards for software development and risk management to standardize the development requirements and reduce the impact of software failures (Trektere et al., 2017).

Medical device cybersecurity is one such risk that must be considered within the product development lifecycle from design to post-market surveillance. Smigielski (2017) warns of the significant concerns hacking and cybersecurity attacks have on the healthcare community. Specifically, the author mentioned direct attacks on infusion pump technologies that are networks within hospital systems as well as those that communicate patient data and therapeutic controls over intranet or intranets (Smigielski, 2017). Medical device developers must incorporate vulnerability analysis, risk management, and verification techniques alongside information technology (IT) professionals in the context of design control processes to ensure

both the device and the IT infrastructure in which they are intended to operate remain secure (Smigielski, 2017). Healthcare security attacks pose far more detrimental and potentially devastating outcomes than typical computer systems by placing not only patient data but patient lives at risk (Owens, 2016). In recent years, the FDA has published guidance documents on the topic of medical device cybersecurity, and it requires a thorough review of the safety measures device manufacturers implement prior to granting market access for moderate and high-risk devices (Schwartz et al., 2018). Schwartz et al. (2018) suggested that the development process include provisions for the cybersecurity evaluations of third-party components acquired throughout the supply chain as security threats may emerge at multiple points in device usage in the clinical setting, including device interconnections, hospital networks, as well as wireless and radiofrequency interfaces throughout the healthcare and home care environments.

Device Risk Classification and Regulatory Pathways

Medical devices marketed in the United States are categorized into three risk classifications based on the device's intended use and characteristics. Devices inherently low in risk, such as manual instruments, scissors, and swabs, fall into the class I category (Grose, 2016; Maak & Wylie, 2016). Class II devices exhibit medium risk to the patient or user and include products such as temporary and permanent implants, whereas high-risk devices, including life-sustaining products such as pacemakers and insulin pumps, are considered class III and require the most regulatory oversight (Maak & Wylie). The majority (99%) of medical products are regulated as class I or II medical devices, with approximately 1% of devices marketed in the United States falling into class III (D. M. Fox & Zuckerman, 2014).

The regulatory pathways vary based on device risk classifications. For example, most minimal risk (class I) devices are exempt from premarket submission requirements; however,

manufacturers are still responsible for registering the establishment, listing the various devices they intend to place on the market, and maintaining applicable elements of the quality system regulations (Maak & Wylie, 2016; Maslach, 2016). Most class II devices require premarket notifications from the FDA, and such devices must follow the 510(k)-submission process (Chatterji & Fabrizio, 2016). Manufacturers achieve market clearance for most class II devices by providing the FDA with sufficient evidence that the newly proposed device is substantially equivalent to another device the agency has already evaluated. These are considered predicate devices (Chatterji & Fabrizio, 2016). While 510(k) submissions require a significant level of documentation and testing to support an FDA decision regarding substantial equivalence, the process is simplified when compared to the pathways for high-risk devices, as clinical trials are typically not required to demonstrate the new device's safety and efficacy (D. M. Fox & Zuckerman, 2014). In other words, the device must be "at least as safe and effective" as the predicate device(s) (Food and Drug Administration, 2018b). The predicate device comparison typically includes testing related to sterilization, shelf-life, and biocompatibility (Sastry, 2014), along with electrical safety, software verification and validation, device interoperability, and cybersecurity risk assessments (Chen et al., 2018).

The burden of proof increases dramatically when a manufacturer plans to bring a novel medical device to the U.S. market. Two primary differences between class II 510(k) premarket clearance and class III premarket approval (PMA) include requirements for human clinical trials and premarket inspection of the submission sponsor's establishment (Ronquillo & Zuckerman, 2017). Class III device manufacturers do not rely on substantial equivalence but rather must demonstrate the new device operates safely and effectively in the clinical setting (Maak & Wylie, 2016). Chen et al. (2018) described the process and stated that significant risk clinical

trials must be approved by the FDA in advance following the investigational device exemption (IDE) process, as well as institutional review board (IRB) approval prior to trial commencement. Following IRB and IDE approvals and completion of the clinical trial, the submission sponsor has the opportunity to submit the entire PMA documentation package in a single submission format or in a modular format as the documentation becomes available (Chai, 2000). In either case, the PMA submission must include detailed information related to design control, preclinical testing, clinical testing, as well as manufacturing processes and procedures (Food and Drug Administration, 2018c).

While not frequently utilized, researchers have highlighted two other significant regulatory pathways to market medical devices in the United States. For example, Maak and Wylie (2016) described the FDA's *de novo* program, which is an evaluation of products for which there is no appropriate predicate pathway or appropriate product code. Such devices receive an automatic class III designation. As part of the application, the submission sponsor may advocate for the reclassification of the device based on its inherent risk factors (Maak & Wylie, 2016). Rather than relying on a predicate device comparison model, devices following the *de novo* regulatory route must demonstrate reasonable assurance of device safety as well as clinical effectiveness through reference or human subject trials (Tolan, 2018); a similar process to typical class III devices that fall under the PMA process, with the exception of the burdensome documentation and preapproval inspection requirements (Chen et al., 2018). The FDA has also instituted the humanitarian device exemption (HDE) pathway as an alternative route to market devices that meet the clinical needs of a small intended patient population (<4000 patients per year) (Sastry, 2014). The HDE approval process is unique in that submission sponsors must demonstrate only clinical safety under continued IRB supervision and that the

clinical benefits outweigh the potential patient risks (Sastry, 2014). Table 3 below highlights several product design factors authors have identified as considerations in strategic decision-making and medical device commercialization.

Table 3

Product Design Factors Associated With Medical Device Commercialization

Factor	Impact or influence	Author
Intended use	Determines whether the product is a medical device and risk classification	Altenstetter, 2013; Grose, 2016; Maak & Wylie, 2016
Device complexity	Introduces new risks and challenges during the market clearance or approval process	Chai, 2000; Ronquillo & Zuckerman, 2017; Sastry, 2014; Tolan, 2018; Trektere et al., 2017
Device interconnectivity	Hacking and cybersecurity concerns, additional requirements during the market clearance or approval process, and compromised patient data or health	Chen et al., 2018; Owens, 2016; Schwartz et al., 2018; Smigielski, 2017
Device risk classification	As risk classification increases, the regulatory pathways become more challenging, time-consuming, and costly for the innovator	Chatterji & Fabrizio, 2016; D. M. Fox and Zuckerman, 2014; Grose, 2016; Maak & Wylie, 2016
Regulatory pathway	Varies based on risk classification and product characteristics	Grose, 2016; Maak & Wylie, 2016

External Factors Associated With Medical Device Commercialization

Startups and spin-offs often elect to gain market access in other regions, such as the European Union (EU), over the United States as the FDA regulatory process is viewed as a more stringent pathway (Lehoux et al., 2014), although reverse innovation presents its own set of challenges once products are designed to meet regulatory obligations in other regions (Hadengue et al., 2017; Laurell, 2018). The FDA is the governmental organization tasked with regulating biomedical product development, market clearance, marketing, and distribution (Kang & Montoya, 2014; Su & Wu, 2015; Wells et al., 2015). Within the FDA's organizational structure, the Center for Devices and Radiological Health (CDRH) is responsible for the agency's

regulatory oversight including (among other elements) quality management systems, regulatory assessment inspections, and regulatory premarket submissions, mainly through the Office of Compliance (OC) and the Office of Device Evaluation (ODE) (Alvarenga & Tanev, 2017; Marcus et al., 2016; Martins et al., 2015; Sastry, 2014). The remainder of this section provides a more detailed discussion of these external factors relative to successful medical device commercialization in the United States.

FDA Compliance Inspections

The FDA inspection process is intended to monitor and measure the level of compliance firms display relative to the regulated industry requirements (Food and Drug Administration, 2018d). These inspections may be announced in advance or conducted on an unannounced basis (Gagliardi, 2009). The latter scenario is typically in response to a prior safety concern or negligence on behalf of the device manufacturer. The agency focuses its routine inspection efforts and resources on medium and high-risk devices. As such, low-risk device manufacturers will experience inspections on an infrequent basis. Additionally, inspections are always conducted prior to high-risk devices as part of the premarket approval process (D. M. Fox & Zuckerman, 2014; Ronquillo & Zuckerman, 2017).

FDA inspectors follow a published quality system inspection technique guideline that describes how the inspection should be conducted, which systems to inspect, what type of documents and records to evaluate, and sample sizes (Food and Drug Administration, 2014a). Inspections typically include the management, design control, corrective and preventive action, as well as production and process control subsystems. Each subsystem is evaluated to determine whether the organization has adequately addressed the applicable requirements by sampling established policies and procedures, in addition to the related raw data and records to verify

compliance (Food and Drug Administration, 2014b). The inspectors are government employees, including law enforcement officers and members of the armed forces, and as such deserve respect due to an individual holding such a position (Gagliardi, 2009). According to Gagliardi (2009), the inspection process can be intimidating and uncomfortable as an outsider analyzes the work and resulting records performed by a firm's employees; however, when personnel have been adequately trained and prepared in advance, the inspections can result in positive outcomes.

Regulatory Timelines

Entrepreneurs and investors alike are faced with many factors that contribute to return on investment (ROI) and regulatory access (Hoerr, 2011). The U.S. FDA, while an independent government agency, has an impact on the development and commercialization of new technologies. In some cases, regulatory approvals or market clearance may not be granted until up to 4 years following clinical trial completion for higher-risk devices (Russell, 2015). Class 1 device manufacturers may register their facility and list their marketed devices within a matter of days (assuming no 510(k) is necessary). However, congressional mandates for 510(k) reviews of moderate-risk devices can take up to 90 days for the FDA to make a decision regarding substantial equivalence (D. M. Fox & Zuckerman, 2014). It is worth noting that the review clock stops anytime the agency presents requests for additional information while the submission sponsor gathers the necessary information to respond (Food and Drug Administration, 2018b). That being said, the average industry experience for class II device market clearances is 31 months, according to a 2010 survey (Maak & Wylie, 2016). In comparison, the FDA's targeted review times for PMA submissions is 180 days (Chai, 2000), whereas the industry is experiencing a 54-month process to achieve approval of novel, high-risk devices (Maak & Wylie, 2016).

Regulatory Cost Burdens

Researchers suggested that the total product development cost (including regulatory and clinical considerations) for a class II device ranges between $10-$20 million and up to $94 million to bring a class III device through the premarket approval process (D. M. Fox & Zuckerman, 2014; Maak & Wylie, 2016). In addition to product development costs, the FDA charges fees to review certain applications as well as annual fees for establishment registrations, although significant discounts are available for organizations qualifying as small businesses (≤$30 million in annual gross revenue) (Food and Drug Administration, 2024). Table 4 provides an overview of the fees associated with regulatory applications based on the latest FDA publication.

Table 4

FDA User Fees (Fiscal Year 2024)

Type of submission	Standard review fee	Small business review fee
510(k) Premarket Notification	$21,760	$5,440
De Novo Classification	$145,068	$36,267
Premarket approval (PMA)	$483,560	$120,890
Establishment registration	$7,563	No discount for small businesses

Regulatory Ambiguity

The FDA regulatory requirements are often perceived as ambiguous, and such ambiguity introduces the potential for threats to success, such as (a) project extensions due to unanticipated testing requirements, (b) FDA feedback loops that cause delays in clinical trial commencement,

and (c) testing results that do not align with expected device risk profile comparisons (Hoerr, 2011). C. O'Dwyer and Cormican (2017) stated that device development organizations face difficulty navigating the regulatory obligations during the NPD process because there is little guidance on how to manage said obligations. Uncertainty continues to rise when truly novel technologies such as combination devices (drug/device, device/biologic, or drug/device/biologic) are seeking market access as the lines truly become blurred regarding which regulatory requirements apply and to what extent, depending on which FDA center(s) within FDA will preside over the regulatory decision associated with a novel application (Anderson et al., 2017).

Bergsland et al. (2014) encouraged early cooperation and collaboration in the testing phases to establish essential elements of NPDs in the context of regulatory approval processes. While developing a regulatory strategy is more likely in larger organizations, research has demonstrated an increased frequency of achieving on-time medical device market access when companies establish a regulatory strategy (C. O'Dwyer & Cormican, 2017). Without an appropriate strategy, the ambiguities of the regulatory process have meant fewer technological advancements available to patients in the United States (Stern, 2017). These timeline discrepancies and potential cost burdens for class II and class III device market access support Schueler and Ostler's (2016) position that regulatory strategy and planning are integral elements of entrepreneurial opportunities and investor due diligence activities, which should be developed early in the product development process.

Other Barriers To Medical Device Innovation

The healthcare market is made up of several industries, of which medical devices are among the largest (Kalcheva et al., 2018), with annual global expenditures on medical devices alone in excess of $200 billion in 2010 (Suter et al., 2011) and expected to reach over $450

billion in 2018 (Ciani et al., 2017). Innovations in the medical device industry tend to be slower than in other industries due, in part, to the barriers to market entry (Bergsland et al., 2014). Krucoff et al. (2012) listed several contemporary impediments innovators face as they seek to commercialize new medical technologies, including, but not limited to, the increasing cost of research, limited availability of financial support, and unpredictable regulatory pathways. Majava et al. (2016) also identified similar medtech innovation growth inhibitors, such as insufficient investment and research funding, as well as uncertainty related to laws, regulations, and FDA approvals. The aforementioned challenges are discussed at length in other sections of this literature review; other market entry challenges are described in the following section.

Medical Device Excise Tax. Occasionally, unexpected barriers require additional strategic navigation, such as when in 2010, the U.S. president enacted the Affordable Care Act (ACA), and as part of the ACA, a new excise tax of 2.3% on gross sales was imposed on taxable medical devices to defray the cost of health insurance coverage (Lee, 2018). Lee (2018) studied the impact of the ACA medical device excise tax on research and development (R&D) investment and financial performance in the medical device industry. The author compared R&D expenditures, sales revenue, and gross and net profits, among other measures, of medical device manufacturers from 2006 to 2015. The analysis revealed that after the tax enforcement, firms experienced a significant reduction in all the measurable variables, causing subsequent decreases in operating costs to counter the added tax burden (Lee, 2018). Additionally, medical device manufacturers reevaluated and prioritized NPD projects and marketing strategies to diversify customer bases and international sales with a focus on potential tax exemption opportunities (Lee, 2018). However, Lee asserted that these reforms might lead to decreased product availability and quality in the U.S. medical device market. While two subsequent moratoriums

on the medical device excise tax have delayed the enforcement until January 2020 (IRS, 2018), this external factor remains a relevant consideration as organizations determine viable product commercialization strategies.

Value-Based Purchasing and Reimbursement. On the heels of the ACA enactment, hospital groups, clinics, and insurance companies have engaged in value-based purchasing more predominantly than in previous years (Ciani et al., 2017; Grose, 2016). Value-based purchasing goes beyond regulatory approvals and evidence of clinical effectiveness to include cost-effectiveness as part of the purchasing analysis process (Krantz et al., 2017). Grose (2016) stated that for a device to be successful in today's marketplace, "it must be cheaper to use than already approved options, or at the very least, cost no more" (p. 37). Krantz et al. (2017) described an equation for value analysis as VALUE=Quality (outcomes, safety, services)/Cost. The ultimate goal of value analysis is to find the balance between clinical effectiveness, outcomes, and price effectiveness (Krantz et al., 2017). Health technology assessments (HTA) synthesize similar product data to inform health policy development initiatives and insurance reimbursement or coverage decision-making (Ciani et al., 2017). Suppliers of medical devices usually tout their products as either clinically equivalent and cost-effective or clinically superior, yet few can articulate clinical superiority and cost-effectiveness (Ciani et al., 2017; Krantz et al., 2017). Krantz et al. (2017) and Kolominsky-Rabas et al. (2015) recommended that innovators realistically consider and plan for factors relative to value-based purchasing and reimbursement criteria before spending significant time, resources, and financial outlays to develop a device that may not be received in the new clinical purchasing paradigm. Table 5 below highlights several external factors in strategic decision-making and medical device commercialization.

Table 5

External Factors Associated With Medical Device Commercialization

Factor	Impact or influence	Author(s)
Food and Drug Administration (FDA)	Regulates medical device safety, effectiveness, quality, and premarket review processes	Alvarenga and Tanev (2017); Lehoux et al. (2014); Kang & Montoya (2014); Marcus et al. (2016); Martins et al., (2015); Sastry (2014); Su and Wu (2015); Wells et al., (2015)
Compliance inspections	FDA conducts announced and unannounced quality management system audits in the post-market phase for low- and medium-risk devices	Gagliardi, 2009
	FDA conducts quality management system audits in the market phase for high-risk devices pre	D. M. Fox and Zuckerman (2014); Ronquillo and Zuckerman (2017)
Regulatory timelines	Often extend beyond published timeline targets for clearance or approval	Maak and Wylie (2016); Russell (2015)
Regulatory ambiguity	Can cause extended FDA feedback loops or lead to additional or misaligned test plans or results	Anderson et al. (2017); Hoerr, 2011
	Increases difficulty in navigating and managing regulatory obligations	O'Dwyer and Cormican (2017)
	Results in fewer technological advancements available to patients in the United States	Stern (2017).
Regulatory cost burdens	Increase significantly as product risk classification rises from class I to II to III	D. M. Fox & Zuckerman (2014); Maak and Wylie (2016)
Medical device excise tax	Although enforcement is delayed until 2020, a tax of 2.3% on gross sales will directly or indirectly increase the cost of healthcare in the US and will cause reprioritization of product portfolios and new product launches, as well as the availability of certain medical devices on the US market	Lee (2018)
Value-based purchasing and reimbursement	Requires innovators to consider cost-effectiveness of their proposed devices along with safety and clinical effectiveness	Ciani et al. (2017); Krantz et al. (2017)

Operational Factors Associated With Medical Device Commercialization

As discussed earlier in this review, the medical device industry is highly regulated and has numerous constraints, including mandated factors related to product design and regulatory costs and timelines. Innovators and entrepreneurs must also deal with other operational factors such as corporate process and quality management, business ecosystems, human resources, and

the financial resource drain necessary to fund the development of new technologies. The next section of this paper provides a discussion of these operational factors within the context of commercializing medical devices.

Business Process Management

Furterer (2015) described business process management (BPM) as "a disciplined approach to analyze, document, measure, monitor and improve business processes with the goal of achieving consistent, targeted results aligned with an organization's strategic goals" (p. 37). The concept of BPM evolved over decades and emerged as the culmination of various process approaches in the areas of quality, productivity, and information technology, such as total quality management, Lean Six Sigma, just-in-time manufacturing, and the utilization of customer relationship management and enterprise planning software (Furterer, 2015). Since the lack of information and knowledge hinders firm competitiveness, Garg, Elshorbagy, Gupta, Narayanamurthy, and Al Orani (2015) recommended the implementation of information systems that map to the various regulatory standards to accelerate strategic decision-making, manage business operations, and improve process performance. According to Furterer (2015), BPM models include (a) policies (directives, organizational assessments, and influencers); (b) processes (value chains, business functions, and process models); and (c) procedures (metrics & scorecards, training, and work instructions & checklists). A comprehensive information system is useful for a number of reasons, such as structuring the organization, open communication and coordination, supply chain management, and creating an interactive workplace environment (Garg et al., 2015). By applying a BPM infrastructure, firms leverage business processes as assets for strategic goal alignment and operational process implementation and improvement

(Furterer, 2015), which are two essential elements of quality management and regulatory compliance requirements imposed on the medical device industry.

Quality Management Systems

Current good manufacturing practices (cGMP) are operational systems mandated by the FDA in 1996 to provide policies and guidelines on establishing quality management systems (QMS) for medical device manufacturers (Martins et al., 2015). GMPs and related governmental guidelines aim to improve product quality, design, and safety, as well as strengthen supply chain management and surveillance (Su & Wu, 2015). More specifically, the FDA published the initial medical device QMS requirements in the Federal Register (FR) in 1978 by way of 43 FR 31 508, making these regulations the most mature among regulated industries (T. Li et al., 2015).

The quality system regulations were then established in 1996 under section 21 of the Code of Federal Regulations (CFR) part 820, which outlines the documentation and records management requirements for medical device manufacturers (T. Li et al., 2015). 21 CFR part 820 includes extensive requirements, including general provisions, quality systems, design control, document control, purchasing control, identification and traceability, production and process control, acceptance activities, control of nonconforming products, corrective and preventive action, labeling and packaging control, handling, storage, distribution, installation, records management, servicing, and statistical techniques (Food and Drug Administration, 2017). The scope and applicability of these requirements vary depending on the medical device risk classification, complexity, and functionality (Chen et al., 2018; Maak & Wylie, 2016).

The FDA has published requirements under the Unique Device Identifier (UDI) regulations under 21 CFR part 830 (Bayrak & Özdiler Çopur, 2017). The new UDI rules were established to provide a level of transparency between the manufacturer and users of medical

devices, as well as to facilitate post-market surveillance within the clinical use environment (Sheffer et al., 2017). Concerns about medical device safety and device tracking prompted the FDA to embark on a 10-year implantation process that incorporates particular device labeling requirements and public database submissions, including certain device characteristics (Bayrak & Özdiler Çopur, 2017; Roper et al., 2015). The database serves as a searchable repository portal through which the general public and users learn about the device, its characteristics, and regulatory status (Bayrak & Özdiler Çopur, 2017).

From a quality management perspective, device labelers face significant challenges implementing the new rules and making database submissions because the organizations lack comprehensive data management systems containing all the relevant information necessary for the individual Global Unique Device Identifier Database (GUDID) submissions (Sheffer et al., 2017). The extensive labeling requirements include device identifiers and production identifiers in both electronic and human-readable formats (Putman, 2016). The general UDI requirements apply to labelers of devices, regardless of the risk classification. However, the FDA has instituted staged compliance timelines based on device risk classification and characteristics (Bayrak & Özdiler Çopur, 2017). While labelers are faced with technological, resource, and implementation deadlines, organizations have the opportunity to leverage compliance requirements to improve product design, quality management processes, and supply chain management via information flow (Sheffer et al., 2017).

Quality management system standardization has become the norm in the medical device industry. The International Organization of Standardization (ISO) has developed a series of standards for the application of quality management in a number of industries, including medical devices. Medical device-specific standards include ISO 13485, which covers quality

management in a regulated environment, and ISO 14971, which covers the application of risk management throughout the medical device product development life cycle (Martins et al., 2015). ISO standards are reviewed and revised on a 5-year interval, and the latest version of ISO 13485 was published in 2016 (Geremia, 2018). Two of the major differences between ISO 13485:2016 and the previous version include a focused emphasis on regulatory requirements and the application of risk-based thinking. While the application of these standards is not compulsory in the United States, there are several countries (i.e., Brazil, Japan, Canada, etc.) in which demonstrating evidence of compliance is mandatory through a comprehensive certification process (Martins et al., 2015). However, there have been substantial efforts between the FDA and other international regulatory bodies to harmonize the quality management system requirements among national and regional authorities to reduce redundancies, implementation costs, and regulatory oversight (Geremia, 2018). For example, the countries of Canada, Australia, Japan, and Brazil have collaborated with the U.S. FDA to create the Medical Device Single Audit Program (MDSAP), a voluntary (with the exception of Canada) auditing model that combines regulatory authority inspections and ISO 13485 certifications (Chen et al., 2018).

Business Ecosystem

Majava et al. (2016) viewed resource needs from an ecosystem perspective rather than from an environmental perspective (the environment is one element of an ecosystem). Lehoux et al. (2017) suggested that spin-offs operating in an institutional ecosystem react dynamically to progressing expectations through operational management, financial reporting, and implementation of regulatory strategies. In a case study on the city of San Diego's health and life science business ecosystem, Majava et al. (2016) identified numerous key actors that contribute to a successful business ecosystem, as depicted in Figure 2 below. Each actor holds a specific

role or role within the ecosystem. For example, (a) health care providers - target market and access to customers and clinical trial opportunities; (b) trade organizations - advocacy, resources, and networking opportunities; (c) universities and research institutes - avenues for funding, technology conceptual creation and licensing; (d) accelerators - mentoring, coaching, and networking for early stage funding; (e) incubators - startups resources, space, and mentoring; (f) angel investors – seed investments; (g) venture capitalist (VCs) – investment in innovation and funding for company growth; (h) large pharma – partnerships and investments; (i) other companies – human resources (talent) and contribute to continuous ecosystem success; (j) business services – ecosystem supporting activities such as legal, financial, human resources, and networking (Majava et al., 2016).

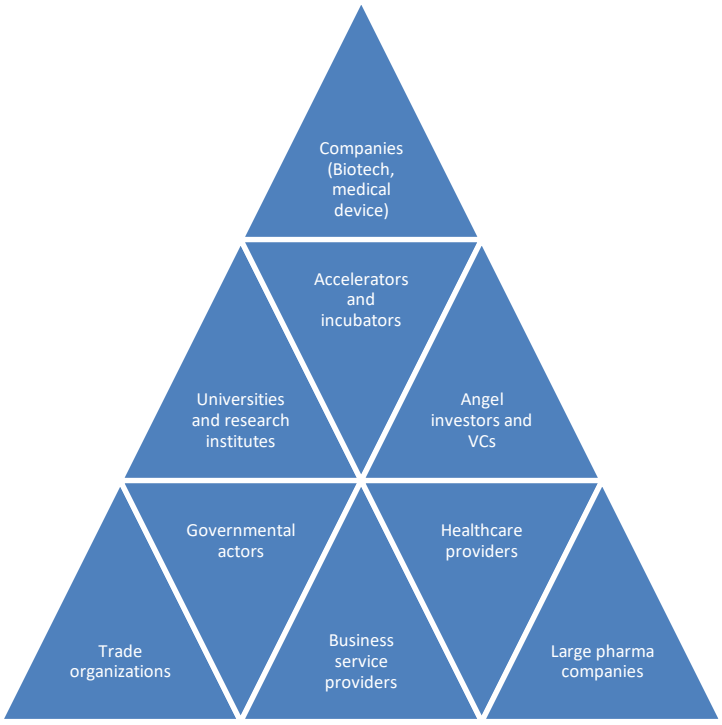

Figure 2. Actors in San Diego's Health and Life Sciences Ecosystem

J. F. Li and Garnsey (2014) stated that "business ecosystems can enable new entrepreneurial firms to work with established business organizations to gain legitimacy and

reduce risk" (p. 763). Appropriate business models are challenging early on in the technology development process (Reymen et al., 2017). Sarkees and Luchs (2015) added that firms embracing strong innovation and marketing tend to engage in alliances with organizations that provide complementary products or services to the firm's core strengths. Entrepreneurs adopting a business model approach to strategic decision-making contribute to the ecosystem by coupling activities with other organizations, offering complementary resources (each party may lack), and, in turn, setting up reciprocating opportunities that align operational and strategic objectives among interested parties (J. F. Li & Garnsey, 2014). Wield et al. (2017) found that in disruptive innovation systems, there are no predetermined business models and value chains to replicate. As such, innovators must develop unique approaches to commercialize such technologies. Wield et al. (2017) argued that business models are theoretical rather than financial, a position echoed by Garud et al. (2014), who stated that entrepreneurs "contextualize innovation through their narratives" (p. 1181) as they seek to mold and shape their reality and infuse meaning to that reality. Effective entrepreneurs make innovations lucid, including business models, business plans, and pitches to the various actors in the ecosystem with the ultimate goal of raising capital and securing future customers in the marketplace (Garud et al., 2014).

While collaboration and strategic alliance relationships can contribute to successful innovation development and commercialization, Dan and Zondag (2016) caution entrepreneurs to consider the drivers of potential alliance termination. For example, the authors discovered that a firm's perception of higher future returns on investment increases the commitment to an alliance. Yet a partner's technological intensity (dedication to ongoing research in-house and development of new technologies) at the time of alliance formation increases the likelihood of a relationship dissolution. Conversely, the higher R&D expenditures are relative to the total assets

of the innovator, increasing the likelihood of the alliance enduring in the long term (Dan & Zondag, 2016).

Public-Private Partnerships

Several authors include public-private partnerships (PPPs) as a central element of a successful business ecosystem. J. F. Li and Garnsey (2014) suggested that innovative entrepreneurs may need to adopt new business models that embrace the concepts of partnerships and strategic alliances in order to gain access to external resources and develop new ways of realizing value streams. Enter PPPs, which have been broadly defined as "working arrangements based on a mutual commitment (over and above that implied in any contract) between a public sector organization with any organization outside the public sector" (Woodson, 2016, p. 1411). These organizational structures lower the barriers to entry when the PPPs align with an entrepreneur's business model by providing funding for R&D, linkages between the company and health organizations, as well as providing assistance with manufacturing, marketing, and distribution activities (Woodson, 2016).

Woodson (2016) described several reasons PPPs form, including (a) partnerships are needed to address complex business problems, (b) groups are more likely to overcome deficiencies in the marketplace, (c) to spread economic risk among interested parties, and (d) to improve economies of scale and availability of talent pools. PPPs also create opportunities for the private sector to influence and contribute to the development of government policies that nurture innovation ecosystems (J. F. Li & Garnsey, 2014). Becton Dickenson, a respected corporation and leader in the medical device industry, as an organization, embraces a collaborative approach to product development, quality management, and regulatory affairs, often becoming involved in public-private partnerships to share industry practice and compliance

approaches with the FDA (Anonymous, 2016). Wield et al. (2017) also emphasized the importance of early collaboration with regulatory agencies and other related stakeholders to avoid future pitfalls and uncertainty associated with the development of innovative life science technologies.

Funding Medical Device Innovation

According to Grose (2016), most medical technology start-ups fail due to a lack of funding associated with the capital requirements of achieving regulatory market access. Innovative product development introduces long time horizons and commercial uncertainty, and, as such, projects require significant upfront investment (Maslach, 2016). A Stanford University (2010) survey of 200 medical device firms revealed that the average FDA activity-related costs range from $24 million for a class II device and up to $75 million for a class III device. However, the total product development costs may exceed $34 million and $94 million, respectively (Maak & Wylie, 2016). Grabowski et al. (2014) found that certain biotechnology developments can exceed $100 million and could take over 5 years to gain regulatory market access. Comparatively, Ahuja and Birge (2016) stated that the cost of commercializing a new drug product could be up to $5 billion, with clinical trial costs for drug products ranging from $300-$600 million. Bains et al. (2016) described an assumption that investors add great value and validation to new biotech ventures; however, the data suggests otherwise, in that a significant fraction of biotech investors have very little experience and expertise in biotechnology. As such, working closely with investees may not add significant support to the project outside funding operational activities (Bains et al., 2016). While many investors are reluctant to fund medical technology projects, Bergsland et al. (2014) suggested that innovators

integrate both technical and medical expertise to accelerate product development, thus improving access to available investment funding.

The life science industry is facing a challenging road forward due to investor reluctance caused by the added time, money, and uncertainty associated with commercializing new medical products (D'Angelo & Benassi, 2015; Russell, 2015). Russell (2015) described the medical device investor dilemma as a drought; despite the resurging U.S. venture capital movement that invested approximately $30 billion in startups in 2013, the medical device industry received only $2.1 billion, which is the lowest funding amount of the previous 10 years. The percentage of U.S. capital investment in the medical device industry dropped from 11% in 2009 to 5% in 2016 (Smith, 2017). Hoerr (2011) stated that regulatory uncertainty is one of the major roadblocks to the availability of venture capital. The perceived uncertainty stems from personal and observed experiences where, in some cases, regulatory market access may not be received for up to 4 years after clinical trials are completed (Russell, 2015). Such potential timelines significantly impact venture capitalists in achieving expected returns on investment (Hoerr, 2011) due to operating cash flow burn rates during the FDA review cycles (Russell, 2015). Smith (2017) suggested that investment returns in the U.S. market would improve if the FDA restructured the risk profile and regulatory application process to achieve faster market access.

While venture capital firms have left the medical device industry in pursuit of markets of more predictable returns, angel investors, small business incubators, and corporate partners have moved in to support NPD (Smith, 2017). Other sources of funding, such as Small Business Innovation Research (SBIR) grants, however, are typically not sufficient to commercialize a new medical device concept (Grose, 2016). Of the 1500 Phase II SBIR grants issued between 2005 and 2011, only 32% of the applicants were considered successful 6 years after the award (Grose,

2016). Bains et al. (2016) stated that companies may be utilizing angel investors or seed funds as bridges to venture capital; however, venture capital-backed projects tend to be more successful than those operating on capital raised from other sources. Investors in the medical device industry must be comfortable with the potential risk of failure and unpredictable commercialization processes (Pahnke et al., 2015; Russell, 2015).

Human Resources and Collaboration

Until the widespread use of artificial intelligence, the development and successful commercialization of new technology will always be dependent on human beings. Knowledge diversity, competence, and collaboration are often associated with groundbreaking innovation, yet many large organizations operating in regulated environments hold so tightly to intellectual property and development processes that they struggle to sustain performance (M. O'Dwyer et al., 2015). According to Garg et al. (2015), a firm's competitiveness in the marketplace is based on its ability to exploit its knowledge-based (human) resource and information flow.

Entrepreneurs typically lack the human resources necessary to organically develop and commercialize new technologies to directly compete in the marketplace, yet also seek to cooperate with industry incumbents to optimize the use of complementary assets (Marx & Hsu, 2015). Innovation clusters promote "learning relationships" and create efficiencies in knowledge transfer (M. O'Dwyer et al., 2015) when startups struggle to develop cooperative partnerships with existing market leaders (Marx & Hsu, 2015). The pharmaceutical industry recently recognized 'open innovation' as an approach to innovation by sourcing knowledge and expertise through multiple external sources. This move may not only reduce R&D budgets but also accelerate the development of novel platforms and acquisition opportunities (Ku, 2015). Wield et al. (2017) found that open innovation is valuable for developing complete value chains and

interorganizational knowledge when contemplating innovative technology commercialization. Such collaborative working and learning environments may also aid entrepreneurs in dealing with supply chain logistics, skillset development, and management of compliance challenges (MacCarthy et al., 2016; Martelli & Hayirli, 2018; Pawar & Chakravarthy, 2014) that emerge during the premarket stages of regulated product commercialization.

Training. While knowledge and information flow are critical to firm competitiveness, training (and documentation thereof), human resources in regulated industries presents a unique set of challenges. Götze et al. (2018) found four major challenges regulated firms face when implementing and managing training programs:

- Motivation – training is scheduled based on regulatory requirements (external factors), employees find minimal, if any, intrinsic motivation to complete training.
- Standardization – training is designed to meet specific regulatory requirements, the content is inflexible and standardized, which causes learning to become more of a checklist of tasks rather than effective and interactive.
- Psychological ownership – due to the nature of training (template, standardized, predetermined, etc.), trainees and trainers lack a connection to or enthusiastic delivery, acceptance, engagement, and application of the information delivered.
- Training delivery – training effectiveness depends on the availability of adequate infrastructure and communication within the firm; the use of web-based platforms adds accessibility and traceability but increases staffing and technology-driven training costs.

To combat these challenges, Götze et al. (2018) recommended applying situational awareness to training programs to avoid the perception of obligatory task-based training, utilizing both voluntary (personally relevant) and work-related (regulatory mandated) training elements, and

promoting the concept of co-creation of training to encourage ownership and appreciation for the training and its application within the organization.

There are several implications for an organization when considering the implementation of strategic human resource development (SHRD). Mello (2014) stated that the first step in strategic management is the review and establishment of an organization's mission statement. Organizational alignment is critical for the effectiveness and profitability of any operational enterprise. The mission statement is the basis and driver for everything the organization undertakes. Alagaraja (2013) found that SHRD can be considered successful when departments are working towards alignment between department goals and strategies and the overall corporate mission and vision. The author stated that alignment "as a process is meaningful for understanding interpersonal (leadership) and interdepartmental dynamics (e.g., quality and operations)" (p. 90). Strategic management also requires an assessment of various resources, including human resources. According to Mello (2014), an organization can be no stronger than its weakest employee. By assessing the resources available along with their respective strengths and weaknesses, a firm can determine which areas of the organization need to be reinforced or reallocated. Other implications for the use of human resource development in an overall strategy include measurable performance improvements, increased job satisfaction, advancements in innovation initiatives, and the development of new competitive advantages (H. L. Fox, 2013). Table 6 below highlights several operational factors authors have identified as considerations in strategic decision-making and medical device commercialization.

Table 6

Operational Factors Associated With Medical Device Commercialization

Factor	Impact or influence	Author(s)

Business process management	Aligns business operations with strategic goals	Furterer, 2015
	Provides mapping of systems to accelerate strategic decision-making and improve process performance, creates an interactive workplace environment	Garg et al., 2015
Quality management systems	Establishes a framework for compliance with FDA cGMP requirements	Bayrak & Özdiler Çopur, 2017; Li et al., 2015; Martins et al., 2015; Putman, 2016; Roper et al., 2015
	Allows for flexibility in implementation practices depending on device risk classification	Chen et al., 2018; Maak & Wylie, 2016
	Standardizes system development, implementation, and auditing across the medical device industry including elements of risk management	Chen et al., 2018; Geremia, 2018; Martins et al., 2015
Business ecosystems	Organizations operating in a business ecosystems can react dynamically to progressive expectations through collaboration	Lehoux et al., 2017
	Encourages alignment between the various actors within the ecosystem to support each other through strategic objectives	J. F. Li & Garnsey, 2014; Majava et al., 2016; Woodson, 2016
	Allows firms to gain legitimacy and reduce risk	J. F. Li & Garnsey, 2014; Woodson, 2016
	Promote unique approaches and business models to commercialize innovative technology	Garud et al., 2014; J. F. Li & Garnsey, 2014; Wield et al., 2017
Funding medical device innovation	Lack of sufficient funding is the source of most medical start-up failures	Grose, 2016
	Extensive and sustainable funding is required to commercialize medical technologies	Maak & Wylie, 2016; Maslach, 2016; Stanford University, 2010
	High investment risk and regulatory uncertainty discourage many investors from entering the medical device industry	D'Angelo & Benassi, 2015; Russell, 2015; Smith, 2017
	Government grant opportunities are not sufficient sources of funding	Grose, 2016
Human resources and collaboration	Organizations struggle to sustain performance and competitive advantage due to a lack of Knowledge diversity, competence, and collaboration	Garg et al., 2015; Marx & Hsu, 2015; M. O'Dwyer et al., 2015
	Innovation clusters and open innovation promote a learning environment and skill set development for regulated industries	Ku, 2015; MacCarthy et al., 2016; M. O'Dwyer et al., 2015; Wield et al., 2017
	Due to dynamic and ambiguous requirements, training programs in regulated industries face challenges such as motivation, standardization, psychological ownership, and training delivery mechanism	Götze et al., 2018
	Training programs may be utilized to create awareness and alignment between personnel engagement and organizational strategic objectives to create competitive advantages	Alagaraja, 2013; H. L. Fox, 2013; Mello, 2014

Leadership Factors Associated With Medical Device Commercialization

Maslach (2016) suggested that as individuals develop competencies associated with technology development, they apply solutions learned during previous projects to censor unsuccessful choices relative to risky decision points. Similarly, Ringel et al. (2013) found that R&D tenure, frequent decision-making, and early project terminations are indicators of good judgment and correlate positively with successful product development. Shluzas and Leifer (2014) identified several predictors of successful product development including entrepreneurial background and selected strategy; additionally, medical device firms founded by an entrepreneurial clinician demonstrate an increased likelihood of successful development of "relevant knowledge" (p. 650). Company founders also play a critical role in new ventures by ensuring employees remain motivated and unified under a shared vision and strategy (Shluzas & Leifer, 2014).

Schwartz et al. (2018) suggested that senior management engagement is essential for the development or articulation of product life-cycle business cases. Ray et al. (2017) described a leadership-driven shift at Johnson and Johnson (J&J) with respect to NPD process best practices as a needs-based approach to innovation, through which the teams focus on clinical needs rather than solutions by articulating "a specific problem to be solved in a specific patient population, by a specific provider type, at a specific setting, to achieve a specific outcome" (p. 91). The company shifted innovation models to create disease-focused activities oriented towards specialization and flexible development processes, including extensive collaboration with clinical specialists and partnering with external physician-innovators seeking to develop novel technological advancements in patient care.

Sharp et al. (2017) examined the top management team (TMT) impact and influence on innovation. The authors sought to better understand the size or level of impact TMTs bring to their respective organizations, which is associated with organizational characteristics and the shaping of the business environment. Sharp et al. (2017) sought to expand on prior studies of technology development in an organizational structure, and the context of TMT characteristics influence on the enhancement or impedance of innovation development. Although the study focused on a single factor, TMT influence over the commercialization of radical innovations, the authors made several relevant discoveries: (a) there is no significant association between TMT average age or average tenure and the radicalness of innovation; (b) increasing diversity or heterogenicity of the TMT suggests the creation of more radical innovations; and (c) the TMT effect in firms with incremental design focused portfolios is significant, whereas the TMT influence is not significant for organizations developing radical innovations (Sharp et al., 2017).

M. O'Dwyer et al. (2015) observed that business leaders in an innovative product development environment acknowledge the importance of dialog amongst stakeholders to eventual innovation success. However, as Sharp et al. (2017) recognized, there is a difference between innovation and commercialization. As such, the success in a given phase of the process is dependent on the differing individual leaders' expertise at each stage. Healey and Hodgkinson (2017) suggested that executive situational awareness aids leadership teams in initiating discourse between collogues to determine strategic decision points and information processing. Such awareness helps to promote communication and gain feedback from peers, which in turn stimulates thinking and refocusing on misaligned strategic solutions (Healey & Hodgkinson, 2017). The authors provided an example of leaders exhibiting the ability to control the emotional trajectory of an opportunity through intentional dialogue when "executives might conceive

regulatory change as a chance to steal a march on the competition, rather than another fight against red tape, or interpret a failed new product launch as an opportunity to learn, rather than a mortal blow to the firm" (Healey & Hodgkinson, 2017, p. 119). Table 7 below highlights several leadership factors authors have identified as playing a part in strategic decision-making and commercialization success.

Table 7

Leadership Factors Associated With Strategic Decision-Making

Factor	Impact or influence	Author
Competence from prior R&D projects	Censor unsuccessful choices	Maslach, 2016
R&D tenure	Positive influence on R&D project success through frequent decision-making and early project termination	Ringel et al., 2013
Entrepreneurial background and strategy selection	Predictors of successful product development	Shluzas & Leifer, 2014
New venture founder's longevity	Motivation and unification under a shared vision and strategy	Shluzas & Leifer, 2014
Leadership engagement	Articulation of business cases and strategic shifts in process models	Schwartz et al., 2018 and Ray et al., 2017
Leadership team heterogenicity	Potential for the creation of more radical innovations	Sharp et al., 2017
Leadership dialog with stakeholders	Essential to innovation success	M. O'Dwyer et al., 2015
Leadership expertise at each stage of the innovation process	Essential to phase-wise success	Sharp et al., 2017
Leadership situational awareness	Promotes communication amongst stakeholders and stimulates strategic refocusing	Healey & Hodgkinson, 2017

Regulatory Strategy in the Medical Device Industry

Many investors avoid opportunities in the medical technology industry due to the regulatory uncertainty companies face when bringing new products to the market (Hoerr, 2011). Such investor hesitation is understandable, considering the high product development costs and timelines for U.S. market access. Acknowledging the high investment risk of medical technology development and commercialization, venture capitalists confirm the importance of regulatory intelligence and strategy early in the product development process (Schueler & Ostler, 2016).

Contract research organizations (CROs) and regulatory professionals express similar opinions; however, entrepreneurs often fail to recognize the value regulatory strategies provide in the context of business planning, modeling, and operations (Ammann, 2008; Kramer, 2014; PRA Health Sciences, n.d.). C. O'Dwyer and Cormican (2017) encouraged management teams to "incorporate regulatory strategy into the corporate agenda" (p. 37). According to Ammann (2008), understanding the regulatory landscape well in advance of major project milestones is crucial to ensuring the organization establishes an appropriate framework for planning the regulatory pathway. Additionally, a comprehensive regulatory strategy identifies potential risks of regulatory interruption or failure based on device features, characteristics, and intended use (Ammann, 2008; PRA Health Sciences, n.d.).

A regulatory strategy has been described as "a plan of action designed to achieve a specific regulatory goal, such as to obtain approval or clearance" for new medical technology (Kramer, 2014, para. 1). According to a recent survey by the Regulatory Affairs Professionals Society (RAPS) (2016), regulatory associates allocate approximately 41% of their time on the job to regulatory strategy, regulatory intelligence, and regulatory operations. MaRS Discovery District (2010) identified three main purposes for a regulatory strategy, including a tracking tool for regulatory activities, a planning tool for required documentation and submission timelines, and a risk register for identifying potential issues impacting timelines, costs, and project valuations. Additionally, a regulatory strategy serves as a scoping exercise to determine the extent of testing that may be required, such as bench, safety, preclinical, and clinical testing (Ammann, 2008). Kramer (2014) outlined several possible steps in the regulatory strategy development process, including (a) product attribute identification, (b) regulatory intelligence

gathering, (c) triangulating and documenting, (d) confirming the strategy's viability, and (e) making the strategy a living process.

The regulatory strategy development process is critically for novel technologies because the regulatory pathways may not be well-defined and require regulatory agency feedback (Ammann, 2008). Hoerr (2011) stated that "clarity in the regulatory requirements and advance notice of potential changes are key to minimizing the effect" on project scheduling and subsequent innovation investment capital (p. 1519); such clarity provides the more predictive environmental information entrepreneurs require for decision-making. Other activities professionals may incorporate into regulatory strategy development may include optimizing labeling claims for upcoming submissions, summarizing applicable standards and guidance documents, regulatory lifecycle management (including post-market surveillance and studies), as well as options for accelerated product development and market access (MaRS, 2014). PRA Health Sciences (n.d.) described the regulatory strategy process as the adjustments an organization navigates through development to market authorization. C. O'Dwyer and Cormican (2017) recommended that medical device developers communicate clear regulatory strategies within the organization to improve the frequency of achieving on-time market access. Kramer (2014) added that a "well-executed regulatory strategy can lead to more predictable product development and (regulatory) clearance process" (para. 12).

Strategic Success Factors

While the current body of literature lacks empirical evidence regarding the factors related explicitly to regulatory strategy success, several authors have reported findings associated with successful research and development (R&D) projects, of which, in the medical technology industry, the regulatory strategy is a critical element of the R&D process. For example, The

Boston Consulting Group analyzed data from 419 drug development companies over a 10-year period and found several indicators of good judgment that positively correlate with success or failure in R&D projects (Ringel et al., 2013). Such indicators include R&D tenure, frequent consideration for return on investment (ROI), frequent use of the term ‘decision-making,' and early termination of projects (Ringel et al., 2013). Several other R&D success factors emerged from the study, such as prior demonstration of scientific acumen through publication, patents, and association with R&D scientific hubs (Ringel et al., 2013).

In a recent study on medical device NPD in Ireland, C. O’Dwyer and Cormican (2017) identified strategy, commitment, team organization, processes, and culture as five elemental drivers of NPD success. The authors also highlighted the importance of ensuring the device's intended use and marketing claims are defined and aligned early in the NPD. Such alignment dictates the regulatory strategy and pathway going forward as products are developed and tested according to applicable regulatory requirements (Krucoff et al., 2012). While a survey of 57 respondents from medical device firms marketing products in the European Union under the Medical Device Directive (MDD) acknowledged the need to organize a collaborative team environment in NPD projects, 50% of the study participants indicated that representatives from marketing departments are not present during the critical early stage product and marketing definitions phases (C. O’Dwyer & Cormican, 2017).

Effective team organization emerges when top management demonstrates a commitment to providing adequate resources and support for the established regulatory strategy (C. O’Dwyer & Cormican, 2017; Ringel et al., 2013). Kirkire and Rane (2017) demonstrated that the availability of experienced experts, stakeholder engagement throughout the product development lifecycle, and well-defined device user requirements are the most influential factors of successful

medical device development. Researchers have also suggested stakeholder integration early in the development process to incorporate academia, industry professionals, as well as government agencies, which may alleviate investor hesitation (Bergsland et al., 2014). Such collaborative environments encourage an organizational culture for regulation where employees understand the regulatory impact of their efforts, observe management's commitment to achieving regulatory compliance through business strategy, and appreciate the benefits of regulatory requirements such as the development of safe and effective medical devices (C. O'Dwyer & Cormican, 2017). Ringel et al. (2013) posited that there "is enormous untapped potential in designing the right organizational context" to facilitate R&D productivity (p. 902), which in turn will "positively influence the speed of market access" (C. O'Dwyer & Cormican, 2017, p. 36). Table 8 below shows a summary the regulatory strategy success factors identified in the literature and the factors under investigation.

Table 8

Regulatory Strategy Success Factors

Factor	Impact or influence	Investigational factors(s)	Author
Good judgement	Positively correlate with success or failure in R&D projects	Operational, leadership	Ringel et al., 2013
Strategy, management commitment, team organization, processes, and culture	Drivers of NPD success	Operational, leadership	C. O'Dwyer & Cormican, 2017; Ringel et al., 2013
Collaborative team environment	Needed for medical device NPD projects	Operational	C. O'Dwyer & Cormican, 2017
	The correct organizational context positively influences the speed of market access	Operational	Ringel et al., 2013
Early alignment between device intended use and marketing claims	Provides framework for developing regulatory strategy	Product design	Krucoff et al., 2012; C. O'Dwyer & Cormican, 2017
Well-defined user requirements	Influential factors in medical device development	Product design	Kirkire & Rane, 2017

Stakeholder engagement and integration	Influential factors in medical device development	Operational, leadership	Kirkire & Rane, 2017
	Alleviates investor hesitation	Operational, leadership	Bergsland et al., 2014
Availability of experienced experts	Influential factors in medical device development	Operational, leadership	Kirkire & Rane, 2017

Anticipated and Discovered Themes

In this study, an in-depth thematic analysis was conducted to compare the themes that were projected in the literature review with those that emerged from the research findings. Although the number of interviews was limited, the research reached data saturation, with themes emerging until no new information was uncovered. The anticipated themes from the initial research suggested that innovation sources, regulatory challenges, compliance, device classification, regulatory pathways, and operational factors such as business process management would be prominent. These were indeed reflected in the findings but with refined nuances and additional depth.

Themes around financial strategy and regulatory economics materialized, affirming the literature's projection of innovation's impact on regulatory strategies and the particular financial considerations with respect to planning regulatory strategy. The theme of agile regulatory strategy development was also realized, which mirrored the literature's foreseen need for proactive and adaptable regulatory strategy approaches.

Themes of mastering regulatory strategy and strategic knowledge integration confirmed the literature's expected emphasis on overcoming regulatory challenges and maintaining compliance. These, alongside themes like proactive regulatory engagement, showcased the essential nature of foresight and interactive dialogue with regulatory bodies, a point the literature had alluded to as vital for strategic planning. Furthermore, themes highlighting collaborative

ecosystems and systems integration resonated with the literature's operational factor themes, underscoring the importance of integrated approaches for successful regulatory implementation. The balancing of innovation and risk considerations echoed the literature's insight on product complexity and the strategic navigation of regulatory requirements.

Additionally, themes such as development dynamics and the necessity of strategic leadership efficacy emerged strongly, aligning with the literature's anticipated importance of leadership in navigating the regulatory landscape. However, unique themes like regulatory uncertainty and supply chain considerations surfaced, revealing intricacies not explicitly detailed in the preliminary research but nevertheless crucial to regulatory strategy success.

Strategic Knowledge Integration and Proactive Regulatory Engagement were among the themes that were discovered and provided new insights into the importance of blending expertise within the regulatory framework and the strategic advantage of initiating early dialogues with regulatory bodies. Regulatory Uncertainty highlighted the unforeseen challenges in FDA interactions, and Supply Chain Considerations in Regulatory Strategy emphasized the interconnectedness of regulatory compliance and supply chain management.

The comparative analysis between anticipated and discovered themes offers a comprehensive view of the nuances in regulatory strategy within the medical device sector. It reveals a complex picture where strategic planning, knowledge integration, proactive engagement, and adaptability are not just beneficial but essential for navigating the regulatory maze and achieving commercial success.

Summary and Transition

Section 1 of this study provided a background of the problem as well as the problem statement, which addresses the gap in benchmarked best practices associated with regulatory

strategy success in the medical device industry as a significant barrier to generating internal or external development capital. The purpose of this case study was to explore the variables that contribute to medical device regulatory uncertainty and regulatory strategy best practices based on the experiences of industry professionals. The theories that ground this study included institutional theory (Turner & Angulo, 2018), systems theory (Yang, 2016), and chaos theory (Hung & Lai, 2016). Regulatory strategy in the medical device industry is an understudied topic, and this study aimed to help fill the research gap.

This research is related to the international business field of study as the United States lags behind other developed nations in NPD and availability of innovative medical devices, making it difficult for U.S. device manufacturers to maintain a competitive advantage over international counterparts (Krucoff et al., 2012; Sorenson & Drummond, 2014). The medical device development and commercialization processes are complex and highly regulated. Venture capitalists hesitate to invest in novel medical technologies due to the high-risk premiums associated with development costs, regulatory uncertainty, and market access lead times. This literature review was intended to provide the reader with detailed information on the medical device innovation landscape, barriers to market entry, design control processes, and regulatory oversight, and includes highlights of the regulatory strategy process, its purpose, and benefits. Section 2 of this study includes details of the research design and methodologies applied, as well as information related to the data collection, organization, and analysis techniques.

Section 2: The Project

Regulatory strategy can have a significant impact on the successful commercialization of new technologies. This qualitative study explored how regulatory affairs professionals and other stakeholders in the medical device industry perceived the various factors involved in developing and implementing a successful regulatory strategy. While a number of variables influence how a strategy is developed and implemented, this study focused on operational, leadership, product design, as well as external factors, as they were most prevalent in the scholarly literature relative to the regulatory uncertainty involved in bringing a new medical device to the marketplace in the United States (Altenstetter, 2013; Bayrak & Özdiler Çopur, 2017; Grose, 2016; Hadengue et al., 2017; Krucoff et al., 2012; Laurell, 2018; T. Li et al., 2015; Maak & Wylie, 2016; Martins et al., 2015; C. O'Dwyer & Cormican, 2017; M. O'Dwyer et al., 2015; Putman, 2016; Ray et al., 2017; Roper et al., 2015; and Schwartz et al., 2018). Identifying industry best practices in this arena aids both innovators and investors as they evaluate NPD projects and investment opportunities. The remainder of this section includes the details related to the following: (a) purpose statement, (b) role of the researcher, (c) participants, (d) research methods and design, (e) population and sampling, (f) data collection, (g) data analysis, and (h) transition and summary.

Purpose Statement

The purpose of this case study was to explore the variables that contribute to medical device regulatory uncertainty and regulatory strategy best practices based on the experiences of industry professionals. Sisodia et al. (2016) conducted a study to demonstrate the impact of regulatory uncertainty on potential investments using NPV and RO values at a macro level. The authors evaluated uncertainty within the context of delayed marketability in the energy sector. While their study demonstrated NPV and RO as viable investment tools to predict financial

outcomes associated with project delays, these assessment instruments do not offer investors or innovators a benchmark of regulatory strategy best practices to be employed during the NPD process. This present study built on this gap by striving to discover the factors industry professionals perceive as contributory to both regulatory strategy success and regulatory uncertainty in the U.S. medical device industry.

Startups and new market entrants typically lack the infrastructure and experience to adequately demonstrate regulatory proficiency simply due to the lack of experience (Chatterji, 2009) when presenting investment opportunities to potential financial partners, a fact that venture capitalists weigh heavily when considering market entry options (Schueler & Ostler, 2016). At the same time, both entrepreneurs and investors lack industry benchmarks for evaluating regulatory strategy success early in the product life cycle, yet investors expect a sound, comprehensive regulatory strategy at the first meeting (Schueler & Ostler, 2016). The primary objectives of this study included the following: (a) to identify, from open-ended questioning operational factors that reoccur across interviews and appear important to examples of successful regulatory outcomes; (b) to identify, from open-ended questioning operational factors that reoccur across interviews and appear important to examples of unsuccessful regulatory outcomes; (c) to identify prerequisites to the formation of successful/unsuccessful operational factors; (d) To identify factors that emerge and define successful regulatory outcomes; and (e) To identify, operational variables that generate regulatory uncertainty. The researcher believed that a study of regulatory strategy best practices would provide a benchmark for both innovators and investors to evaluate regulatory strategies associated with new medical device market entry projects for the U.S. marketplace.

Role of the Researcher

Stake (2010) described the target of a research project as "the thing" (p. 25). "The thing" in this qualitative study were the factors surrounding successful regulatory strategy in the U.S. medical device industry. A preliminary exploration of this research topic came in the form of a comprehensive review of the literature delineating the focal point of the study (Fry et al., 2017). To further examine the individuals involved in the regulatory process, the researcher conducted interviews with participants to understand the experience (Fry et al., 2017) surrounding and supporting the development and implementation of regulatory strategy.

The qualitative data in this study was collected by way of semistructured interviews to determine what variables industry professionals perceive as essential to regulatory strategy success. Semistructured interviews allow improvised questions in follow-up discussions to gain deeper knowledge from the interviewee's narrative (Kallio et al., 2016). Interviews were appropriate for this study as they facilitate interaction between the researcher and participant, which improves contextual understanding (Buckley, 2015). The researcher was responsible for identifying and contacting study participants for primary data collection by conducting the interviews, which were later transcribed, codified, and analyzed to identify themes and variables that emerged. The researcher sought to achieve thematic data saturation. Data saturation is defined as the point at which no new themes emerge from the interview data analysis (Saunders et al., 2018).

The researcher's interest in this field stems from a 25-year career in the medical device and pharmaceutical regulatory environment. While having practical and personal experience with developing and implementing regulatory strategies, the researcher intended to utilize qualitative inquiries of other individual "situational experiences" to better understand "how the

thing works" (Stake, 2010, p. 57) and what factors industry professionals perceive as contributing to best practice in achieving regulatory strategy success.

Participants

The researcher recruited participants who were knowledgeable and experienced in regulatory affairs and regulatory strategy. A copy of the recruitment letter is located in Appendix A. To mitigate the risk of recruiting inexperienced individuals, the study primarily targeted mid- to senior-level managers and directors. To ensure participants interviewed are responsible for the planning and / or implementation of regulatory strategies within their respective organization, a participant qualification screening took place prior to participant involvement in the study. A copy of the interview screening guide is located in Appendix B. To provide triangulation of the results, the study also includes interviews from the perspective of investors, entrepreneurs, and other venture capital professionals involved in medical device innovation commercialization. The researcher acknowledged that qualitative research involves "investigating, embracing, and challenging one's beliefs and experiences" (Roger et al., 2018, p. 533). To address the risk of researcher bias and jeopardizing the identification of thematic data, the interview questions were purposefully designed to elicit the personal experience of the participants (Salter & McGuire, 2015) based on prior studies, interviews, and surveys identified in the literature.

Study participants were recruited using purposive and snowball sampling methods. The initial phase of participant recruitment involved publicizing the opportunity on platforms such as the Regulatory Affairs Professionals Society (RAPS), the Association for the Advancement of Medical Instrumentation (AAMI.ORG), and LinkedIn, which did not yield any participants. Subsequently, direct purposive recruitment was more successful in identifying individuals who were both qualified and willing to participate. Recruitment efforts were sustained until the point

of data saturation was reached, indicated by the lack of new information that added to the understanding of the research questions, as well as informational redundancy, where further data did not alter the emerging themes (Francis et al., 2010; Grady, 1998; Saunders et al., 2018). Specifically, thematic saturation occurred after seven interviews, with no new themes or insights emerging (Guest et al., 2006).

Once qualified, participants were required to read and sign an informed consent form (Beskow et al., 2004), which outlined the study parameters of the data collection process, including confidentiality and privacy (Appendix C). Each participant was identified by pseudonyms to safeguard response anonymity (J. W. Creswell, 2013). Qualitative research often requires establishing a relationship with the participants (Roger et al., 2018) to ensure the most robust experiential and contextual narratives are gathered. To that end, the researcher approached the interview process as a mutual learning and research experience (Roger et al., 2018). Initial contact with participants included a phone call, text message, or email to briefly describe the study and its purpose to develop a working relationship. To ensure the researcher adopted an ethical approach to data collection, participant privacy, and confidentiality, the proposed study was reviewed and approved by the Institutional Review Board (IRB) at Liberty University. The IRB deemed the study to be exempt from further oversight and granted permission to proceed with the study. A copy of the IRB Exemption is located in Appendix G.

Research Method and Design

According to Stake (2010), qualitative research is interpretive, experiential, situational, and personalistic. The topic under study was best practices for achieving regulatory strategy success in the medical device industry. Numerous studies utilized qualitative research methods while investigating perceptions on the topics of regulatory processes and strategies. Buckley

(2015) utilized qualitative methods to examine interactions between U.S. Food and Drug Administration (FDA) regulators and small food processing organizations through interviews and field observations. Buckley found that collaborative interactions between small businesses and inspectors appear to play a role in improved regulatory compliance, although the study was limited to food establishments and compliance inspections in the state of Michigan. Kesselheim et al. (2017) chose qualitative methods to assess individuals' knowledge and perception of FDA regulatory processes. de Vries et al. (2017) employed qualitative research to understand the influential factors of reporting adverse events to the FDA in healthcare environments. This study aimed to better understand the variables regulatory professionals perceive as important to regulatory strategy success in the medical device industry. The study required the interpretation of subjective personal narratives based on experiences within a particular context (FDA-regulated environment).

Qualitative research is intended to provide a better understanding of how things are happening and working in a particular situation (Stake, 2010). This study utilized a case study qualitative method design, an appropriate approach to gathering the necessary data to address and answer the research questions. Regulatory strategy success factors are an understudied topic, with most scientific journal articles reporting individual case examples or generalized stepwise methods to fulfill regulatory requirements (Fisher et al., 2015; Johnson et al., 2014; King, 2015; Kwon & Lee, 2017). As such, interviewing was an acceptable qualitative method of collecting insights on the underexplored problem (Crowther et al., 2017).

According to Cypress (2018), "An interview is a discussion with purpose" (p. 303). Through the use of interviews with industry professionals, the researcher aimed to qualitatively identify and analyze themes related to operational factors that appear to be essential in realizing

desired strategic regulatory outcomes. Open-ended interviews provide an interactive environment in which the participants respond to questions comprehensively in their own words based on their experience (Cypress, 2018). Bril-Barniv et al. (2017) added that open-ended questions "allow for personal stories" (p. 575) and minimizes the potential for predetermined responses (Cypress, 2018), which, in turn, results in a deeper understanding of the situation and richer contribution to the professional practice (Stake, 2010) of regulatory strategy in the medical device industry.

During this study, interviews were scheduled and recorded using Microsoft Teams. Participants were designated with unique identifiers from P1 to P7 in the order they were scheduled. Each participant was notified that the interviews would be audio-recorded; all participants consented to this process. Employing a semistructured format, the interviews adhered to a topic-based guide yet allowed room for additional questions, offering a deeper dive into each participant's insights. Questions were systematically organized to align with the study's five central research questions, ensuring focused and relevant discussions. The five key topics of the interviews encompassed (a) regulatory strategy process variables, (b) operational factors, (c) product variables, (d) leadership factors, and (e) external variables.

Population and Sampling

The researcher interviewed medical device industry professionals who had been involved in the development and implementation of regulatory strategy activities associated with the commercialization of medical technology in the United States as the primary source of data. In an effort to ensure the professionals have adequate industry experience, the individuals targeted for the study will be mid- to senior-level management and directors either in their current or recent (within the last 5 years) job functions. By limiting study participants to those involved in

the development and execution of regulatory strategies to the last 5 years is key due to the fact that the regulatory landscape is somewhat fluid and consistently changing with new FDA guidance documents and applicable testing standards (Russell, 2015). To triangulate the data from a different perspective, a secondary group of participants was selected from investors and entrepreneurs involved in financing and capital contributions to medical technology start-ups. Insights from these individuals will aid in answering the research questions.

A purposeful sampling strategy for the selected sample population was intended to ensure that the study participants have experienced the event (e.g., regulatory strategy success) in question (J. Creswell & Poth, 2018). Multiple authors have indicated that the number of study participants should not be considered as critical as the depth of the experience of the participants (Englander, 2012; Robinson, 2014). Qualitative research may involve a range of sample sizes of 3-16 (Robinson, 2014) to 5-25 and up to 30 (Cypress, 2018). When a researcher questions, "How many cases?" J. W. Creswell (2007) indicated that while no set number of cases can be determined, usually 4-5 cases, no more are selected by the researcher. As such, the researcher focused on achieving data saturation rather than achieving a quantitative and specific statistical sample size more typical in quantitative research studies (Cypress, 2018; Robinson, 2014; Saunders et al., 2018). The recruitment process was carried out until data saturation and informational redundancy were reached, ensuring that each of the research questions was comprehensively addressed (Francis et al., 2010; Grady, 1998; Saunders et al., 2018). Specifically, thematic saturation was achieved after conducting seven interviews, at which point no additional themes or insights were identified in the data (Guest et al., 2006). Interviews that utilize open-ended questions permit study participants to respond to the interviewer in their own words and thoughts, through which the experiential themes are identified and later analyzed

(Cypress, 2018). Table 9 below describes the researcher's four-point approach to qualitative sampling utilizing an adaptation to the approach described by Robinson (2014).

Table 9

Four-Point Approach to Qualitative Sampling

Point	Name	Definition	Key Decision(s)
1	Define a sample universe	Establish a sample universe, specifically by way of a set of inclusion or exclusion criteria	Geographic homogeneity: limited to US medical device regulatory strategy; inclusion criteria: mid- to senior-level managers and directors involved in regulatory strategies in the last 5 years
2	Decide on a sample size	Choose a sample size or sample size range, by taking into account what is ideal *and* practical	6-12 participants (or until data saturation was achieved)
3	Devise a sample strategy	Select a purposive sample strategy to specify categories of persons to be included in the sample	Primary data source group (regulatory professionals); secondary data source group (investors/ capitalists)
4	Source the sample	Recruit participants from the target population	No incentives; database recruitment and snowball / chain sampling

Data Collection

Qualitative data collection may involve a number of potential activities, including, but not limited to, observation, interviews, exhibit questions, and surveys (Stake, 2010). According to J. W. Creswell (2007), case study researchers rely on the interview method to study an event, program, or activity experienced by the study participants. Through the interview, the research becomes the primary instrument in the data collection process and attempts to enter the participant's "world and perspectives" (Cypress, 2018, p. 304).

Instruments – Qualitative Studies

According to Stake (2010), there are three main purposes researchers utilize interviews:

1. "Obtaining unique information or interpretation held by the person interviewed

2. Collecting a numerical aggregation of information from many persons
3. Finding out about ‘a thing’ that the researchers were unable to observe themselves” (p. 95).

The interview is intended to be interactive and conversational (Cypress, 2018; Stake, 2010). To promote an efficient and consistent interview process, an interview guide was developed to ensure the interviewees had an opportunity to present their individual experiences. The open-ended interview questions were designed to facilitate an in-depth conversation on the topic of the regulatory strategy process in the context of U.S. medical device commercialization. The general problem addressed by this study was that entrepreneurs operating in regulated industries face challenges raising sufficient investment capital to start up a new business and comply with the regulatory requirements necessary to achieve commercialization and sustainability as venture capitalists focus investments towards industries that offer greater and higher returns than those facing less regulatory risk. To stimulate a discussion on the general problem, the researcher developed the following questions:

Primary Data Source - Regulatory Professionals

General questions:

1. What has been your role in developing and/or implementing regulatory strategies for the commercialization of medical devices for the U.S. marketplace?
2. Could you please describe your experience or involvement in regulatory project budgeting and fund raising?
    a. What elements of the regulatory strategy do you think contribute most to successful fund raising or capital investment in a new product development project?

   b. What challenges have you encountered when attempting to acquire the funds necessary to implement regulatory strategies in your organization?

3. What advice would you give to new product development teams, entrepreneurs, and fellow regulatory professionals involved in developing and implementing regulatory strategies as they prepare budgets and seek to secure capital investments?

Secondary Data Source - Investors and Venture Capitalists

1. What has been your role in assessing and evaluating potential investment opportunities for new product development projects in the context of the U.S. medical device industry?
2. From your perspective, how influential is a regulatory strategy when it comes to securing capital investment for new product development?
   a. At what stage in the development process should an entrepreneur or innovator have developed a regulatory strategy?
   b. Relative to developing regulatory strategies, what challenges do entrepreneurs and innovators face when attempting to secure the funds necessary to implement proposed regulatory strategies?
3. What advice would you give to new product development teams, entrepreneurs, and regulatory professionals involved in developing and implementing regulatory strategies as they prepare budgets and seek to secure capital investments?

The specific problem addressed in this research is that the lack of generally accepted best practices to mitigate regulatory risk is a significant barrier to generating internal or external development capital. To stimulate a rich discussion about the process variables and factors (e.g., operational, leadership, external, process, and product) associated with regulatory strategy and

uncertainty, the following interview questions were utilized to address the specific problem statement:

Primary Data Source - Regulatory Professionals.

Regulatory Strategy Process.

1. Could you please describe the regulatory strategy process at your organization (e.g., activities, stakeholders, data collection, documentation outputs, etc.)?
2. Could you please describe an example of a regulatory strategy you have developed or executed specifically for a U.S. medical device commercialization project?
3. From your experience, are there any factors you encounter during the strategy development and implementation process that cause you to make revisions to a strategy?
    a. Could you describe an example of when a follow-up strategy or modification to an existing strategy was required?
4. What elements of the regulatory strategy process are most challenging in your organization?
5. What elements of the process contribute most to regulatory strategy success?
6. Is there anything you would change about the regulatory process at your organization?
    a. Why is that?

Operational Factors.

1. What type of business ecosystem or work environment is most beneficial for the development and implementation of regulatory strategies? (e.g., collaborative, resistant, engaged, apathetic, innovative, etc.)?
    a. From your experience, how does that business ecosystem effect the outcomes of regulatory strategy development and implementation?

2. Please describe your recommended approach to the requirements associated with managing business processes and quality systems.
3. From your perspective, how does the development or implementation of a regulatory strategy affect other business processes (e.g., marketing, design and development, production, post market surveillance, etc.)?

Leadership.

1. How would you describe the different stakeholder engagements you have experienced during the regulatory strategy development and implementation process?
2. Please explain when and how leadership at your organization gets involved with the development or implementation of regulatory strategies.
3. How would you describe your organization's leadership's commitment to and understanding of the medical device regulatory strategy process?
4. Is there anything you wish your leadership team did differently to support the regulatory strategy process?

Product Design.

1. What elements of product design present challenges when developing a regulatory strategy?
2. How would you describe the impact device complexity and innovation have on the development and implementation of regulatory strategy?
3. How does the regulatory strategy process change when you consider different device risk classifications (e.g., Class 1, Class 2, Class 3, etc.)?
4. Based on your experience, at what point in the design process is it most appropriate to develop a regulatory strategy?

5. How do modifications made to a regulatory strategy in later design stages impact the successful implementation of a strategy?

External.

1. What external elements, or things outside your control, prove most challenging when attempting to design or implement a regulatory strategy?
    a. How do you address those challenges?
2. How would you describe your experience with the U.S. Food and Drug Administration (FDA) with respect to the development or implementation of regulatory strategies?
    a. What elements of this interaction surprised you?
3. Have you been involved in an FDA inspection associated with a premarket application?
    a. How would you describe that experience?
4. How would you describe the FDA's level of transparency regarding their expectations regarding premarket activities (presubmission meetings, regulatory applications, inspections, etc.)?
5. How do regulatory costs imposed by the FDA impact your organization's decision to pursue a particular regulatory pathway?
6. What advice would you give to new product development teams, entrepreneurs, and fellow regulatory professionals involved in developing and implementing regulatory strategies with respect to engagement with the FDA?

Secondary Data Source - Investors And Venture Capitalists.

Regulatory Strategy Process.

1. How would you describe the level of importance of having an established regulatory strategy when a project team or innovator seeks funding or investment?

2. What concerns you the most about how project teams or entrepreneurs development and implement regulatory strategy?

Operational Factors.

1. What type of business ecosystem or work environment is most attractive to you as an investor in medical device technology projects?
2. From your perspective, how does the business ecosystem or work environment affect the success or failure of regulatory strategy design and implementation?

Leadership.

1. What type of leadership do you look for when considering investing in or sponsoring a medical device commercialization project?
2. How do those leadership characteristics influence the design and implementation of a regulatory strategy?

Product Design.

1. What product design factors are most attractive to you as an investor in medical device technology?
2. How do those design factors appear to influence the success or failure of regulatory strategy design and implementation?

External.

1. What is your perception of the Food and Drug Administration (FDA)?
2. From your perspective, what value (if any) does early engagement with the FDA bring to a medical device commercialization project?

3. Are there any external factors (things outside the control of an entrepreneur or project team) that appear to impact the success or failure of a project requiring regulatory strategy?

The complete interview guide is located in Appendix D.

Data Collection Technique

Qualitative studies typically utilize interviews as a data collection method (Cypress, 2018*;* Stake, 2010). In this study, the researcher collected data via personal one-on-one interviews conducted through Microsoft Teams. The basis of the interview approach and questions stemmed from a thorough review of the scientific and academic literature, which identified the elements on which the research focused, mainly concepts associated with the design and implementation of regulatory strategies in the U.S. medical device industry. To provide a robustness and depth of perspective, the researcher interviewed both regulatory professionals and individuals involved in the financing or capital financing activities. Such a duel perspective provided triangulation of the data collected and strengthened the understanding of the cases under study.

Data Organization Techniques

After the interviews were conducted, the audio files were uploaded to Trint, a subscription-based transcription service (www.Trint.com). Within Trint's platform, the transcriptions underwent a manual review for accuracy and were then exported as Microsoft Word documents. To enhance the validity and accuracy of the data, the transcriptions were sent to the participants for a member checking process (J. Creswell & Poth, 2018; Cypress, 2017). Following this, the verified transcripts were imported into NVivo 14 for detailed coding and thematic analysis. While NVivo 14 offers an auto-coding feature, it did not yield significant

results for this research. Therefore, ChatGPT was employed to perform an initial screening of the codes. The anonymized data was inputted into ChatGPT, which preliminarily identified potential codes. These initial findings were then cross-referenced and manually coded by the researcher within NVivo 14 for further comprehensive analysis. Email communication with the participants was received via email through the Liberty University email system and was maintained on the researcher's laptop, which is secured via password or fingerprint access. The transcriptions were also maintained as Microsoft Word documents, which provided a platform for further analysis and thematic coding. The researcher recorded notes during the interviews as a hedge against the potential loss of electronic data or digital recording equipment failures. Any paper copies of documentation were maintained at the researcher's home in a securely locked file cabinet to which only the researcher has access.

Data Analysis

Following the data collection and organization phase of the project, the researcher began the data analysis process. Stake (2010) described the qualitative study of individuals or local experience as microresearch. J. Creswell and Poth (2018) outlined five activities that make up the qualitative "data analysis spiral" (p. 187). Rather than a series of linear tasks, the authors described the process as interrelated and often simultaneous activities in "analytical circles" as the researcher progresses through the project. Table 10 below summarizes the activities, strategies, and outcomes for the data analysis spiral as described by J. Creswell and Poth (2018, p. 187).

Table 10

The Data Analysis Spiral Activities, Strategies, and Outcomes

Data Analysis Spiral Activities	Analytical Strategies	Analytical Outcomes
Managing and organizing the data	Preparing files and units	File naming system and organizing database of files

		and units of text, images, and recordings
	Ensuring ongoing secure storage of files	Creation of long-term file storage plan
	Selecting mode of analysis	Use of software, by hand or hybrid
Reading and memoing emergent ideas	Taking notes while reading	Written memos leading to code development, reflections over time, or summaries across files or questions or project
	Sketching reflective thinking	
	Summarizing field notes	
Describing and classifying codes into themes	Working with words	Naming of initial codes
	Identifying codes	List of code categories and descriptions
	Applying codes	Assign the codes to units of text, images, and recordings
	Reducing codes to themes	Finalized codebook
Developing and assessing interpretations	Relating categories/themes/families	Contextual understandings and diagrams
	Relating categories/themes/families to analytical framework in literature	Theories and propositions
Representing and visualizing the data	Creating a point of view	Matrix, trees, and models
	Displaying and reporting the data	Account of the findings

Reading and Memoing Emergent Ideas

The early stage management and organization of data have been described in the preceding paragraphs. The next loop in the spiral involved the researcher getting an appropriate appreciation for the entire data set by reading and rereading the transcripts prior to breaking them apart in the later project phases (Cypress, 2018). J. Creswell and Poth (2018) stated that writing notes and memos during this immersive process builds a sense of the complete data set and aids in synthesizing the information into “major organizing ideas” (p. 188). Memoing emergent ideas is a process itself and can be viewed at three different levels, including (a) segment memos, which are intended to identify ideas that emerge from reading particular phrases in the data to help in the initial coding process; (b) document memos are intended to identify ideas that emerge from reading the individual document(s) and helps the researcher recognize different coding categories for later theme development or comparison activities; and (c) project memos are

intended to integrate ideas into concepts or concepts into a project and help to ensure all major thoughts are available for use as the project progresses (J. Creswell & Poth, 2018).

Describing and Classifying Codes Into Themes

Coding is the process of "making sense of the text from interviews, observations, and documents" (Cypress, 2018, p. 307) and is "heart of qualitative data analysis (J. Creswell & Poth, 2018, p. 189). This next loop in the data analysis spiral involved breaking down the qualitative text from the researcher's point of view in the context of the research questions and literature (Cypress, 2018; Elliott, 2018). Breaking down the dataset into smaller categories or codes created more meaningful and impactful groups of information to interpret, as not all data collected during the interviews will be included, and an initial list of 25-30 categories of data are typically identified for analysis (J. Creswell & Poth, 2018).

Cypress (2018) posited several strategies researchers utilize during the theme development process, such as memoing, identifying noteworthy interview quotes, diagramming code or concept relationships, summarizing recurring data aspects, and focusing on the interpretation process. Theme development is an aggregation of the data into smaller, broad categories consisting of multiple codes into one idea (J. Creswell & Poth, 2018; Cypress, 2018; Elliott, 2018). J. Creswell and Poth (2018) described the final output of the theme development process as a codebook that provided a guide throughout the process. The codebook could include the code name, code definition, boundaries of use (inclusion/exclusion criteria), and example(s) of the code using study data.

While there is some debate regarding the use of software tools in qualitative research (Leech & Onwuegbuzie, 2011), Elliott (2018) surmised that while not an explicit requirement, with the advancements in technology and algorithm development, "the question to be asked is

not ‘should I’ but ‘how should I’” (p. 2858). The researcher in this study implemented a hybrid approach by using a manual code development process in combination with software tools. The interview transcripts were input into NVivo 14, a qualitative data analysis tool, for coding and thematic analysis. While NVivo 14 is equipped with an auto-coding function, this feature was not effective for the specific needs of this study. Consequently, ChatGPT was employed to perform an initial screening of the codes. After anonymizing the transcripts, they were processed through ChatGPT, which accomplished a preliminary code identification. These initial codes were then employed as a basis for the manual coding process within NVivo 14.

During the manual coding phase, each transcript was thoroughly examined and annotated. Following the primary manual coding and subsequent review, a total of 54 subthemes or codes were delineated. Each code corresponded to at least two unique references across the interview transcripts. These subthemes were then grouped based on commonalities, which ultimately informed the formulation of the salient themes that were distilled from the data. The researcher paid careful attention to the code conceptualization rather than relying fully on the software to “drive” the code and theme development (Elliott, 2018). In conjunction with the software tools employed, the researcher followed the strategies developed by J. Creswell and Poth (2018) in creating a codebook to guide the data assessment process. The codebook was developed following the conversion of interview transcripts to Microsoft Word documents for individual reading and rereading. The researcher utilized features native to Microsoft Word, such as text highlighting and comments, to identify significant statements and record memos of ideas or concepts that emerge during the review process (J. Creswell & Poth, 2018). The researcher developed a modified codebook, which ultimately included (a) the theme and description, (b)

definition, (c) included codes, and (d) inclusions/exclusion criteria. The details for each theme that emerged are identified in the thematic analysis results included in Section 3.

Developing and Assessing Interpretations

Interpreting data within qualitative research involves a method that is both iterative, as indicated by J. Creswell and Poth (2018), and driven by the researcher's intuition (Stake, 2010). In the context of this study, the codes and themes extracted from the initial analysis were instrumental in interpreting the nuanced experiences of the participants. Drawing from the codes and themes that emerged, the researcher embarked on a journey to construct meaning, sift through the data, and highlight what was significant in relation to the research questions posited at the study's outset (J. Creswell & Poth, 2018).

Following the guidance of Cypress (2018), significant statements were distilled and aggregated into clusters of meaning, facilitating the identification of patterns and underlying structures in the participant narratives. The analysis went beyond mere categorization, as J. Creswell and Poth (2018) advocate for an in-depth examination of data that reveals not just the expected and confirmatory evidence but also the unexpected, the intriguing, and the divergent perspectives.

Such an approach unearthed dominant narratives as well as those that deviate from the norm, offering a richer, more diverse set of interpretations. The connections forged between categories, themes, and the existing body of literature enriched the analysis, grounding the findings in a broader theoretical and empirical framework. This synthesis, in turn, leads to the construction of a comprehensive understanding and the development of theoretical propositions that illuminate the significance and implications of the findings within the wider research field.

Representing and Visualizing the Data

Following the coding and interpretation (including triangulation) data analysis loops, the researcher presented the results in a final report (Section 3). J. Creswell and Poth (2018, p. 199) suggested that researchers texturally (the "what") and structurally (the "how") describe "the thing" (Stake, 2010, p. 25) under study to present the experience in a composite description.

Representation and visualization of qualitative data are crucial techniques designed to systematically illustrate the nonnumeric and often complex information gathered in research. These methods help reveal nuanced and context-rich insights that traditional statistical analyses might overlook. For qualitative case studies, network models, flow models, and matrix models can serve as valuable tools for visualization, as described by Spinuzzi (2023). Paulus et al. (2017) highlighted the role of qualitative data analysis software (QDAS) like NVivo and ATLAS.ti in aiding researchers to enhance clarity and transparency. These tools are adept at presenting coding outputs, supplying delineated themes, and generating diagrams that graphically represent analytical outcomes.

In this research, data visualization and representation employed various formats, including tables, diagrams, graphs, charts, and mindmaps. NVivo 14 was used as a central hub for storing interview transcripts and for facilitating the coding and thematic analysis process. Additionally, a treemap was created using the QDAS following the coding and thematic analysis to visualize the distribution and frequency of the themes and codes within the dataset. Treemaps, as noted by Nielsen (n.d.), are particularly effective in helping researchers to quickly discern which themes are most prevalent or to observe their distribution across the dataset. This visualization technique aids in making patterns or characteristics in the data more discernible, which could be easily missed with purely text-based data analysis methods.

Qualitative Reliability and Validity

The concepts of reliability and validity in qualitative research are not as well defined as in quantitative research (Cypress, 2017), and the topic has been contested by traditional researchers (J. Creswell & Poth, 2018). Qualitative research is an ongoing, iterative, and complex interactive process; researchers must ensure that sufficient rigor has been applied throughout a given project to ensure the results are not overly influenced by the subjectivity that is a natural characteristic of this type of research (Cypress, 2017).

Reliability

"Reliability is based on consistency and care in the application of research practices" (Cypress, 2017, p. 256). Noble and Smith (2015) stated that while there is no "universally accepted terminology and criteria used to evaluate qualitative research" (p. 35), the authors stressed the importance of incorporating strategies to enhance the research and researcher's credibility. J. Creswell and Poth (2018) added that reliability relates to clarity and consistency between the data collection and analysis processes. Researchers have described numerous techniques to ensure reliability in qualitative research. Table 11, below, provides an outline of the researcher's strategy for addressing reliability concerns in this qualitative research study based on the current body of literature.

Table 11

Study Reliability Strategy

Reliability concern	Strategic action	Value	Reference(s)
Researcher bias	Bracketing and reflexivity	Ensures the researcher has considered personal position and potential influence on data collection and interpretation processes	Cypress, 2017; Merriam & Tisdell, 2015
Inconsistency in data collection	Interview guide	Ensures a consistent methodology for	Kallio et al., 2016

		collecting and recording information in the participants' lived experience	
Transcription accuracy	Member checking	Provides participants with an opportunity to review transcription to ensure accuracy and identify errors.	J. Creswell & Poth, 2018; Cypress, 2017
Inconsistency in data interpretation	Consistent code development and use of codes	Ensures that deviations from established codes does not occur during the research	J. W. Creswell, 2013
	Use of high-quality interview recording devices, digital transcription of audio files, generating field notes	Ensures data accuracy and supports effective triangulation	J. Creswell & Poth, 2018; Cypress, 2018

Validity

Validity is associated with a number of terms, including "credibility, authenticity, transferability, dependability, reliability, and objectivity" (J. Creswell & Poth, 2018, p.256). Cypress (2017) described validity as the "state of being sell grounded or justifiable, relevant, meaningful, logical, confirming to accepted principles" (p. 256). Noble and Smith (2015) added that validity in qualitative research relates to the integrity of the research methods applied and the accuracy with which the study results reflect the reality of the data collected. Validity in qualitative research is not the result of an individual test or task in a project; rather, it is process-oriented activities that take place over the course of the research (Hayashi et al., 2019).

Triangulation. To promote credibility in qualitative research, researchers triangulate data sources, theories, and methodologies (Cypress, 2018). According to Hayashi et al. (2019), triangulation is one of the most recognizable qualitative research strategies for ensuring validity and credibility. The authors described triangulation as the "interrelationship between information obtained from the data that was collected from different sources to increase the understanding of the study in question" (p. 101). Triangulation is intended to improve the researchers'

understanding of the meaning and interpretation of the data by introducing an additional perspective to check the research results (Stake, 2010). The multiple perceptions presented via triangulation provide evidence of consistency, thus reducing the potential for researcher bias and misinterpretation (Cypress, 2018).

While there are a number of different approaches to triangulation, the present study utilized data triangulation and theoretical triangulation. According to Hussein (2015), data triangulation refers to the use of multiple data sources within the same research project, and theoretical triangulation is the use of multiple theories in the same study to support and challenge findings. In addition to field notes, the researcher applied data triangulation by conducting interviews with both primary and secondary participants. These perspectives of regulatory professionals involved in the development and implementation of regulatory strategies as well as investors, entrepreneurs, and other venture capital professionals involved in medical device innovation commercialization. Additionally, member (participant) checks aided in triangulating the data and provided "richer descriptions" (Cypress, 2018, p. 308). The conceptual framework for this study includes three distinct elements, including systems theory, institutional theory, and chaos theory, within the context of the study topic. To provide theoretical triangulation, the researcher evaluated the framework itself against the significant statements and themes that emerged during the data collection and analysis activities.

Data Saturation. Data saturation is defined as the point at which no new themes emerge from the interview data analysis (Saunders et al., 2018). Saturation is an operational construct in qualitative research and is equivalent to representative sampling and sample size in quantitative research (Hayashi et al., 2019). Saunders et al. (2018) referred to saturation as a "matter of identifying redundancy in the data, with no necessary reference to the theory linked to these data;

saturation appears to be distinct from formal data analysis" (p. 1896). Achieving data saturation is one of the essential strategies for ensuring validity in qualitative research (Cypress, 2017). The researcher continued interviewing until no new themes emerged from the data analysis process rather than focusing on a defined sample size (J. Creswell & Poth, 2018). In this study, the recruitment process persisted until the point of data saturation and informational redundancy was reached, ensuring that each research question was fully addressed (Francis et al., 2010; Grady, 1998; Saunders et al., 2018). Specifically, thematic saturation was achieved after the seventh interview, a stage at which no additional themes or novel insights were being generated from the data (Guest et al., 2006). Table 12, below, outlines the researcher's study validation strategy.

Table 12

Study Validation Strategy

Validity concern	Strategic action	Value	Reference(s)
Research credibility	Data triangulation - Use of multiple data sources (regulatory professionals and investors) Theoretical triangulation – Use of multiple theories (Systems Theory, Institutional Theory, and Chaos Theory) Member checking	Improve the researchers understanding of the meaning and interpretation of the data. Allows for deeper data comparisons and rich descriptions	J. Creswell & Poth, 2018; Cypress, 2018; Hussein, 2015
Sample size adequacy	Data saturation	Identifies redundancy in new data relative to what was previously collected and analyzed. Prevents collection of additional information that is not useful in the study context.	J. Creswell & Poth, 2018; Hayashi et al., 2019; Saunders et al., 2018

Summary of Section 2 and Transition

The purpose of this study was to explore the variables that contribute to medical device regulatory uncertainty and regulatory strategy best practices based on the experiences of industry professionals involved in the commercialization of medical devices in the United States. Section 2 of this study included details of the research design and methodologies applied, as well as information related to the data collection, organization, and analysis techniques. To address the research questions, the researcher sought first-hand perspectives from individuals involved in the medical device commercialization process, from regulatory strategy design and implementation to investors and venture capitalists. The primary mode of data collection was through semistructured interviews conducted via web-based conferencing tools. To ensure reliability and validity, the researcher recorded the interviews and transcribed the information into Microsoft Word documents. Following transcription, the researcher reviewed the data and returned the transcripts to the participants to confirm accuracy. The collection and analysis of the interview data triangulated the differing points of view along with information derived from the researcher's notes and memos, as well as the comprehensive literature review, to provide rich insights into the emerging best practices employed for the successful implementation of regulatory strategies. Section 3 of this study presents the findings, results, and recommendations for the practical application of regulatory strategies in new medical device product development projects.

Section 3: Application to Professional Practice and Implications for Change

Regulatory strategy is an integral element of medical device commercialization and capital investment (Schueler & Ostler, 2016). This section provides the culmination of the research efforts associated with the study of best practices associated with medical device regulatory strategy success, as previously described. Section 3 includes application to the professional practice and implications for change. The intent of this section is to provide a presentation of the findings, including identification of the themes discovered, interpretation of those themes, representation, and visualization of the data, and the relationship of the findings to the (a) research questions, (b) conceptual framework, (c) anticipated themes, (d) literature, and (e) problem. This section will also provide an application of the study results to the professional practice, as well as recommendations for future study and personal reflections of the researcher.

Overview of the Study

The medical device industry is characterized by its rapid innovation and the stringent regulatory environments it operates within, particularly in the United States, under the oversight of the Food and Drug Administration (FDA). The path to commercializing medical devices is laden with complexities, from product conception and development through to regulatory clearance or approval and market entry. Navigating this landscape requires not only scientific and engineering expertise but also strategic acumen in regulatory affairs—a critical determinant of a medical device project's success or failure.

Against this backdrop, this study emerged as an investigation into the factors that contribute to successful regulatory strategies within the medical device sector. The primary motivation stemmed from a recognized gap in both academic literature and industry practice: a lack of comprehensive understanding and benchmarking of what constitutes effective regulatory

strategy in the medical device domain. This gap poses significant challenges for medical device companies, particularly startups, in securing the necessary capital for development and commercialization, given that regulatory strategy efficacy significantly influences investment decisions.

The justification for the study is further underscored by the evolving nature of medical device regulations, which continually adapt, albeit at times slower than industry demands, to new technological advancements and changing public health priorities. This dynamic regulatory environment necessitates a proactive and nuanced approach to regulatory strategy, one that balances innovation with compliance and effectively manages the risks associated with regulatory uncertainty.

This research sought to address these challenges by exploring and identifying best practices in regulatory strategy through the lens of industry professionals with firsthand experience in navigating FDA regulations and investors in medical device technology. By focusing on the U.S. medical device industry, the study aimed to provide insights that are directly applicable to one of the largest and most influential markets for medical technologies globally.

The implications of this study extend beyond academic contributions, offering tangible benefits for a broad range of stakeholders within the medical device ecosystem. For medical device companies, especially startups, the research provides a foundation for developing more robust and effective regulatory strategies that align with FDA expectations and facilitate smoother pathways to market. For investors and venture capitalists, the insights from the study offer a framework for assessing the viability and risk of medical device projects, informed by an understanding of their regulatory strategy strengths and weaknesses.

Furthermore, the study has the potential to influence policy discussions by highlighting areas where regulatory processes may be optimized to support innovation while maintaining high standards for patient safety and efficacy. By fostering a deeper understanding of the regulatory strategy landscape, the study contributes to a more efficient and effective medical device industry capable of delivering innovative solutions to healthcare challenges while navigating the complexities of regulatory affairs.

Employing a qualitative research design, the study leveraged semistructured interviews to tap into the experiences and narratives of medical device industry professionals and investors. This methodological choice was aimed at facilitating an in-depth understanding of the perceived challenges and best practices associated with regulatory strategy development and implementation. The research questions were crafted to dissect the regulatory strategy landscape, focusing on identifying critical process variables, operational factors, product characteristics, leadership influences, and external pressures that define success in regulatory strategy within the U.S. medical device sector. These questions served as the foundation for the investigative journey into the regulatory intricacies faced by the industry.

By offering actionable insights into strategic regulatory planning, the study was intended to bridge organizational gaps and highlight risk factors related to product characteristics, thereby enabling investors and innovators to make more informed decisions. The anticipated findings aimed to reduce regulatory uncertainties, offering a strategic framework for evaluating NPD projects and investment opportunities, thereby fostering a more predictable environment for venture capital investment in the medical device industry.

Data collection was planned and executed through semistructured interviews with industry professionals and investors, ensuring a comprehensive capture of participants'

experiences and perspectives. Interviews were transcribed, reviewed, and member-checked to ensure an accurate reflection of the participants' experience. Thematic analysis was conducted using a combination of manual coding and qualitative analysis software. This process enabled the identification of salient codes and themes, providing a structured insight into the complexities of medical device regulatory strategy.

The analysis spiral included managing and organizing data, memoing emergent ideas, classifying codes into themes, developing interpretations, and visualizing data. This approach facilitated a distinct understanding of the operational, leadership, and product variables critical to regulatory strategy success. Themes such as financial planning, agile regulatory strategy development, mastering regulatory complexities, strategic knowledge integration, and proactive regulatory engagement emerged as pivotal to navigating the regulatory landscape.

The study's methodological rigor, coupled with the depth of insights gained from participants, highlighted the intricacies of regulatory strategy in the medical device industry. By dissecting the operational, leadership, and product-related challenges and best practices, the research illuminated the path forward for enhancing regulatory strategy development and implementation. This comprehensive approach was intended to enrich not only the academic discourse on regulatory strategies but also to offer practical, actionable guidance for industry practitioners aiming to navigate the regulatory maze with greater efficacy and strategic foresight.

The study served as an exploration into the intricacies of regulatory strategy in the medical device industry, set against the backdrop of a rapidly evolving technological landscape and stringent regulatory standards. By identifying best practices and key variables that influence regulatory strategy success, this research not only fills a gap in the academic and industry literature but also provides actionable insights for practitioners and investors. Through this

approach, the study stands to positively impact the medical device industry's capacity to bring innovative, safe, and effective devices to market efficiently. Through a methodologically sound approach to data collection and analysis, the study has illuminated key insights that enhance the efficiency, competitiveness, and regulatory compliance of medical device companies, thereby contributing significantly to the field of international business and medical device commercialization.

Presentation of the Findings

The purpose of this study was to explore the variables that contribute to medical device regulatory strategy best practices and regulatory success in the medical device industry. Successful regulatory strategies are essential to the eventual commercialization of medical technology. Innovators and entrepreneurs must address and integrate numerous factors into the strategic process to achieve successful product launches. The findings presented in this section reflect the analytical results from semistructured interviews conducted with multiple participant cases. The results of this study provided insight into the best practices and advice provided by the participants. The participants included industry regulatory professionals, as well as investors in the medical device technology space, to provide multiple perspectives on the topic. The data analysis spiral, as described by J. J. Creswell and Poth (2018) and further detailed in Table 10 was followed for analysis activities including: (a) managing and organizing the data, (b) reading and memoing emergent ideas, (c) describing and classifying codes into themes, (d) developing and assessing interpretations, and (e) representing and visualizing the data.

Purposive and snowball sampling techniques were utilized to recruit participants. Initial recruitment included posting the recruitment opportunity to public databases and social media, including the Regulatory Affairs Professionals Society (RAPS), Association for the

Advancement of Medical Instrumentation (AAMI.ORG), and LinkedIn. However, these efforts did not garner any willing participants. Following the indirect recruitment, direct purposive recruitment efforts identified qualified and willing participants. Recruitment continued until data saturation (Grady, 1998; Saunders et al., 2018) and informational redundancy (Francis et al., 2010) were achieved, including answering each of the research questions. More specifically, thematic saturation, where no new themes or insights have emerged from the data (Guest et al., 2006), was attained within seven completed interviews.

Each interview was conducted and recorded utilizing the Microsoft Teams meeting scheduler. The participants were assigned a unique participant numbers P1, P2, P3, P4, P5, P6, and P7 based on the linear sequence of their interview scheduling. The participants were informed that the audio interviews were being recorded, and none of the participants objected to the recordings. The interviews were semistructured and followed a topic-based approach yet allowed for additional probing questions to explore the participants' perspectives at a deeper level. The interview questions were organized in relative alignment with the five research questions to consolidate the responses accordingly. The five topics covered in the interviews include: (a) regulatory strategy process variables (RQ1),(b) operational factors (RQ2), (c) product variables (RQ3), (d) leadership factors (RQ4), and (e) external variables (RQ5).

Upon completion of the interviews, the recordings were uploaded to a subscription-based transcription software tool called Trint (www.Trint.com). The transcriptions were manually reviewed and verified within the software and subsequently exported as a Microsoft Word document. The transcripts were also forwarded to each participant for review as a member check to improve the data validity and accuracy (J. Creswell & Poth, 2018; Cypress, 2017). The transcripts were eventually uploaded to a research tool, NVivo 14, for coding and thematic

analysis. NVivo 14 includes an algorithm for auto-coding; however, this element of the software did not provide meaningful coding with respect to this study. As such, an additional research tool, ChatGTP, was utilized as an initial code screening. The anonymized transcripts were uploaded to ChatGTP, and the software completed a preliminary identification of codes. These codes were used as a reference for manual coding within NVivo 14.

During the manual coding stage, each transcript was read, reviewed, and coded. Upon completion of the initial manual coding, review, and consolidation, a total of 54 codes or subthemes were identified. Each code is related to at least two individual interview transcript reference points. The codes were then clustered and organized into common associations, which ultimately became the final salient themes that emerged. Figure 3, below, provides a diagrammatical representation of the coding and thematic analysis process workflow.

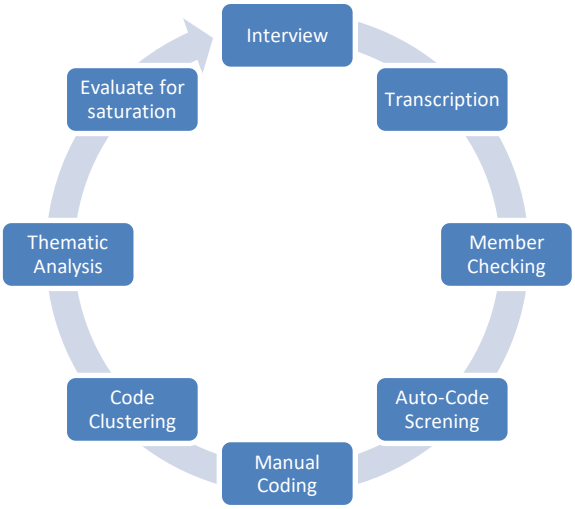

Figure 3. Coding and Thematic Analysis Process.

Themes Discovered

Numerous themes were discovered over the course of the coding and analysis process. The themes were identified and categorized in association with one of the five research questions (RQ1 to RQ5). The relationship between the findings relative to the research questions is discussed later in this section. A total of 12 themes were identified across the five research questions. These themes include) (a) Financial Planning and Regulatory Economics, (b) Agile Regulatory Strategy Development, (c) Mastering Regulatory Strategy, (d) Strategic Knowledge Integration, (e) Proactive Regulatory Engagement, (f) Collaborative Regulatory Ecosystem, (g) Systems Integration and Streamlining the Framework for Regulatory Strategy, (h) Balancing innovation and risk considerations in regulatory strategy, (i) Balancing Innovation in Regulatory Strategy, (j) Development Dynamics and Regulatory Requirements, (k) Strategic Leadership Efficacy, (l) Regulatory Uncertainty, (m) Supply Chain Considerations in Regulatory Strategy. Table 13 below demonstrates an overview of each of the themes, definitions, codes, and inclusion/exclusion criteria.

Table 13

Thematic Analysis Results

Theme and description	Definition	Codes	Inclusion/Exclusion Criteria
Theme 1: Financial Planning and Regulatory Economics	This theme encapsulates the financial aspects of regulatory strategy within the medical device sector, focusing on the formulation of budgets, securing funding, and the broader impact of regulatory activities. It involves strategic guidance for financial planning, understanding the cost implications of regulatory compliance, and conducting thorough due diligence to assess and mitigate the financial risks. Investor concerns and reimbursement models are also central to this theme, highlighting the need for clear economic narratives that address return on investment and the path to market reimbursement, which are critical for successful medical device commercialization.	Budgeting and fundraising Advice for budgeting and funding Regulatory cost impact Due diligence Investor concerns Reimbursement	Inclusion: Financial aspects directly related to regulatory strategy, cost management, and funding activities/ Exclusion: General financial information not directly linked to regulatory actions or market access
Theme 2: Agile Regulatory Strategy Development	This theme covers the proactive development and ongoing refinement of regulatory approaches in response to evolving information, competitive analysis, market needs. The theme incorporates the necessity of having comprehensive, timely information and utilizing tools to inform the strategy. It underscores the importance of strategic timing, continuous evaluation, and the agility to adjust to new developments, ensuring that regulatory planning is both through and responsive.	Regulatory strategy process Information availability Timing for strategy development Strategy revisions Competition and market pathway Predicate device identification Regulatory strategy and IP Planning Flexibility and adaptability Gap analysis Indication for use Periodic strategy reviews	Inclusion: Aspects of strategic planning and development of regulatory planning and strategic activities. Exclusion: Nonstrategic activities and information unrelated to the dynamics of regulatory strategy.

Theme and description	Definition	Codes	Inclusion/Exclusion Criteria
Theme 3: Mastering Regulatory Strategy	This theme captures the essence of overcoming regulatory hurdles through informed, strategic action. It involves recognizing success and risk factors inherent in the process and implementing expert advice to navigate the regulatory maze effectively.	Regulatory strategy challenges Success factors Risk factors Advice for strategy Support networks	Inclusion: Tactics and advice focused on overcoming specific regulatory hurdles and leveraging access to resources. Exclusion: Broad strategies not addressing regulatory challenges or lacking targeted advice.
Theme 4: Strategic Knowledge Integration	This theme reflects the synthesis of specialized expertise and comprehensive understanding within the regulatory processes. It underscores the value of having a talented team capable of navigating complex regulations, the proactive education of stakeholders on these matters, and the critical need to address interpretation concerns to ensure regulatory alignment and strategic clarity.	Team talent Interpretation concerns Stakeholder education Stakeholder engagement	Inclusion: Activities that demonstrate integrating expertise withing regulatory processes, addressing complex regulations. Exclusion: Nonregulatory team functions and general stakeholder interactions without strategic regulatory focus.
Theme 5: Proactive Regulatory Engagement	This theme highlights the importance of early and proactive interactions with the FDA, specifically through presubmission meetings that facilitate mutual understanding of regulatory expectations and submission requirements. It emphasizes the using these engagements to refine regulatory strategies and mitigate potential roadblocks in the market access process.	FDA presubmission meetings FDA interaction experience Advice for engaging with the FDA	Inclusion: Measures, experiences, and strategies for proactive engagement with the FDA. Exclusion: Interactions with the FDA that are not proactive or do not provide strategic value
Theme 6: Collaborative Regulatory Ecosystem	This theme highlights the importance of a cooperative network of stakeholders, encompassing internal teams, external partners, regulatory bodies, and other interested parties. It underscores an environment where shared knowledge, open communication, and joint efforts streamline the regulatory process, ensuring the ecosystem is effectively leveraged for successful regulatory strategy implementation.	Ecosystem Collaboration	Inclusion: Collaborative efforts and networks involving key regulatory stakeholders and partnerships. Exclusion: Siloed or individual efforts not contributing to the shared regulatory strategy ecosystem.
Theme 7: Systems Integration and Streamlining the Framework for Regulatory Strategy	This theme explores the intersection of business operations and quality management systems within medical device companies. It reflects the influence of regulatory requirements on business processes. The theme underscores the impact that established quality systems have on shaping business processes and ensuring that regulatory compliance is embedded, where appropriate. This theme also refers to the strategic integration of tools within an organization's	Business processes and quality systems Impact on business processes Digital organization Structure Efficiencies	Inclusion: Integration of business operations and quality systems affecting regulatory compliance or regulatory strategy development and implementation. Use of tools and processes enhancing regulatory strategy clarity, agility, and efficiency.

Theme and description	Definition	Codes	Inclusion/Exclusion Criteria
	structure to enhance regulatory processes, fostering an environment that emphasizes clarity, agility, and efficiency. It encapsulates the alignment of systems with regulatory tasks, from compliance documentation to stakeholder communication, ensuring a coherent approach to navigating the medical device industry's regulatory landscape.		Exclusion: Operational aspects, tools, or structural processes with no direct impact on regulatory processes.
Theme 8: Balancing Innovation and Risk Considerations in Regulatory Strategy	This theme concerns how the risk classification and innovation of a medical device influences its development and regulatory journey. It involves understanding the implications of risk categories on submission requirements, documentation, and overall strategy formulation to align with the unique challenges of each risk classification presents to the regulatory process. This theme also considers how starting with less complex medical device designs can offer a swifter route to market entry. It notes that while innovators often work towards advanced technological solutions, they may first pursue regulatory submissions for simpler iterations. This pragmatic strategy allows for more immediate market presence which can be built upon with subsequent innovative enhancements.	Risk classification impact Complexity and innovation impact Start simple	Inclusion: Considerations and implications of risk classifications on regulatory submissions and documentation to streamline market entry. Exclusion: Risk assessments and processes unrelated to regulatory implications or product classifications.
Theme 9: Development Dynamics and Regulatory Requirements	This theme explores into the interplay between medical device design, the stringent testing it undergoes as part of the regulatory submission process, and the significant effects that design changes have on compliance and market readiness. It underscores the need for a fluid regulatory strategy that accommodates evolving testing and the potential iterative adjustments required to meet regulatory requirements.	Product design challenges Testing requirements Modifications and Implementation impact	Inclusion: Interactions between product design, testing, and regulatory requirements, including design changes. Exclusion: Product development and design processes without direct relevance to testing or regulatory requirements.
Theme 10: Strategic Leadership Efficacy	This theme highlights the strategic acumen required of leadership in guiding the regulatory process for medical devices. It encompasses the need for engaged leadership that is committed to steering the development process, capable of setting and managing realistic goals, and decisive in making pivotal choices that align with the regulatory demands.	Leadership involvement Leadership commitment Managing leadership expectations Leadership changes needed Decision making	Inclusion: Actions and decisions that have a direct impact on guiding regulatory strategy. Exclusion: Activities and decisions unrelated to regulatory strategy or not impacting development processes.

Theme and description	Definition	Codes	Inclusion/Exclusion Criteria
Theme 11: Regulatory Uncertainty	This theme centers on the challenges of unexpected outcomes and the level of openness in FDA communications. It deals the strategies to anticipate and respond to unforeseen demands or feedback from the FDA and the importance of flexibility in managing the inherent unpredictability of the regulatory submission review process.	FDA surprises FDA transparency Unpredictability	Inclusion: Challenges related to unpredictability and transparency win FDA communications and how they are addressed. Exclusion: Predictable interactions or standard communications with the FDA not contributing to regulatory uncertainty.
Theme 12: Supply Chain Considerations in Regulatory Strategy	This theme explores the critical role that suppliers and vendors play in the regulatory strategy of medical devices. It reflects the need for integration and coordination with these external partners to ensure that components and materials are available, meet regulatory standards, and that the supply chain supports timely and compliant market entry.	Suppliers and vendors	Inclusion: Impact of suppliers and vendors on the regulatory strategy, including material availability, information about vendor supplied materials, and supply chain management. Exclusion: Supplier and vendor interactions that do not influence regulatory compliance or strategy.

Interpretation of the Themes

Theme 1: Financial planning and regulatory economics. In addressing financial planning and regulatory economics withing medical device development, insights from Participants 1, 2, 3, 4, 5, 6, and 7 illuminated the complexities and strategic considerations pivotal to navigating the regulatory landscape efficiently. Participant 1 emphasized the necessity of developing a robust regulatory strategy before budgeting, noting the significant cost difference between marketing pathways and the impact of regulatory strategy on design and development processes. This sentiment was echoed by Participant 2, who has direct experience in budgeting for regulatory submissions, underlining the importance of strategic de-risking to ensure financial viability.

Participant 3 expanded on the necessity of aligning regulatory strategy with commercial goals, particularly focusing on the role of regulatory discussions in enhancing investment appeal and fundraising efforts. They noted that regulatory pathways significantly influence fundraising activities, especially when innovating devices may offer a fast-track to market through unique pathways. P3 stated,

> …regulatory strategy plays a big part in terms of being able to, you know, sort of create a budget or raise money for a particular development project… if a device is being used is unique enough to be some sort of a fast-track device or… used in a way that is unique, it could lead to additional fundraising.

Participant 4's responses delved into the operational challenges of adjusting project budgets in response to unanticipated regulatory demands, advocating for regulatory dialogue to mitigate the need for costly retesting and budget overruns.

From an investor's perspective, Participant 5 stressed that a coherent regulatory strategy is a gating requirement for investment decisions, pointing out the risks associated with misjudging regulatory pathways, which can lead to drastic shifts in a project's risk profile and financial requirements. Specifically, P5 indicated, "Having a perspective on the regulatory pathway is a gating question for me to invest or not, or to recommend investments. So…If you don't have one, then I'm not interested." Similarly, Participant 6 discussed how a comprehensive regulatory strategy is crucial from the outset, particularly in securing funding and navigating the technological spectrum from discovery to market. P6 stated, "I think it's as I said, the important strategy, the regulatory strategy has to be in place. I think that's a given… Yeah, I think it's very important…it has to be…It has to be in place."

Lastly, Participant 7 shared insights on internal budgeting practices, the financial implications of testing new materials or processes, and the importance of reimbursement strategies. P7 also highlighted the challenges of budgeting for larger sample sizes when testing novel technologies and strategic timing for developing regulatory strategies post-proof of concept to manage costs effectively.

In the context of regulatory strategy and reimbursement in medical device development, Participants 3, 4, and 7 shared insights on this unique intersection. Participant 3 pointed out that manufacturers may overlook other market access and reimbursement considerations, which are crucial for attracting investor interest. Specifically, P3 stated,

> …oftentimes device manufacturers don't think too much about what's going to happen after the regulatory hurdles have been cleared. So, an area that is more and more becoming valuable is understanding the market access requirements for a device. So, things like reimbursement, how the insurance companies will adopt their device if it's

> cleared or…Medicare, Medicaid, etc.. So, getting a favorable signal from a market access perspective has also helped in terms of creating additional excitement for investors.

Participant 4 highlighted the importance of incorporating reimbursement strategies, particularly for startups with novel products, into clinical study designs to ensure market adoption. Meanwhile, Participant 7 focused on the significant role of reimbursement in determining a device's economic impact on healthcare providers and insurers, underscoring the need for strategic planning to communicate the device's value to various stakeholders. Together, these insights stressed the importance of integrating reimbursement considerations early in the regulatory strategy process to secure both regulatory compliance and market success.

Collectively, these perspectives emphasize the integral role of well-defined regulatory strategy in financial planning and regulatory economics. Clear regulatory strategies and strategic financial planning are paramount in mitigating risks, managing costs, and securing the necessary investments for successful market entry and adoption for financial sustainability.

Theme 2: Agile Regulatory Strategy Development. The feedback from the participants highlighted the critical nature of having a structured (P1, P4, and P7) yet flexible (P1, P2, P3, and P4) approach to regulatory planning in the medical device sector. The interview responses underscored the necessity of basing regulatory strategies on comprehensive expertise, ensuring that strategies are not only well-informed by current standards and guidance but are also adaptable to changes in product information or intended use. This adaptability is essential for incorporating additional information as required and for adjusting strategies in response to new insights or feedback from authorities reviewing submissions (P2 and P3). The ability to modify regulatory plans in light of emerging data or regulatory quires underpins the agile approach,

emphasizing the importance of robust initial information gathering and clear communication, both within companies and with regulatory bodies. To that end, P2 stated,

> I think the collaboration and the uptake from the primary consumer of the regulatory strategy is very important. So, you can have a very clear regulatory strategy that is never really understood by the end user, which then results in them not following what might be the crystal clear roadmap to success. So that I think is critical in making sure that that information is digested appropriately.

Several participants highlighted the intertwined relationship between regulatory strategy and intellectual property (IP) in the medtech sector, emphasizing their critical role from the inception of a product development roadmap. The feedback suggests that understanding the regulatory pathway is as crucial for devising an IP strategy. This is because the chosen regulatory path has significant implications for funding requirements and the overall time to market, making it essential to integrate regulatory considerations early in the development process.

The importance of regulatory strategy can vary depending on the stage of technology development and its position within the market-to-discovery spectrum. In cases where technologies are at early development stages, IP considerations, such as freedom to operate and potential competition from larger organizations, can overshadow the specifics of the regulatory pathway. This underscores the need for a balanced approach that addresses both regulatory compliance and IP positioning to ensure a viable path to market. P6 stated,

> I think the importance of the regular strategy … may vary based on … where such a technology lies within the spectrum from…discovery to…market…there may be a time when…other aspects regarding technology such as IP or USP… maybe.. more important,

but there's always an ongoing thread… of having a path towards market that needs to be in place.

P7 provided an example that illustrated a situation where a device's development did not follow the typical strategy process due to the involvement of a key stakeholder with an existing patent. This scenario highlights the complexity of aligning regulatory strategies with IP considerations, especially when navigating partnerships and leveraging existing patents to bring a product to market. The outcome of such can lead to unique product attributes that align with regulatory requirements while also respecting the IP landscape.

Several respondents across the interviews (P1, P2, P3, P4, and P7) highlighted key challenges in information availability impacting regulatory strategy development. A common issue is the struggle with evolving or incomplete product details, as mentioned by Participant 1, which complicates strategy formulation. The lack of readily available guidance or precedents for specific devices, combined with the FDA's evolving requirements, as mentioned by Participants 2 and 3, poses significant hurdles. Effective communication, comprehensive initial data gathering, and the strategic use of digital tools like the electronic quality management system (eQMS), as emphasized by Participant 4, are crucial for managing these challenges. Additionally, difficulties in acquiring necessary information from suppliers due to proprietary concerns further complicate the regulatory process, necessitating alternative compliance strategies and potentially leading to increased costs and delays in market approval were concerns raised by Participants 4 and 7.

Challenges such as navigating the regulatory landscape without clear precedents or guidance, especially for novel or high-risk devices, necessitate a proactive research stance. For example, P1 stated,

> The most challenging element is usually determining… the testing approach and based on available guidance from FDA…but just because of where we are in the marketplace serving many unique novel devices. The type of strategy that we face are often without a lot of precedent.

Participants 4 and 7 described companies leveraging existing market precedents and closely monitoring regulatory updates to align their development and testing strategies with the latest regulatory expectations. Early and ongoing engagement with regulatory agencies, particularly the FDA, is deemed crucial for clarifying requirements, addressing potential questions, and integrating regulatory feedback into strategic planning (P1, P2, P3, and P4). This engagement is aimed at reducing uncertainties and aligning product development timelines with regulatory milestones, thereby facilitating a smoother path to market.

The participant feedback emphasized the dynamic nature of regulatory strategy development, where thorough preparation, strategic flexibility, and proactive stakeholder engagement are key to navigating the complex regulatory environment. By adopting an agile approach, companies can better manage risks, adapt to regulatory changes, and ensure that their medical devices meet the current standards and that design documentation reflects current FDA expectations, thereby enhancing their potential for market success.

Theme 3: Mastering Regulatory Strategy. The study participants provided clarity on how to master regulatory strategy during medical device development, with each one highlighting various elements deemed essential for successful maneuvering through the intricate regulatory process. For example, Participants 1 and 2 shared insight into the importance of a comprehensive approach to regulatory planning, highlighting the necessity for thorough research, understanding of FDA guidance, and awareness of competitive devices. They stressed the

challenges posed by novel devices lacking clear presidents, which often require more extensive predicate research and innovative thinking to navigate the regulatory pathway. The risk associated with rapid innovation and the potential for requirement changes to undermine the strategy was noted, alongside the difficulty in finding predicates for higher-risk devices.

Participant 3 pointed to the significance of early engagement with regulators to build a viable strategy and minimize surprises while emphasizing the execution of gap analysis and risk management as essential components in preparing for potential challenges in the development process. Specifically, P3 noted,

> …having some initial discussions with the regulators helps to build a strategy… I think it's execution and of a gap analysis and knowing where the hurdles and the challenges that can be are having, I guess, minimizing the number of surprises in the development process I think is very important. So, the strategy tries to account for any kind of potential surprises or potential issues that could arise.

Similarly, Participant 4 shared their experience on the crucial role of presubmission meetings with the FDA to ensure alignment on the regulatory pathways and testing requirements. They discussed the challenges of balancing management expectations with regulatory realities and the importance of considering US-specific requirements for clinical data, suggesting a phased approach to product development to manage complexity and regulatory burdens. To that end, Participant 5 stressed the criticality of understanding the regulatory implications of funding and risk profiling from and investor perspective. Specifically, P5 stated,

> I think typically entrepreneurs have not… considered the risk reward from an investor perspective…In terms of, particularly in terms of regulatory… I find entrepreneurs,

> particularly first-time entrepreneurs… in medtech, are not really savvy when it comes to risk reward vis-a-vis regulatory.

They also cautioned against underestimating the regulatory pathway's complexity and advocated for leveraging external regulatory expertise to optimize strategy development. According to P5, who is an avid investor in the medtech space,

> The only advice I would have for them is… that you don't necessarily need to have a full-time regulatory person when you're when you're a startup, because that's not a great use of your resource. Um, there is a ton available out there … that are…on-demand regulatory teams…that you can do a better job, and probably a more effective job, with the regulatory strategy because they're more experts at it than you having to attract a regulatory team.

Similarly, Participant 6, another investor, discussed the impact of macroeconomic factors on funding and emphasized the value of support networks in providing comprehensive assistance, including regulatory advice, for startups. P6 stated,

> I think that if I were to bring a new technology, you know, from or if I were to develop a new technology, I would certainly early on try to get some initial regulatory input, um, from an experienced entity…

The importance of early regulatory input, flexibility in strategy and effective team leadership in navigating regulatory and market environments was also emphasized. P6 further indicated,

> …typically, you know, somebody coming with the from academic science backgrounds, they neither have the business acumen, but they also don't have the regulatory acumen…I would say early the earlier the better…early conversations to start guiding the strategy...

Participant 7 reflected on the challenges of educating stakeholders on regulatory requirements, the benefits of leveraging existing technologies to expedite market access, and the difficulties posed by limited regulatory staffing and reliance on contract help. They also mentioned the obstacles faced in obtaining critical information from suppliers, underlining the need for effective communication and collaboration across all stages of device development.

To summarize the theme, these perspectives illustrated the multifaced nature of mastering regulatory strategy, highlighting the importance of early and ongoing regulatory engagement, comprehensive planning and research, effective risk management, and the strategic use of resources and expertise.

Theme 4: Strategic Knowledge Integration. Participant feedback related to strategic knowledge integration within the context of medical device regulatory strategy emphasized the significance of collaboration, clarity, and flexibility in the strategic planning and implementation processes across the organization. Participant 1 highlighted the importance of engagement and responsiveness from those commissioning strategies, noting that their interest in assisting and understanding the process is crucial for the success of strategic initiatives. This underscored the necessity for active participation and clear communication from all stakeholders involved in strategic development. Participant 2 discussed the critical nature of clearly articulating strategy outcomes to ensure understanding across different organizational levels. The need for detail in the strategy to guide execution and the importance of collaboration for the successful uptake of regulatory strategies were stressed, pointing towards the essential role of precise and accessible communication in strategic planning. P2 stated,

> I think ensuring that the output is clearly articulated within the strategy in a way that can be understood by all is very important. Having general statements of you "must test

> something" isn't as clear as "must test it in this way with this many samples, etc. per recent clearance of x, y, z, and what they did in their submission". So, the more detail that can be provided, the more successful you can be with following that vision to completion.

Participant 3 elaborated on several facets of integrating knowledge into the strategic process, including the challenges of predicting regulatory feedback, the importance of surrounding oneself with the right talent, and the crucial role of accurate and timely plan implementation. Regarding team talent, P3 stated, “surrounding yourself and hiring the right talent, whether it's in-house or its contract, knowing, having the right people around you and people with experience and companies that can help you develop something the right way is very important because that way you don't lose money and time working with folks who may not have the relevant experience to help you develop that device. That's that's, I think, paramount.” The participant discussed the necessity of educating stakeholders about potential challenges, integrating feedback into coherent organizational strategies, and the balance between internal and external resources in supporting strategic objectives. P3 also addressed the significance of unified and integrated approaches across all departments to ensure the strategy’s success, highlighting the intertwined nature of strategic development and organizational unity.

While the FDA does make an effort to provide and update guidance on a regular basis, not all guidance documents are up to date with current technological trends and healthcare delivery practices. P4 added perspectives on dealing with outdated FDA guidelines and the importance of understanding regulatory requirements thoroughly. The participant lamented,

> But many times it happens that… sometimes guidance are so old from the FDA and you know, with the evolvement of science… and the FDA may have different expectation, you know, so sometimes it happens that once you submit the… application and

> without…the proper understanding from the FDA guidance or the requirement, and they may come up with the… the requirement that, "okay, whatever testing you have done didn't meet our expectation because you didn't meet so-and-so conditions" and they ask for the… the repeat test.

The participant also touched on the challenges of adjusting strategies based on regulatory feedback and the importance of presubmission meetings with the FDA to avoid costly mistakes.

Similarly, Participant 7 shed light on the challenges of educating stakeholders about the regulatory requirements and the continuous need for teaching and learning withing the strategic development process. When asked what the most challenging aspect of regulatory strategy at the organizations, P7 responded, "I would say is teaching my stakeholders…what's required…both, uh, you know, from…from a US standpoint and from an international standpoint… it's a lot of it is educating nonregulatory people…or stakeholders and…the FDA requirements for…submitting a 510(k). That's probably my biggest challenge." This participant's experiences highlight the ongoing effort required to maintain strategic focus and ensure compliance amidst the diverse needs and understanding of various stakeholders.

The investor perspective on strategic knowledge integration followed a comparable line of thinking. For example, P5 focused on the entrepreneurial approach to regulatory strategies, advising startups on the judicious use of resources for regulatory compliance and the importance of balancing caution with decisiveness in regulatory processes. For example, P5 stated,

> …what I've seen with regulatory people in general is they tend to be a little cautious. So, if you are going to, and that's a good thing, but if you are going to leave them for long periods to, to their, you know, processes and approach, they may … wind up turning every decision into a one-way decision, which means every single time they're going to

> want input. So, you got to empower them to make that decision…Keep making decisions, right? and you can be wrong. It's okay to be wrong. Um, but on the flip side… having more regular check ins with a regulatory team, um, be it your vendor or be it your team…because, I think left to their own devices, you're going to wind up with the most conservative approach.

The insights also delved into leadership qualities necessary for early-stage businesses, emphasizing the need for a balanced team dynamic to navigate the medtech industry effectively. More specifically, P5 indicated, "I'm more of an investor in teams than an investor in an individual, like single person lead companies." Participant 6, who is also an investor, discussed the necessity of adequate resourcing for strategy execution and the value of collective expertise over individual knowledge in regulatory strategy development. For example, P6 indicated,

> You need to rely on expertise which not one single person has. So, I think that's just the fact… you will be talking about different markets, um, the different… regulations. I mean, it's impossible for one person to say, "Well, I know it and I know it for India, I know it for Europe, I know it for the US and know for South America." Somebody says that it's not credible.

Collectively, these responses underscore the multidimensional nature of strategic knowledge integration, highlighting the importance of clear communication, stakeholder education, collaborative development, and adaptive planning to navigate both regulatory and organizational landscapes effectively.

Theme 5: Proactive Regulatory Engagement. The theme of Proactive Regulatory Engagement illustrated the consensus among participants on the importance of initiating early and sustained dialogue with regulatory bodies, notably the FDA, to navigate the evolving and

intricate regulatory landscape efficiently. This approach is supported by various strategies and experiences shared by the participants.

Navigating the unpredictable landscape of FDA inquires, especially for novel products, necessitates strategic foresight. The unpredictability associated with these inquiries emphasizes the utility of presubmission meetings in reducing uncertainty. One participant (P1) reflected, "Presubmission meetings are very useful…a great tool for reducing uncertainty… bringing FDA in on the conversation through these presubmission meetings to the extent that they will comment. There's usually some good information to be gleaned using the presub process." And advised, "engage with the FDA on any significant questions that remain, as early as possible." This advice underscores the importance of early engagement to mitigate risks associated with significant project alterations, which could lead to "new costs, a new timeline, everything bad from a business perspective."

The importance of initiating dialogue with regulators from the outset is echoed by P3's perspective, which advocates for companies not to hesitate in engaging with regulators. This participant's experience revealed potential inconsistency and surprises in FDA feedback, suggesting "the dialogue is always helpful with the agency in unique, such situations,' particularly in areas of emerging technology or when employing novel testing methodologies. The guidance provided is to "engage early and often" to clarify strategic uncertainties and incorporate FDA feedback into regulatory strategies.

Participant 4 reiterated that aligning regulatory strategies with FDA feedback early in the product development process is crucial. The participant shared, "it is always better to have a discussion with FDA in advance," and proposed making such discussions a mandatory element of regulatory strategy to "identify all the requirement and then discuss your plan…with FDA to

get it aligned." This approach highlights the importance of preemptive discussions to save time and resources. Participant 6 viewed FDA engagement as a critical component of a comprehensive regulatory strategy and emphasized the balance between seizing early engagement opportunities and understanding the associated risks. They highlighted the strategic need to "identify opportunities for early engagement but also clearly explaining what the risks are," aiming to manage investor expectations and prepare for potential challenges effectively.

Incorporating insights from individuals with direct FDA experience into regulatory strategies offers valuable perspectives. Participant 7 shared their experience of engaging a former FDA staffer to validate their regulatory strategy. This approach not only provides "a whole lot of insight" not readily available through direct agency interactions, but also reflects the broader political pressures influencing FDA processes and the variability in reviewer expertise. P7 stated,

> …politically, there was a lot of pressure put on FDA to speed things, to market, uh, speed development to market, especially having to do what was…pushed along…Covid vaccine… development…shone a spotlight on that, that whole process. And, uh, there was a lot of pressure … to speed things through FDA, uh, cut red tape and…to try to to help manufacturers innovate, I think. Unfortunately, we're going the opposite direction in Europe.

Contrasting the FDA's operations with the regulatory environment in Europe, P5 described the FDA as "a sleek startup," noting "the more revolutionary a project the earlier you should be engaged." This observation points to the critical timing of regulatory engagement and challenges posed by the variability of FDA reviewers and the impact of political landscapes on regulatory priorities, with comments like, "You wind up at sometimes the whims and fancies of a political landscape."

These observations highlight the critical role of proactive engagement with regulatory bodies in maneuvering through the intricacies of the FDA regulatory process. Early discussions, strategic adaption based on FDA feedback, and leveraging regulatory expertise form the cornerstone of an effective approach to mitigating risks and ensuring a smoother path to market.

Theme 6: Collaborative Regulatory Ecosystem. In the intricate process of regulatory strategy development and execution, the diversity of expertise required for success underscores the critical need for collaboration. Participant 1 captured this necessity with the following statement, "Collaboration is required because of all the different specialties that are required to execute the strategy." However, P1 cautioned against environments that might be too fluid or undefined, warning that "if the requirements…of the product…are not well defined then any change to that can completely undermine the strategy that is being developed," pointing out the need to balance rapid innovation and the need for clear, stable foundations in collaborative efforts.

Participant 2 discussed the significance of establishing a collaborative environment to enhance clarity and consistency. As P2 puts it, "…anytime you can have a collaborative environment for consistent discussions, improve clarity, that's going to be beneficial. P2 further emphasized the importance of the end user's understanding and adherence to the regulatory strategy, highlighting a key aspect of collaboration: "So, you can have a very clear regulatory strategy that is never really understood by the end user." Delving deeper into collaboration, Participant 3 discussed the integration of gap analysis tools and collaboration with both internal and external stakeholders, presenting a model where "outsourcing a majority of the tasks that are needed to support a regulatory strategy" complements the in-house expertise. This collaborative

model, as P3 noted, relies on “a very strong and trustworthy network of consultants that can support the in-house team,” showcasing how diverse expertise enhances the regulatory process.

The practical aspects of collaboration within regulatory strategies were further illuminated by Participant 6 and Participant 7, who shared experiences with hybrid work models and the importance of open communication. P6 noted the prevalence of a hybrid work model as “pretty much the most common model,” while P7 stressed the routine of open communication and regular meetings, “we don’t go too long without meeting as a group…we typically meet every every Thursday afternoon,” showcasing how regular interaction among stakeholders is pivotal to fostering a collaborative regulatory environment.

These narratives highlighted the central role of collaboration in the regulatory landscape, demonstrating through diverse participant insights the multifaceted benefits of open communication, leveraging technology, and integrating various expertise to achieve more effective regulatory outcomes.

Theme 7: Systems Integration and Streamlining the Framework for Regulatory Strategy. The conversation around integrating systems and consequential impact on regulatory strategy across business processes reveled a complex interplay between regulatory requirements and various business operations. This complexity necessitates a congruous integration of systems to ensure regulatory compliance and streamline the regulatory process while fostering business growth and innovation. Participant 3 introduced the concept of setting up a governance structure to navigate the intersection of business processes and quality systems. This governance framework facilitates critical decision-making regarding the implementation stages of the quality system and related processes, ensuring resources are utilized efficiently and effectively. P3 stressed, “understanding what aspects of the quality system or the business process makes sense

at what stage is very important." This approach is grounded in the belief that while quality systems are crucial, they need not be fully implemented from Day 1 but rather developed as the company evolves. The participant elaborated, "having a very solid and knowledgeable governance structure in place allows us to, kind of, pressure test these business processes, pressure test the quality system," which underscores the strategic management of regulatory and quality processes as dynamic elements that can be optimized over time.

Participant 7 touched on the separation of business processes and quality systems, pointing out that "some parts of your business processes…should be part of your quality system and then some are not," which speaks to the nuanced approach needed when integrating systems across an organization. Participant 2 also advocated for managing business and quality aspects separately, suggesting that quality results lead to good business outcomes without necessarily needing to intertwine financial or strategic business information with quality systems. P7 also mentioned the significance of auditing and compliance quality management standards, like ISO 13485 and the Medical Device Single Audit Program (MDSAP), in facilitating market access and the efficient completion of regulatory strategies. Specifically, P7 stated, "if you've got a good quality management system and your design assurance processes are well-defined…that itself speeds things to market.

Participant 4 discussed the benefits of employing an electronic quality management system (eQMS) to aid in the efficient management of regulatory documentation and decision-making. P4 noted the ease with which an eQMS facilitates traceability and documentation, stating, "it's easier, in my opinion, to demonstrate the traceability and maintain…your technical documentation." Furthering the discussion, P4 mentioned that the use of specialized software can simplify the regulatory process. By compiling dossiers and maintaining technical

documentation more efficiently, an eQMS facilitates operational excellence and strategic focus. As the participant noted in relation to demonstrating compliance, “if you have a proper software system…the traceability of different things, it is easier for you to demonstrate.” P4 also strongly advocated for integrating mandatory inclusion of presubmission meetings with the FDA in the regulatory strategy process, highlighting the importance of these interactions in streamlining the regulatory processes. Participant 7 added the practical application of forms and templates in streamlining regulatory strategies across different markets, including considerations for 510(k) submissions, PMA, and breakthrough device designations. By systematically capturing critical data and decision factors, such as sterile versus nonsterile classifications and sales call points, the process becomes more efficient and aligned with regulatory objectives.

Hybrid work models were highlighted by Participant 6 in that they serve as an asset in the realm of regulatory strategy execution. These models provide a blend of on-site and remote work, ensuring that team members can engage in bench work or development tasks in person when required, while other aspects of the project can progress through virtual means. P6 outlined this approach by noting the combination of “some physical presence…most related to bench work or development work…but the rest of the team work was pretty much virtual,” showcasing the adaptability and flexibility of hybrid models. This balance between in-person and remote collaboration underscores their efficacy in meeting the varied demands of regulatory frameworks and enhancing the efficiency of strategy deployment across dispersed teams.

Participant 1 outlined the critical cooperation needed between business operations and quality systems requirements, asserting, “for any long-term viability, there needs to be as much synergy between the business operations and quality system requirements as possible.” P1 further elaborated on how regulatory strategy can influence aspects of the business, such as

marketing limitations and design and development processes, highlighting the role of regulatory strategy as a significant input that "would be an input" affecting costs, the need for specific equipment, expertise, and overall project scope. Expanding on this, Participant 2 emphasized the limitations that may be imposed by regulatory strategies on marketing and commercialization efforts. P2 explained how the speed at which a product can reach the market is affected by how "you limit what you can actually say" and "how you can market and sell the product."

These insights illuminate the intricate relationship between regulatory strategies and business processes, highlighting the necessity for integrated systems that support regulatory compliance, operational efficiency, and market access. The discussion emphasized the importance of governance structures, digital tools, and strategic alignment across departments to ensure that regulatory strategies bolster rather than hinder business objectives. By adopting these practices, organizations can navigate regulatory challenges more effectively and ensure compliance while maintaining agility and strategic focus.

Theme 8: Balancing Innovation and Regulatory Risk Considerations. This theme provided an exploration into regulatory risk considerations from the participants' experiences, elucidating how risk classifications significantly shape the development and execution of regulatory strategies. The nuanced interplay between a device's risk profile and regulatory requirements necessitates a strategic and adaptable approach. This theme also shed light on the interplay between pursuing innovation and navigating the stringent regulatory landscape. Participant 1 outlined the direct correlation between risk classification and regulatory demands, stating, "In general, a higher risk class introduces more stringent requirements for both the device and the manufacturing process of the device." This connection highlighted the additional complexities and efforts required for compliance with higher-risk devices due to the scarcity of

predicate devices and clear regulatory pathways. P1 further noted, “A higher-risk device that’s maybe more novel may not have a well-defined pathway,” emphasizing the challenges in strategizing for these novel, high-risk devices compared to their lower-risk counterparts. P1 elaborated on the challenges of integrating complex technologies or novel materials into medical devices, noting that such innovations “add a lot of complexity to the regulatory strategy itself as well as uncertainty,” especially when these technologies push the boundaries of traditional regulatory paradigms. P1 also noted that caution is needed when innovation might lead to rapid changes or undefined product specifications, stating, “if the requirements, if the understanding of what the product is going to do and what it’s going to be are not well-defined, then any change to that can completely undermine the strategy that’s being developed.”

Strategic considerations for product classification were illustrated by Participant 2, who discussed how slight modifications in product descriptions can shift a product’s classification between Class II and Class I, significantly altering the regulatory strategy needed. The impact of a device’s risk classification on regulatory scrutiny was further detailed by Participant 4, who noted the influence on post-market-surveillance and clinical testing requirements that exist for certain higher-risk devices. “For example, if the product is not much novel, then maybe it is possible that FDA may give you clearance, maybe without the clinical data,” P4 explains, indicating how risk factors dictate regulatory oversight levels.

Emphasizing the importance of proactive risk management, Participant 3 highlighted the necessity of having contingency plans to mitigate unexpected challenges, stating, “So taking time to step back and look at risk management and the risk profile of the device, I think, was very, very helpful.” This proactive stance ensures readiness over reactivity in regulatory strategy formulation. Participant 5 highlighted the linkage between innovation and regulatory risk by

succinctly stating, “the more revolutionary…definitely…the higher risk profile,” illustrating how groundbreaking technologies may inherently entail higher regulatory considerations, affecting strategic positioning. P3 also discussed the practical challenges of designing innovative medical devices that meet regulatory standards for safety and efficacy. They recounted the iterative process of design modifications to comply with FDA and ISO testing requirements, illustrating the tension between innovation and regulatory compliance: “it’s one thing to go out and try to design something unique but at the same time it still has to hold up to the rigor of safety and efficacy testing that’s required.”

Participant 5 and participant 6 reflected on their preferences and experiences with evolutionary versus revolutionary innovation, respectively. P5 expressed a preference for focusing on evolutionary work, building on previous innovation, focusing on internal efficiencies, and leveraging distribution and supply-chain networks to advance the next generation of devices. In contrast, P6 discussed an example of a complex technology that was in its early development stages, highlighting that the key decision factor for investment at that stage was not solely the regulatory strategy but included other key due diligence elements such as intellectual property considerations.

A unique strategic regulatory decision was exemplified by Participant 7, where a somewhat novel product, despite the FDA’s down classification, was presented as if requiring a higher approval, illustrating strategic foresight in regulatory planning. P7 detailed, “we felt like we’d be in a better position if we went to the FDA and said, ‘we know you reduced the risk class or risk category of this device. However…we're going to present it to you, as if we needed a 510(k) anyway,” showcasing a calculated approach companies could undertake in aligning regulatory strategies with device risk profiles. P7 also touched on how the device class impacts

the rigidity of required testing, noting that “the lower the class…the less rigid your testing has to be,” which further illustrates how risk classifications influence regulatory strategies and the testing requirements necessary to demonstrate compliance.

Participant 4 suggested a strategic approach for product development teams, emphasizing the benefits of simplicity. P4 advised, “it could be ideal if they go with simple product first in the US market,” before adding more complex features. This phased approach allows the team to introduce a fundamental product and then later “add the add-on feature,” which can be favorably compared to the already cleared baseline product. P4 Reasoned that by doing this, teams can demonstrate to the FDA that the new, improved product is “more-or-less equivalent or better than the…cleared device.” This advice encapsulates a strategy of incremental innovation, where the participant recommends, “they don’t try maybe…making the first product very complex and with all the features, but rather to just, you know, land first and then expand.” This approach is posited as a way to navigate regulatory processes more efficiently by initially focusing on the baseline device essentials.

The insights shared by the participants draw a vivid picture of the complex interplay between the risks associated with a product, the stringent nature of regulatory requirements, and the intricacies of strategic planning. They revealed that successful navigation through the regulatory terrain demands not only adaptability but also a thorough analysis of risk and proactive strategic thinking. These discussions further stressed the importance of having precise product definitions in place, the ability to foresee and adjust to changes in classification, and the agility to respond to the ever-present uncertainties inherent in the regulatory process.

Theme 9: Development Dynamics and Regulatory Requirements. Navigating the complexity of medical device development requires balancing innovative product design with

rigorous testing and an agile regulatory strategy process. Participants shared their experiences, shedding light on the intrinsic challenges and strategic decisions that play a critical role in the process.

The need for meticulous planning and change control in product design was a central topic discussed by several participants, particularly when the design incorporates novel or untested elements. As Participant 1 noted, any significant change to the device's intended use or technology can trigger a cascade of regulatory repercussions, potentially necessitating a complete overhaul of testing protocols and submission routes, with substantial cost implications. P1 stated, “A change in the device intended use or fundamental technology could completely change the regulatory requirements…”. Such changes can disrupt business operations and inflate budgets, particularly when transitioning from a 510(k) to a PMA, where submission costs multiply. The participant also posited, “Depending on the type of modification, that can be disastrous if you’re late in the design phase…”.

Other participants highlighted the weight of modifications to device design throughout the development process. Design adaptations, while sometimes essential, can disrupt the regulatory strategy, especially if they occur late in the process. P3 underscored the importance of foresight and flexibility in regulatory planning with the statement,

> So, it's not favorable to change your strategy late in the design process or late in the development process. But sometimes you don't have a choice because you understand or see something happening with the device, whether it be as part of the clinical trial or, you know, the FDA may come back with some oddball question or request. So certainly, you have to have the flexibility to change your regulatory strategy. But knowing that the later

> a strategy changes in the development process, the wider the impact in terms of market success.

In that case, the dialogue with the FDA was considered pivotal, particularly when presenting a regulatory strategy for unique situations or emerging areas such as digital therapeutics or software as a medical device, which are relatively new to the FDA. P3 indicated that, "…sharing your strategy with the agency is also very helpful in areas that are emerging."

Participant 4 reiterated the need for strategic planning during product development, where engaging the FDA early in the process through presubmission meetings was advocated to prevent unforeseen testing and design iterations. This approach can save time and resources, as unanticipated FDA requirements or feedback can lead to repeated tests or design changes that can hinder market entry and add financial strain, "and when that happens and they you have to go back to management, you know, and ask for the new budget to repeat the testing." Participant 3 reiterated the concept of presenting a clear and coherent regulatory strategy to the agency, especially for emerging areas like digital therapeutics or when employing new methods like modeling and simulation testing. A transparent dialogue with the FDA can be advantageous, particularly in situations where nontraditional data must be interpreted in the context of regulatory requirements. P3 indicated that:

> …there's been times when I've taken a regulatory strategy and presented that to the agency saying, 'look, this is how we plan to bring this device to market. Here's why we're doing it. Here's who benefits from it.' So sometimes in unique situations, sharing your strategy with the agency is also very, very helpful, especially in areas that are emerging. ... Also using like modeling and simulation to support testing, which traditionally is being done on nonsimulated environments. So now that the agency is starting to look at more

> and more of simulating certain testing, you know, you want to share your strategy with the agency and say, 'look, we're going to we're going to give you data that may not be traditional, but it certainly still is qualified data that meets the needs part of the requirement.' So yeah, I think the dialog is always helpful with the agency in unique such situations.

Participants pointed out the paradoxical nature of innovation and regulation; while the former pushes the boundaries of design, the latter anchors the process in a state of uncertainty due to evolving standards and testing requirements. P4 succinctly captured the essence of this dynamic and mentioned that while regulatory strategies can significantly affect the budget, particularly in cases of unforeseen additional testing for the U.S. market, understanding and meeting FDA expectations from the outset can mitigate the risk of costly retesting and project delays. According to P4, "…sometimes the main challenge…once you submit…they may come up with the requirement that…'you didn't meet so-and-so conditions."

These testing requirements are a cornerstone in device development, as underscored by several participants. Participant 2 discussed the fluidity of regulatory guidance, which can change over time and affect the testing strategy. For instance, guidance documents and standards evolve, necessitating additional testing or reevaluation of the product's classification, which can pivot from Class 1 to Class 2 designation and vice versa, fundamentally altering the regulatory requirements. P2 also indicated that since standards and guidance change, what was acceptable during initial design phases may no longer be so later on, thereby altering testing requirements and, by extension, regulatory pathways.

> I think you'll find that guidance documents will change. Standards will be updated and require additional testing. The FDA can, in essence, raise their bar to support a…

> guidance document or something that's maybe even in draft form that will change the way things are reviewed. Biocompatibility testing and things that are readily accepted tend to shift over time as well. So, knowing where a product was and what your strategy was 2 years ago may be completely different today, but it also may be different in 3 to 6 months depending on how things are changing.

Participant 7 elaborated on the concept of design assurance, particularly for novel devices with no historical data. P7 stated, “Design assurance is one of the biggest things… We're putting together this regulatory strategy and determining, you know, different design inputs that we're going to need…” New device technologies may lead to larger sample sizes for testing and, consequently higher costs.

> So, we're always constantly looking at ways to reduce sample sizes. If we can gather, gather enough data to to do that… So yeah, sample size development, especially for something that's expensive to… develop and sample, say like, uh, for instance…bioabsorbable material that we are using…is pretty expensive.”

They stressed the importance of developing a regulatory strategy early, after proof of concept, to integrate manufacturing capabilities and process validation, which affect time and resources.

On the topic of design assurance, Participant 6 discussed the importance of end-user feedback in design features and usability, pointing out that the lack of such input could render a design impractical despite theoretical usefulness, which can affect funding opportunities. Specifically, P6 pointed out,

> You know speaking to the end users having input from end users as to whether these features and whether they were…actually something that in practical use would make sense, let's put it that way. So, there…was no testing done with the target patient pool and

> caregiver pool related to key features of the design, which made the design theoretically useful, but more practical point of view, not because it was just too burdensome… and actually that company did not get funded.

Product design intricacies and regulatory strategy are acutely interconnected. The insights offered by these participants paint a picture of the balance between innovative impulses driving product design and the stringent demands of testing and regulatory requirements. The collective wisdom suggests that successful device development hinges on an anticipatory regulatory strategy, adaptability to changing guidelines, and a robust dialogue with the regulatory agency, all while keeping the goal of market success in sight.

Theme 10: Strategic Leadership Efficacy. Strategic leadership efficacy within the context of regulatory strategy requires not only the identification of necessary resources but also an understanding of the process by those in executive roles. Leadership teams must be adequately informed to ensure a cohesive strategy, as their engagement is crucial from the initial decision-making phase to the final approval stages of a regulatory plan. One participant expressed that leaders are not just figureheads but are integral in resource allocation and strategy review, ensuring the right expertise is consulted throughout the process. P1 stated, “Leadership will help identify any resources that we need and make sure there’s someone available to review the results or to consult with if any other expertise is needed.” Participant 2 followed that thought by voicing related concerns, saying:

> I believe this may be common…but having enough appropriate staff that has the competency to do the work. I think it's usually you find there are very few people that that have the skill sets necessary in an individual organization, and it's hard to flex that muscle to find more folks or review things.

Participant 6, an investor, voiced a correlated opinion, “nowadays, I think it's more about leadership means that…you can bring people with the, with the relevant experience, um, together. So…they work effectively together and you have to lead them…towards success.” P6 closed the idea, when they stated, “…leadership is really, you know, personal integrity…you know, define the priorities, work with your team…and…make sure that they can provide their experience to this process.”

Leaders also play a crucial role in ensuring diverse opinions within a team contribute to informed decisions, as highlighted by Participant 3, who stated, “When you talk about strategy…it usually involves senior members of the company…you’re going to get a very informative discussion, but it’s also going to be a discussion that’s full of contrasting opinions.” P3 expanded on the topic, saying:

> So, I think when…you do have that type of environment, again, it needs to be controlled to the point where you're not stifling innovation, you're not stifling ideas. But at the same time, you also need to make sure that you don't stifle progress because too many cooks in the kitchen can certainly lead to a disaster, but you still can benefit from the experience levels of different leaders across the different areas within the company, as long as it's done in a very methodical, controlled way where, you know, you gain the opinions and solicit the opinions.

Leadership does retain the role of decision-maker, but they are also responsible for setting the tone and managing the ecosystem for productive and informed discussions.

Managing leadership expectations was a common discussion point among the participants. For example, P3 emphasized the importance of setting realistic expectations, suggesting a preference for conservative estimates over aggressive ones: “It’s better to sort of say

you're going to deliver something in 3 months and then come ahead of that timeline rather than agree to timelines and then miss them by 2 or 3 months." This perspective was echoed by others who recognized that inflated expectations can lead to significant issues within startup environments, where leaders may not fully comprehend the nuances of regulatory pathways (P2). This caution underscores the balance leaders must strike between ambition and achievable goals.

From an investor perspective, Participant 5 shared a nuanced view of decision-making inspired by Jeff Bezos. They describe a strategy that categorizes decisions into two types: one-way and two-way doors. One-way decisions are significant and irreversible – once you pass through, there is no going back, hence requiring careful deliberation and confidence in the choice made: "Is it a two-way or a one-way decision…if you walk through that door, can you get back to where you started? Therefore, that's a really important decision. Right? You better be right on that decision." In contrast, two-way decisions are less risky and allow for a return to the starting point if the outcome is not as expected. These decisions, according to P5, do not necessitate extensive consensus: "If it's a two-way door…you can always get back to the starting point. You don't need consensus building for that."

P5 also touched on the leadership's role in navigating these decisions, emphasizing that strong leadership can steer away from default conservative approaches and guide towards more effective strategies: "If you have strong leadership in that area, I think they're going to do a better job guiding the strategy so that it doesn't become just the default, overly conservative approach." This approach advocates for recognizing the type of decision at hand and adjusting the decision-making process accordingly while emphasizing the importance of leadership strength and agility in guiding these decisions toward successful outcomes.

Several participants weighed in on the topic of leadership engagement within the regulatory strategy process. From Participant 2's perspective, a significant challenge with startups is that leadership often lacks a deep understanding of the regulatory requirements, which can lead to misaligned expectations and strategies. This participant also noted a potential disconnect between leadership's directives and the practical execution of tasks, indicating that while leadership may set the direction, there is sometimes a lack of involvement in the granular details of the strategy's execution: "…from a leadership perspective, I find that sometimes the executive or the business folks in a startup don't have the proper aptitude or comprehension or don't are not taking the time to digest it. So that can cause some significant issues." Participant 4 provided a different perspective in that leadership's involvement spans from the beginning to the end of the regulatory process, from deciding to enter a market to reviewing and then approving the final strategy. This participant's experience revealed that top management's active participation is crucial, especially in navigating the complexities of the U.S. market: "the top management is usually highly involved in all these aspects."

Participant 7 illustrated how leadership at their organization is also directly involved in discussions around regulatory strategy, particularly when focusing on specific markets like the United States and how they facilitate the transition of new products through R&D to market release, "The stakeholders that sit in on these meetings are going to be our executive team, which is our… CEO and president, it's our vice president of operations…and then our director of …operations." Other participants echoed the commitment levels of their respective organizational leadership. Table 14 below summarizes their responses.

Table 14

Leadership Commitment to Regulatory

Participant	Leadership Commitment
P1	"we have an extremely committed… management for this…activity."
P2	"fairly high."
P3	"I think the commitment is good, and I think at the end of the day, everybody wants to see the product succeed."
P4	"So in a nutshell, I would say…if…the management is experienced enough in this industry, they would understand…the importance of regulatory strategy."
P5	"…if it's an early-stage business, I want the guy who's the leader to be, like, a crazy evangelist for the technology."

In sum, this theme of strategic leadership efficacy paints a picture of leadership's critical role and commitment to regulatory strategy as visionaries and operators. Leaders must navigate the balance between strategic oversight and operational involvement, ensuring their teams are well-resourced, that strategies are based on a rich diversity of experiences, and that is a clear, actionable path forward.

Theme 11: Regulatory Uncertainty. Navigating the complexities of regulatory uncertainty with the FDA is a multifaceted challenge, marked by the need for strategic foresight and adaptability. The participants, across various experiences, have shared their encounters with FDA transparency, unexpected surprises, and the overall unpredictability of the regulatory process, shedding light on the interaction between regulatory bodies and companies seeking to gain market access in the U.S. market.

Participant 1 praised the FDA for adhering to its published guidance and highlighted the utility of presubmission meetings as a strategy for reducing uncertainty. Regarding transparency, the P1 stated, "I think it's pretty high where they've written something down…presubmission meetings are very useful." This sentiment underscores a perception that the FDA is generally transparent when it comes to its guidelines and processes. Echoing this view, Participant 3 noted

the FDA's objectivity and reliance on regulations and guidance documents, "I think the FDA usually tends to be very objective in terms of citing regulations, citing guidance documents." However, they also acknowledge that while the FDA aims for transparency, there can still be "some curious questions…and comments or quires that are not necessarily as transparent," suggesting a nuanced experience of transparency in practice. P3 added,

> Once the agency looks at a device and they come back with a lot of feedback, you know, the challenge always is not knowing what additional testing or what additional requirements will be placed on a on a particular device. So, it's always challenging, you know, because some of that is not predictable. So, it's challenging to educate investors, to be flexible around potential feedback from the agency, which could lead to some delays.

Participant 4 appreciated the FDA's readiness to provide advice and viewed the process as transparent, especially when inquiries are clear and scientifically-based, "If you ask the right questions they always give the...proper answers…I would say FDA is very transparent." They further commend the FDA for its structured guidance documents and the wealth of information available online, enhancing the agency's transparency, "I find the FDA very transparent because…they have very well-structured guidance documents." Regarding the presubmission meeting request program, P4 added, "they develop this program, especially for … helping the medical device manufacturers so that they can bring product faster to the market, to the patient, what they need. So yeah, I would say…they're very transparent."

On the other hand, Participant 5 introduced a note of caution, pointing out how political changes can affect regulatory priorities and create inconsistencies, "You wind up at sometimes, the whims and fancies of a political landscape. This point of view highlighted a less predictable

aspect of FDA interactions, where shifts in administration or FDA leadership can lead to changes in regulatory pathways and reviewer consistency, particularly for innovative or novel products.

Participant 7 offered a more mixed perspective, noting variability in the quality of interactions with FDA reviewers, “Oh it’s hit or miss. You know, it depends on who you’re talking to.” This comment reflects the personal element of FDA interactions, where the experience can vary significantly depending on the individuals involved in the review process. Regarding the variable nature of regulatory pathways, especially for higher-risk devices. P1 suggested a proactive approach, “Whereas it may be there may be more unpredictability in the higher risk devices, that’s why you have to do more research to understand what the most likely regulatory pathway can be.” The same participant also highlighted the FDA’s improved efforts in defining requirements, yet pointed out the challenges that arise in areas lacking specific criteria: “So, certainly, in recent years FDA’s done a much better job at defining requirements…but unfortunately, wherever there aren’t…they tend to just ask any theoretical question they can dream up.”

As P1 pointed out the inherent unpredictability when navigating through regulatory guidance that are not well-defined, leading to unexpected inquiries from the FDA, “Oh there always seems to be a surprise, but I’d say its…the areas where things are not well-defined.” P1 also offered the following suggestion as a risk mitigation,

> Using research. Anything we can find, it might even…resemble a precedent…Any devices that are on the market. Any other types of device that could conceivably be regulated in a similar way and how that's been treated by FDA in the past? Any examples of something similar ish that's on the market that we can try and learn from. What requirements were applied to it? And sometimes the…precedent can just be hard to find.

> Sometimes you can like if you know who a competitor is something similar you can backtrack and try to figure out how they got to market.

Participant 3 shared a similar sentiment, noting the astonishment companies may feel upon receiving feedback from the FDA, especially when the requirements seem extensive and daunting, “organizations when they first encounter feedback from the FDA, they’re very surprised.” This participant emphasized the importance of strategic planning to minimize surprises by conducting thorough gap analysis to anticipate potential challenges.

For Participant 4, surprises came in the form of changing FDA stances, which required significant adjustment to their regulatory strategy. One notable instance involved an unexpected shift from the FDA, which initially suggested a de novo process, but later agreed to a 510(k) submission. P4 stated, “that was actually surprising to me that the FDA can also change their stand, basically.” Such instances underscore the dynamic nature of regulatory strategies and the need for adaptability. P7 recounted an unexpected demand from the FDA to validate cleaning processes for neurological use of a device, despite its initial nonneurological market positioning, “they made us jump through a lot of hoops to revalidate that…especially the cleaning process for neurological use.” This experience highlighted the FDA’s cautious approach and unforeseen demands that can arise late or even post regulatory clearance and also brings the need to incorporate adequate reviews of claims across all marketing and sales print materials.

Participant 6 reflected on external surprises unrelated directly to FDA feedback, but equally impactful on the regulatory process, such as supply chain issues and delays caused by capacity constraints in prototyping and lab services, “there’s waitlists to get certain stuff, certain things done.” This broadens the scope of surprises to include operational challenges that can indirectly affect regulatory timelines and strategies.

While there is consensus among participants that the FDA strives for transparency, particularly through its guidance documents and the presubmission process, experiences of transparency are nuanced by the variability in reviewer interactions and the broader context of political and administrative changes. These factors can introduce unpredictability into what is generally perceived as a transparent process. Surprises also arise when processing FDA interactive feedback as well as those associated with supplier and vendor considerations. Companies navigating this landscape must remain vigilant, adaptable and prepared to address unexpected inquires and requirements, ensuring a smooth regulatory journey despite the inherent uncertainties.

Theme 12: Supply Chain Considerations in Regulatory Strategy. This theme reflected the complex interplay between regulatory planning and external supplier/vendor dynamics, as experienced by the participants. These narratives underscore the challenges and strategies for navigating supplier-related surprises and ensuring compliance with regulatory requirements.

Participant 3 discussed the challenges of procuring vendors and supplies, highlighting the unpredictable nature of these relationships and their impact on development timelines, “That’s always a long-standing challenge because a lot of that is out of our control.” This participant also emphasized the importance of accounting for potential delays from external factors in the regulatory strategy, suggesting that having backup vendors might mitigate potential strategy downfalls.

P4 shared the difficulty in sourcing materials or components, especially when specifications are unique or when reliant on a single source, “…you may have to outsource…sometimes some processes, and sometimes it’s challenging that you always don’t get

what you want." The challenge of dealing with proprietary processes of suppliers, especially in the context of disclosing necessary information to regulatory authorities, was highlighted in the statement, "and as you know, in the regulatory world, we have to disclose many things to regulatory authority…sometimes it's also challenging." This participant also noted the strategy of developing alternative suppliers over time to mitigate the risks associated with single-source dependencies.

Participant 7 focused on the difficulties in obtaining critical information from suppliers, which can add cost and time to regulatory strategies. Regarding the challenge, P7 stated, "By far, I would have to say cooperation from our suppliers…It's things like trying to gather biocompatibility information…they come back to you and say 'it's proprietary'.". P7 offered the following proposal, "I have found it easiest if I can have a one on one conversation with the head of regulatory." P4 suggested,

> …to mitigate that… the risk that, well, the supplier don't provide information like that directly to us, then, then we need to… convince them that…if they don't supply information to us, but at least they supply information directly to the regulatory authority. Because then safe option for them and we don't get their… the proprietary information with regard to accessing this type of information.

The challenge of accessing critical information underscores the tension between proprietary business interests and regulatory compliance requirements.

Participant 6 spoke to additional operational challenges posed by supplier and vendor issues, such as waitlists for prototyping and lab services, which can significantly delay development processes. P6 stated, "there's waitlists to get certain stuff, certain things done…It's not necessarily something you can influence, but I think it's important to have a remediation

strategy in place. This highlights the need for strategic foresight and flexibility in managing supply chain logistics as part of a broader regulatory strategy.

These responses illuminate the intricate relationship between regulatory strategy and supply chain management, emphasizing the challenges posed by vendor reliability, access to critical materials and information, and the need for contingency planning. Effective regulatory strategy, as articulated by the participants, requires not only navigating the complexities of FDA requirements but also managing the unpredictable nature of supply chain dynamics to ensure timely and compliant regulatory strategy implementation.

Representation and Visualization of the Data

Representation and visualization of qualitative data involve methods and techniques designed to systematically display or illustrate nonnumerical information. This form of data, which can include text, images, videos, observations, and more, requires distinct approaches for effective visualization, as it often encapsulates complex, nuanced, and context-rich insights that do not necessarily lend themselves easily to traditional statistical analysis or graphical representation. Spinuzzi (2023) described the use of network models, flow models, and matrix models as examples of potential tools for visualizing certain aspects of case studies. Paulus et al. (2017) introduced the use of qualitative data analysis software (QDAS) such as NVivo and ATLAS.ti to provide support for researchers by presenting the outputs of the coding process to improve clarity and transparency. The authors further noted that QDAS is capable of supplying delineated themes and diagrams for the graphical depiction of analytical outcomes.

Data visualization and representation in this research included tables, diagrams, graphs, charts, and mindmaps. The researcher utilized NVivo 14 as a repository for the interview transcripts and to organize the coding and thematic analysis. In addition to the other

visualizations provided in this research, upon completion of the coding and thematic analysis, the QDAS was utilized to create a treemap to visualize the distribution and frequency of the themes and codes. According to Nielsen (n.d.), treemaps can help researchers quickly identify which themes are most prevalent or how they are distributed across the dataset. This method can make patterns or characteristics in the data more visible, which might be overlooked in text-based data analysis approaches. Figure 4 below shows the treemap of the emergent themes and codes from the present study. The researcher organized the themes as 'children' to each of the five research questions (RQ1 – Process Variables, RQ2 – Operational Factors, RQ3 – Product Variables, RQ4 – Leadership Factors, and RQ5 – External Variables). Within this treemap, there are two main dimensions to visualize: a positive quantitative value, which is shown by the size of the rectangles, and a categorical or secondary quantitative value represented by the color of the rectangles. In this case study, RQ1, which had the most themes and coding inputs, is represented in the yellow rectangles, RQ3 is represented by the green rectangles, RQ2 is represented by the grey rectangles, RQ5 is represented by the blue rectangles, and RQ4 is represented by the orange rectangles. Appendix 1 provides a screenshot from NVivo 14, including the hierarchy of the themes and input codes.

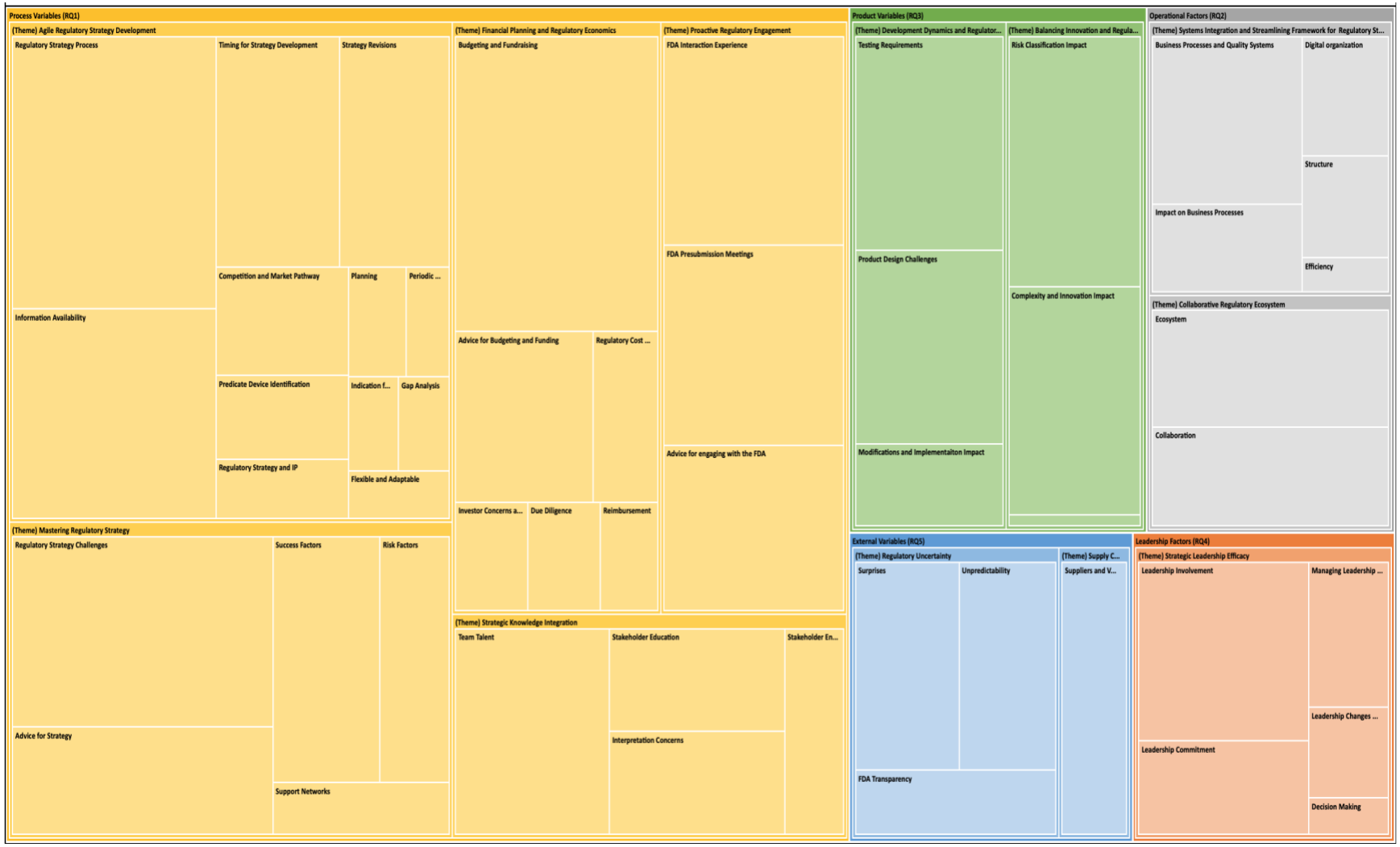

Figure 4. Treemap of Emergent Themes and Code Inputs

Relationship of the Findings

This section provides a discussion of the relationship of the findings with five elements of proposed research, mainly discussed in Section 1. These five elements include the relationship to the research questions, the relationship to the conceptual framework, the relationship to anticipated themes, the relationship to the literature, and the relationship to the problem.

The Research Questions. Based on the thematic analysis and coding described earlier in Section 3, the resulting themes were related across each of the five research questions (RQs) in the context of best practices for regulatory strategy success in the U.S. marketplace. The following narrative was constructed to illustrate the relationships and insights derived from the analysis.

RQ1 - What process variables do industry professionals perceive as the most important to regulatory strategy success in the U.S. medical device industry? The analysis identified several critical themes around the financial, strategic, and knowledge integration aspects of regulatory strategy. Financial Strategy and Regulatory Economics emerged as fundamental, highlighting the vital role of financial planning and understanding the economic impact and investor expectations associated with regulatory strategy and market access. This theme underscored the need for clear economic narratives and thorough due diligence to mitigate financial risk and increase investor confidence. Agile Regulatory Strategy Development and Proactive Regulatory Engagement themes emerged and emphasized the importance of adaptability and proactive FDA interactions. These themes illustrate the necessity for continuous strategy evaluation and the benefits of engaging early with regulatory bodies, respectively. The Mastering Regulatory Strategy and Strategic Knowledge Integration themes were highlighted as essential for overcoming regulatory challenges. These themes illustrated the necessity of leveraging expert advice, recognizing

project risk factors, and integrating specialized expertise to navigate regulatory complexities effectively. Moreover, Proactive Regulatory Engagement with the FDA through presubmission meetings was emphasized as a cornerstone for refining regulatory strategies and mitigating potential roadblocks, underscoring the critical role of early and strategic dialogues with the agency.

RQ2 - How do industry professionals describe the operational factors that lead to regulatory strategy success in the U.S. medical device industry? Operational factors that lead to regulatory strategy success were characterized by the importance of collaboration and systems integration. The theme of the Collaborative Regulatory Ecosystem sheds light on the significance of a cooperative network among stakeholders, enhancing the regulatory process through shared knowledge and joint efforts. This collaborative approach is complemented by the theme Systems Integration and Streamlining the Framework for Regulatory Strategy, which delved into the intersection of business operations and quality management systems. Insights from industry professionals illuminated the necessity for integrated systems that support regulatory compliance, operational efficiency, and strategic alignment, emphasizing the role of organizational governance structures and digital tools and templates in achieving regulatory objectives.

RQ3 - What product variables do industry professionals perceive as factors that generate regulatory uncertainty in the U.S. medical device industry? The discussions around product variables and their influence on regulatory uncertainty revealed a nuanced understanding of balancing innovation and risk considerations. Two themes emerged in relation to this research question. Balancing Innovation and Risk Considerations in Regulatory Strategy and Development Dynamics and Regulatory Requirements highlighted the complex interplay

between product design, risk management, and regulatory compliance. Industry professionals emphasized the need for a pragmatic approach toward device design and a fluid regulatory strategy that accommodates evolving testing and design changes, reflecting the intricacies of aligning innovative product development with stringent regulatory requirements.

RQ4 - How do industry professionals describe the leadership factors that lead to regulatory strategy success in the U.S. medical device industry? The role of leadership in guiding regulatory strategy success was acknowledged, with Strategic Leadership Efficacy emerging as a critical theme. This theme painted a picture of leadership's role in steering the regulatory process, marked by a commitment to strategic oversight, realistic goal setting, and decisive decision-making. Insights emphasized the need for leaders to navigate the balance between strategic vision and operational involvement, ensuring their teams are equipped and strategies are informed by a rich diversity of experiences.

RQ5 - What external variables do industry professionals perceive as factors that generate regulatory uncertainty in the U.S. medical device industry? The exploration of external variables contributing to regulatory uncertainty brought to light the themes of Regulatory Uncertainty and Supply Chain Considerations in Regulatory Strategy. These themes underscored the challenges posed by unpredictability in FDA communications and the critical role of supply chain dynamics in regulatory strategy. Participants highlighted the importance of flexibility, vigilance, and preparedness to address unforeseen demands and ensure compliance and timely market entry, pointing to the nuanced experiences of navigating the FDA's transparency and the unpredictable nature of supply chain management.

Through these narratives, a comprehensive view emerges of the multifaceted factors that industry professionals perceive as instrumental to the success of regulatory strategies in the U.S.

medical device industry. From the essential role of financial planning and agile regulatory approaches to the significance of collaborative ecosystems, product innovation, strategic leadership, and the management of external uncertainties, these insights paint a vivid picture of the complex, yet navigable landscape of medical device regulatory market access. Figure 5, below, provides a visualization of the research questions and the associated themes.

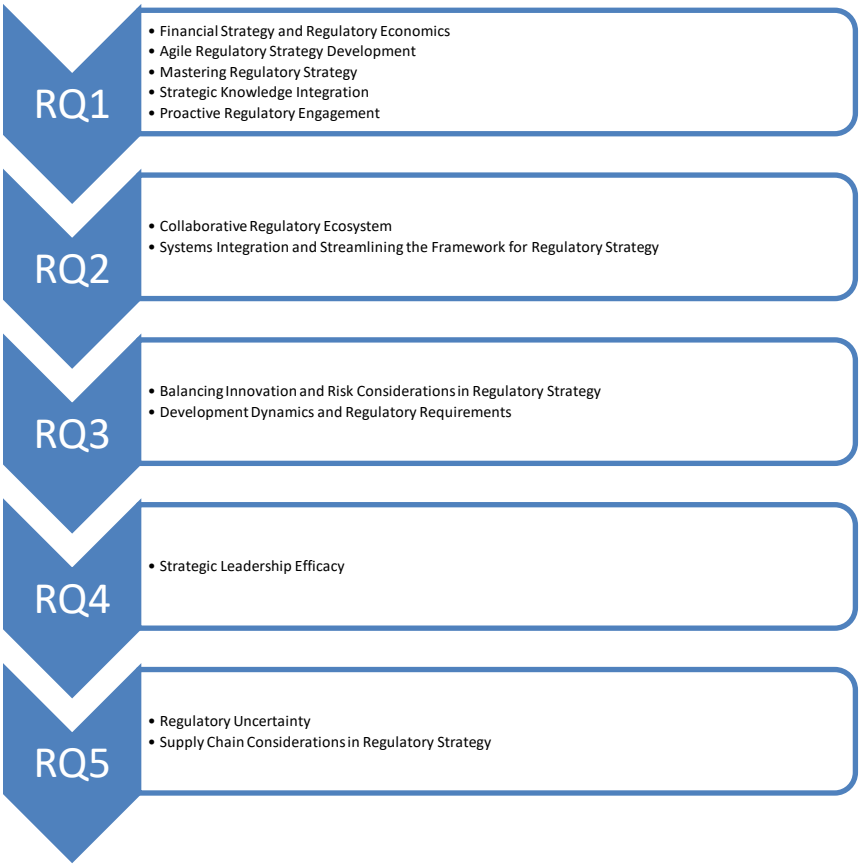

Figure 5. Research Questions and Associated Themes.

The Conceptual Framework. The conceptual framework of this study integrates Institutional Theory, Systems Theory, and Chaos Theory to explore the variables essential to successful regulatory strategy outcomes in the medical device industry. Drawing from the themes identified in the thematic analysis, the following narrative was constructed to describe how the themes fit into and contribute to the conceptual framework, highlighting the dynamic interplay between regulatory strategies, corporate strategies, and the overarching goal of successful medical device NPD and commercialization.

Institutional Theory and Regulatory Strategy. Institutional Theory emphasizes the role of institutions, such as the FDA, as regulatory bodies that dictate normative behaviors and levels of conformity, affecting the development and commercialization of medical technologies. Themes like (a) Financial Strategy and Regulatory Economics, (b) Proactive Regulatory Engagement, and (c) Mastering Regulatory Strategy reflect how medical device companies navigate these institutional pressures. Companies develop strategic financial planning and engage proactively with regulatory bodies, like the FDA, to ensure compliance while still striving for innovation and market success. (d) Strategic Knowledge Integration further illustrates how companies assimilate specialized expertise to ensure regulatory alignment and strategic clarity, embodying the institutional push toward standardization and compliance. This adaption to institutional constraints is also evident in the (e) Agile Regulatory Strategy Development theme, showcasing how companies must remain flexible and responsive to evolving regulatory information and market needs within the confines of regulatory authority expectations. These themes illustrate how companies adopt standardized approaches to regulatory strategy to comply with institutional constraints while attempting to innovate within these confines.

Systems Theory and the Role of Quality Systems. Systems Theory posits that elements within a system are interconnected, impacting the overall performance of the system. This perspective is reflected in themes such as (7) Systems Integration and Streamlining the Framework for Regulatory Strategy and (6) Collaborative Regulatory Ecosystems, which highlight the importance of quality systems and collaborative networks in the medical device industry. These themes underscore the complexity of regulatory strategies that incorporate both internal and external operational processes. They illustrate how the performance of the regulatory strategy system relies on the integration of a quality management system, operational processes, and the collaboration between various stakeholders, including regulatory bodies, to navigate potential constrictions and enhance the system's effectiveness.

Chaos Theory and Navigating Regulatory Uncertainty. Chaos Theory underscores the unpredictable outcomes that can arise from complex systems relevant to the medical device industry's high-risk environment characterized by regulatory uncertainty. Eleven Regulatory Uncertainty and (12) Supply Chain Considerations in regulatory Strategy underscore the challenges of navigating the unpredictable outcomes inherent in regulatory submissions and the medical device supply chain. These themes highlight the necessity for medical device companies to develop strategies that are both flexible and robust enough to manage the asymmetrical nature of risk profiles, including the complexities of device innovation, regulatory risk classification, and supply chain dynamics. (8) Balancing Innovation and Risk Considerations Further elaborates on this, showcasing how companies strive to innovate within regulatory confines, balancing the push for technological advancement against the imperative to mitigate risk and comply with regulatory standards. These themes highlight the strategic imperative for companies to develop flexible, well-defined regulatory strategies that can adapt to and mitigate the chaotic elements of

the regulatory process, thereby reducing the risk of catastrophic results and enhancing the likelihood of successful commercialization of new medical technologies.

Integrating the Themes With the Conceptual Framework. The themes identified in the thematic analysis demonstrate a complex interplay of strategic considerations that medical device companies must navigate within the constraints and uncertainties of the regulatory landscape. This aligns with the conceptual framework's theoretical underpinnings, illustrating how companies operating in the medical device sector employ regulatory strategies that reflect an understanding of institutional pressures, the systemic nature of regulatory activities, and the need to manage chaos and uncertainty encountered in the regulatory process. Through this integration, this study sheds light on the multifaceted variables that contribute to regulatory strategy outcomes, providing a richer understanding of the strategic process and offering actionable insights for stakeholders involved in medical device NPD.

Anticipated Themes. Looking back to the initial project research, detailed in Section 1, there were several themes that could be anticipated based on the data at hand at the time. For example, it is imperative to recognize innovative sources and the significant contributions from both startups and large companies. This understanding could be crucial for developing regulatory strategies that address the distinct challenges and advantages presented by organizations of varying sizes. Regulatory challenges and compliance were also anticipated themes, highlighting the essential nature of navigating complex regulatory frameworks and the necessity of compliance for market access and trade viability. The medical device development process was presented as iterative, with design control and risk management being critical to meeting regulatory standards and ensuring user safety.

The classification of medical devices and the corresponding regulatory pathways were anticipated as significant, including the varied requirements across device classes and strategic implications for market entry. External factors, those outside the control of medical device companies directly, influence commercialization strategies, necessitating a comprehensive regulatory strategy that anticipates and addresses these challenges.

Operational factors, including business process management, quality management systems, and fostering a supportive business ecosystem, were viewed as pivotal for implementing a successful regulatory strategy. This underscored the need for alignment between operational practices and regulatory objectives. Leadership and strategic decision-making emerged as anticipated themes, and they are key in guiding companies through the regulatory landscape. In addition, a focus on innovation, risk management, and ensuring product development processes align with regulatory requirements were likely themes to emerge. Overall, the initial research on this topic advocated for the development of a proactive and informed regulatory strategy, incorporating product design considerations, market entry barriers, and stakeholder engagement, to navigate the complex regulatory environment and achieve success in the medical device industry.

Comparing the themes identified from the thematic analysis with the anticipated themes from the preliminary research revealed both overlaps and distinct differences in focus, specifically in the context of regulatory strategy success.

1. **Theme 1 - Financial Strategy and Regulatory Economics Vs. Understanding the Source of Innovation**. Both themes emphasize the importance of strategic planning, whether it is understanding innovation sources or managing financial aspects directly tied to regulatory strategy. The thematic analysis specifically highlighted financial

strategy as crucial to navigating regulatory economics, a perspective that compliments the broader view of innovation sources influencing regulatory approaches, vis-a-vi larger companies are likely to have more financial resources at their disposal to implement regulatory strategies.

2. **Theme 2 - Agile Regulatory Strategy Development**. This directly corresponds to the theme of Proactive Regulatory Strategy Development from the initial research, emphasizing the need for flexibility, timely information, and adaptability in regulatory strategies to respond to evolving market and regulatory requirements.
3. **Theme 3 – Mastering Regulatory Strategy and Theme 4 – Strategic Knowledge Integration Vs. Regulatory Challenges and Compliance.** These themes underscore the importance of expertise, strategic action, and integration of specialized knowledge to overcome regulatory hurdles, closely aligning with the emphasis on navigating regulatory frameworks and maintain compliance identified in the preliminary research.
4. **Theme 5 – Proactive Regulatory Engagement**. Echoes the significance of early and proactive interactions with regulatory bodies, underscoring the need for clear communication and strategic adaption based on regulatory feedback to ensure smooth market entry, a theme that aligns with the over aching discussion of regulatory strategy development.
5. **Theme 6 – Collaborative Regulatory Ecosystem and Theme 7 - Systems Integration and Streamlining the Framework for Regulatory Strategy**. These themes highlight the importance of collaboration and integrated systems for effective regulatory strategy implementation, reflecting the operational factor themes

anticipated from the initial project research that emphasize business process management and quality management systems.

6. **Theme 8 – Balancing Innovation and Risk Considerations in Regulatory Strategy**. This theme, focusing on the interplay between innovation, risk classification, and regulatory requirements, resonates with the initial research on classification and regulatory pathways, emphasizing strategic planning around product complexity and risk.
7. **Theme 9 - Development Dynamics and Regulatory Requirements.** Aligns with themes around the medical device development process and design control from the earlier research, focusing on the need for a fluid regulatory strategy that accommodates evolving product designs and testing requirements.
8. **Theme 10 – Strategic Leadership Efficacy**. Corresponds with the early research that emphasized leadership and strategic decision-making, highlighting the crucial role of leadership in guiding regulatory strategies and making pivotal decisions that align with regulatory demands.
9. **Theme 11 – Regulatory Uncertainty and Theme 12 – Supply Chain Considerations in Regulatory Strategy**. These themes, unique to the thematic analysis, delve into the challenges of unpredictability in FDA communications and the impact of supply chain dynamics on regulatory strategy, aspects that are less explicitly covered in the preliminary project research but are critical to the overall success of regulatory strategy.

The thematic analysis revealed several themes not explicitly addressed in the initial project research, offering fresh insights into the challenges medical device companies encounter.

For example, Strategic Knowledge Integration emphasizes the role of blending specialized expertise and comprehensive understanding within the regulatory framework. It highlights the necessity for teams adept at navigating complex regulations, as well as proactive engagement and education of stakeholders to ensure regulatory alignment and strategic clarity. This theme illustrates the importance of clear communication and collaborative development to effectively traverse regulatory and organization landscapes.

Proactive Regulatory Engagement is another theme that surfaced, underscoring the significance of early and ongoing dialogues with the FDA to facilitate a mutual understanding of regulatory expectations. This theme spotlights the strategic advantage of using presubmission meetings to refine regulatory strategies and preempt potential obstacles, illustrating the role of such proactive interactions in smoothing the regulatory pathway.

Additionally, Regulatory Uncertainty emerged as a theme, focusing on the challenges of navigating unforeseen outcomes and the level of transparency in FDA communications. It discusses the strategies for anticipating and responding to unexpected regulatory demands, emphasizing the need for flexibility to manage the unpredictability inherent in the regulatory submission and review process. This theme revealed the nuanced experiences of transparency with the FDA's guidance, highlighting the importance of adaptability and preparedness to tackle unexpected inquiries and requirements.

Lastly, the theme of Supply Chain Considerations in Regulatory Strategy delved into the role of suppliers and vendors in a medical device's regulatory strategy. It pointed to the necessity for integration and coordination with external partners to ensure components, materials, and proprietary information are available to support timely and compliant market entry. This theme brings to light the complex interplay between regulatory strategy and supply chain management,

stressing the need for contingency planning and the challenges of ensuring regulatory compliance amidst supply chain dynamics.

In summary, the thematic analysis provided a more detailed exploration of specific challenges and strategic approaches within regulatory strategy development, including financial planning, agile development, proactive engagement with regulatory bodies, and the critical role of leadership and supply chain management, complementing and extending the broader themes that originated in this project's preliminary research. Table 3 below provides a summary comparison between the emerging themes and anticipated themes.

Table 15

Thematic Comparison

Emergent Themes	Anticipated Themes	Comparison
Financial Strategy and Regulatory Economics	Understanding the Source of Innovation	Focuses on strategic financial planning vs. broader view on innovation sources.
Agile Regulatory Strategy Development	Proactive Regulatory Strategy Development	Direct correspondence on the need for agility and adaptability in regulatory strategy.
Mastering Regulatory Strategy	Regulatory Challenges and Compliance	Highlights overcoming regulatory hurdles with expertise vs. navigating regulatory frameworks.
Strategic Knowledge Integration	-	Emphasizes the integration of expertise, not directly covered in the literature review.
Proactive Regulatory Engagement	-	Stresses early interactions with regulatory bodies, complementing literature themes.
Collaborative Regulatory Ecosystem	Operational Factors	Aligns with the importance of collaboration and integrated systems for regulatory strategy.
Systems Integration and Streamlining	Operational Factors	Reflects on the impact of regulatory requirements on business processes, aligning with operational factors.
Balancing Innovation and Risk Considerations	Classification and Regulatory Pathways	Focuses on strategic planning around product complexity and risk, similar to literature themes on regulatory pathways.
Development Dynamics and Regulatory Requirements	Medical Device Development Process	Aligns with the literature review's emphasis on the development process and design control.
Strategic Leadership Efficacy	Leadership and Strategic Decision-Making	Corresponds with the crucial role of leadership in guiding regulatory strategies.
Regulatory Uncertainty	-	Unique to thematic analysis, explores challenges in FDA communications not covered in the review.
Supply Chain Considerations in Regulatory Strategy	-	Highlights the impact of supply chain dynamics, a perspective less explicitly covered in the review.

The Literature. The literature review, detailed in Section 1, provided the basis and framework for the research project. Several findings correlate to the data discovered during the literature review. For example, the literature review included device risk classification and regulatory pathways, providing a comprehensive structure of the U.S. regulatory landscape for

medical devices, categorizing them into three classes based on risk – Class 1 for low risk, Class 2 for medium risk, and Class 3 for high risk. These classifications inform the regulatory pathways devices must follow for market access, with class 1 devices typically exempt from premarket submission requirements but still needing to adhere to establishment registration and quality system regulations. In contrast, Class 2 and Class 3 devices face more stringent requirements, including premarket notifications (510(k) submissions) for Class 2 devices and premarket approval (PMA) processes for Class 3 devices.

Participant insights gathered from the interviews enrich the understanding of these regulatory frameworks by shedding light on the practical challenges and strategic considerations involved in navigating this landscape. Participant 1 articulated the linear relationship between device risk and regulatory stringency, stating, “In general, a higher risk class introduces more stringent requirements for both the device and the manufacturing process of the device.” Participant 4 discussed the particular challenges posed by software-based devices, highlighting the complexities of innovation and classification: “When you have more innovative feature…it becomes more complex.” The strategic complexities involved in managing high-risk devices were further illuminated by Participant 3, who noted the increased effort required to develop a regulatory strategy for such devices: “The effort that goes into [it] requires to learn new things and the regulatory process is much higher for high-risk devices. This reflects the literature’s emphasis on the rigorous scrutiny applied to Class 3 devices, which may require clinical trials to demonstrate safety and effectiveness rather than relying soled on substantial equivalence comparison.

The strategic integration of regulatory pathways within financial planning is essential for mitigating risks and ensuring market success. This concept is supported by Ammann (2008),

who emphasized the financial implications of regulatory strategy, and PRA Health Sciences (n.d.), who discussed the economic impact of regulatory decisions. Participant 3's statement, "…regulatory strategy plays a big part in terms of being able to…sort of create a budget or raise money for a particular development project…," illustrates the practical application of this principle, showing how regulatory pathways can influence fundraising activities and budgeting processes.

Kramer (2014) highlighted the importance of a flexible regulatory strategy that can adapt to changing regulations and product information. This necessity for adaptability is mirrored in Participant 3's insight, "Always when you roll a strategy out, you know, version one of the strategy is, you know, great on paper, but when you try to implement it, there's definitely things that you didn't think about or challenges that you didn't quite make into the equation… And in order to do that, you know, there has to be a nimble, flexible sort of approach," which underscores the dynamic nature of regulatory strategy.

Hoerr (2011) discussed the significance of comprehensive planning and early engagement with regulatory bodies. Participant 1's reflection on the complexities of strategizing for novel devices, "The most challenging element is usually determining…the testing approach and based on the available guidance from FDA…the type of strategy we face are often without a lot of precedent," aligns with the literatures' emphasis on innovative thinking and thorough research in developing effective regulatory strategies for new technologies.

On that topic, early and sustained dialogue with regulatory bodies is a theme that was echoed across the literature and participant experiences. Participant 1 stated, "And I have found that Presubmission meetings are very useful…a great tool for reducing uncertainty". Participant 3 advised, "don't be afraid to engage the regulators. I think the regulators are more and more

looking to advocate for you as long as they understand what your device is or what your goals are. They could be very, very much in your corner if you involve them and make them stakeholders in your development project." These perceptions highlight the value of these interactions in reducing uncertainty and refining the strategy.

The literature review and participant insights both stressed the importance of collaboration and communication. For example, Kramer (2014) discussed the need for effective collaboration in regulatory strategy execution. Bergsland et al. (2014) advocated for the initiation of joint efforts and teamwork during testing stages to pinpoint critical components of NPDs within the framework of the regulatory approval process. Participant 2 indicated, "anytime you can have a collaborative environment for consistent discussions, improve clarity, that's going to be beneficial." Participant 7 described the ideal environment for regulatory strategy success as, "it would be a collaborative… type environment where we're…all the stakeholders are working together to, you know, to develop the regulatory strategy…we don't go too long without meeting as a group…we typically meet every Thursday afternoon." These statements exemplify the practical implementation of this principle, show how regulator communication fosters a collaborative regulatory environment.

The integration of systems and processes to suppler regulatory compliance and operational efficiency is highlighted by Participant 3, who introduced a governance structure to navigate business and quality systems, "understanding what aspects of the quality system or the business process makes sense at what stage is very important… having a very solid and knowledgeable governance structure in place allows us to kind of pressure test these business processes, pressure test the quality system, because, you know, quality systems are important, but they don't have to be fully implemented on day one." This aligns with Kramer (2014), who

emphasized the importance of strategic management of regulatory and quality processes for operational success.

Multiple authors identified the need to incorporate supply chain management into general operations and quality management systems (Garg et al., 2015; Su & Wu, 2015). However, it was only through the interview process that the risks associated with supply chain limitations emerged. Specifically, Participants 3, 4, 6, and 7 indicated challenges associated with regulatory strategy (either directly or indirectly) and suppliers or vendors. For example, Participant 3 lamented,

> And then the…challenge is around procurement of vendors and supplies and so forth. That's always a long-standing challenge because a lot of that is out of our control. And depending on the economic conditions or the geopolitical conditions of the world, we sometimes pay the price in terms of not being able to speed up our development activity because third party vendors are also strapped in terms of being able to supply what's needed to to design and test our product.

Participants 4 and 7 both stressed the challenges of gaining access to information to submit to the FDA in regulatory submissions when those requirements related to proprietary supplier material information or manufacturing process details. Participant 6 advised that contingency plans and remediation strategies should be prepared with regard to long lead times with supplier production or testing service providers.

Comparing the regulatory success factors from the literature with the strategies and solutions provided by study participants highlights several areas of overlap as well as unique insights into managing regulatory challenges in medical device development. The literature emphasizes early strategic planning, stakeholder engagement, and the importance of experienced

experts for successful regulatory navigation. These themes resonate with the detailed insights provided by study participants, each of whom highlighted specific challenges and solutions within the regulatory process for medical devices.

Participant P1 stressed the importance of enhancing knowledge about regulatory expectations for novel devices and engaging early with the FDA, a strategy that aligns with the literature's emphasis on early alignment between a device's intended use and marketing claims (Krucoff et al., 2012; C. O'Dwyer & Cormican, 2017). P2 highlighted the challenges of misconceptions about regulatory pathways, such as the 510(k) process, and the necessity of investing in proper regulatory strategy planning, echoing the literature's findings on the critical role of strategic management and expert guidance (C. O'Dwyer & Cormican, 2017).

P4 addressed the challenge of balancing management expectations with the regulatory process's rigorous demands, advocating for presubmission meetings with the FDA, which mirrors the literature's advice on stakeholder engagement throughout the product development lifecycle (Kirkire & Rane, 2017). P5 discussed the risk-reward considerations from a regulatory standpoint that entrepreneurs often overlook, underlining the need for education on regulatory complexities, a factor that the literature identifies as part of fostering an organizational culture aware of regulatory impacts (C. O'Dwyer & Cormican, 2017).

P6's feedback on macroeconomic factors and the need for end-user input in design features adds a dimension not directly covered in the reviewed literature but is crucial for understanding broader contexts affecting regulatory strategy and product development. Lastly, P7 emphasized educating stakeholders about FDA requirements and overcoming staffing limitations, advocating for regular meetings to drive the strategy forward, which supports the

literature's findings on the importance of collaborative team environments and effective communication (C. O'Dwyer & Cormican, 2017).

In summary, the integration of participant feedback (P1, P2, P4, P5, P6, P7) with the literature provides a nuanced perspective on the regulatory strategy success factors in the medical device industry. While theoretical foundations offer a structured understanding of these factors, participant insights highlight the practical challenges and solutions encountered in the field, from misconceptions about regulatory pathways to the impact of macroeconomic factors and the critical importance of early and continuous stakeholder engagement. This comprehensive overview underscores the necessity of both strategic foresight and practical adaptability in navigating the complex regulatory landscape of medical device development. Table 16 below provides a breakdown of the challenges and solutions gleaned from the participant feedback.

Table 16

Regulatory Strategy Challenges and Solutions

Participant	Challenge	Solution	Participant Statement
P1	Determining the testing approach for novel devices lacking clear FDA guidance and precedent.	Enhancing knowledge about regulatory expectations for novel devices and leveraging available guidance for similar devices to inform testing strategies and engage with FDA early in the process.	"As soon as possible also applies because timeline for FDA interaction is long, and if you wait until it's time to to start doing something, the meeting with FDA may not come until after you have to make a decision."
P2	Overcoming the misconception that regulatory pathways like 510(k) are straightforward and underestimating the effort required.	Investing in proper regulatory strategy planning and avoiding the pitfalls of self-filing submissions without sufficient expertise.	"I think understanding what's truly required today from a testing perspective. Oftentimes you can find guidance that provides some details of what might be required, but it's never 100% prescriptive, which then leaves a lot of room for error…So I think early on, if that is misinterpreted by either the person writing the strategy, the engineering team, or the primary business folks getting funding, then those things can result in lack of funding or inappropriate testing being performed."
P4	Balancing management expectations with the rigorous and time-consuming regulatory process.	Engaging in presubmission meetings with the FDA to validate strategies and integrating regulator considerations into the product development lifecycle to prevent costly mistakes.	"So I think it's hard to, you know, sometimes convince to management that, you know, we should really do the presub meeting with the FDA and, you know, to get their opinion before we… venture into, um, costly testing and so on. So that, uh, to ensure that we don't do the costly mistakes…because it's very hard to correct this kind of, uh, the mistakes that we've made. So that's… I think the hard part to, you know, convince management… to involve, you know, this kind of presub meeting into the project plan and into the regulatory strategy."
P5	Entrepreneurs not adequately considering the risk-reward from a regulatory standpoint.	Providing education on the complexities of regulatory pathways and their impact on investment and risk profile.	"so you see a lot of companies that think that, oh yeah, this is going to be a simple 510(k). And you know, that's all going to cost us. $50 grand or whatever the number is, right? It's completely out of line with what reality is. And then more importantly, yeah, a 510(k) reduces the regulatory barrier, I mean, hurdle, uh, and risk versus an IDE, a PMA, any of those other approaches. But if you're wrong on that and you wind up in that other bucket, then you've just changed your risk profile completely…So I find entrepreneurs, particularly first-time entrepreneurs… in medtech, are not really savvy when it comes to risk / reward vis-a-vis regulatory."
P6	Macroeconomic factors affecting investment in	Seeking funding during favorable economic conditions	"So, you know, if the market is just not conductive to investments in biotech, medical device pharma, which for example, last year was certainly the case, then only real

Participant	Challenge	Solution	Participant Statement
	medical device development and a lack of end-user input in design features.	and involving end-users early in the design process to ensure practicality and usability.	unicorns have a chance of securing funding independently of…other factors. So, I have one client that…has the technology, which is, you know, great. It was just impossible to get funding last year. But it was macroeconomic. So those macroeconomic trends I think are independent of the opportunity. They always exist. There's years when there's better environment and there's a growth number is that, you know, we're not such a conductive environment for funding in uh, in technologies." "You know, speaking to the end users or having input from end users as to whether these features and whether they were the, this is actually something that in practical use would make sense, let's put it that way. So there wasn't there wasn't um, there wasn't the there was no testing done with the target patient pool and caregiver pool related to key features of the design, which made the design theoretically useful but more practical point of view, not because it was just too burdensome…and actually that company did not get funded."
P7	Educating stakeholders about FDA requirements and overcoming staffing limitations on the regulatory side.	Meeting regularly with the stakeholders to promote awareness, drive the strategy, and contracting expert support.	Investigator: "I think what you, what I heard was… open communication… helps drive a strategy forward." P7 "Absolutely. Absolutely… we don't go too long without meeting as a group…and we typically meet every every Thursday afternoon…unless, you know, something major gets in the way. We very rarely missed that meeting…and that's all stakeholders are there…but it's very rare that anybody misses meeting."

Each participant identified specific aspects of regulatory strategy that are challenging in the context of medical device development. The common threads among the solutions are the emphasis on increasing understanding of regulatory requirements, strategic planning, early engagement with the FDA, and ensuring input from all stakeholders, including end-users. This can help streamline the regulatory process, enhance device safety and effectiveness, and enhance a company's position to secure funding.

The study's examination of investor perspectives, both from the literature review and direct interviews with investors in the medical device industry, offered a comprehensive look into how regulatory strategies impact investment decisions. The literature underscored the

pivotal role of regulatory compliance as not just a hurdle but a vital component of market access and the sustainability of medical device ventures. O'Dwyer and Cormican (2017) highlighted that for medical device companies, navigating regulatory requirements is not merely a compliance exercise but a critical factor synonymous with the ability to enter and remain competitive in the market. This viewpoint is supported by discussions on the innovation landscape, where the agility to adapt to stringent regulatory demands is often seen as more feasible for smaller, more nimble companies despite the common belief that groundbreaking innovations predominantly originate from such entities (Grose, 2016; Kalcheva et al., 2018; Ringel et al., 2013).

The direct insights from the interviews provide a nuanced understanding of how regulatory strategies influence investment attractiveness and decision-making processes in real-world scenarios. Investor P5 places a significant emphasis on the clarity and presence of a regulatory pathway as a fundamental criterion for investment decisions. This investor's perspective reveals a pragmatic approach to evaluating medical device ventures, where the clarity of regulatory strategy, including the assessment of risk-reward considerations and the robustness of budget justifications, is paramount. The insistence on integrating regulatory strategy considerations from the earliest stages of product development underscores the importance of regulatory foresight in securing investment.

Investor P6, meanwhile, introduces the concept of variability and the importance of regulatory strategy based on the technological development stage. This perspective offers a more differentiated view of how regulatory considerations factor into investment decisions, suggesting that the emphasis on regulatory strategy may shift depending on the maturity of the technology and the specific market dynamics at play. For instance, in cases where technologies are at a nascent stage, the primary focus might be on other aspects, such as intellectual property rights,

whereas for more developed technologies, especially those navigating complex regulatory environments, a well-articulated regulatory strategy becomes a critical component of the investment evaluation process.

The comparative analysis between the literature and investor interviews enriched the researcher's understanding of the complex interplay between regulatory strategy and investment decisions in the medical device industry. It revealed a spectrum of considerations that investors weigh, from the indispensability of a clear regulatory path and risk-reward assessment to the strategic timing and articulation of regulatory plans. These insights not only affirm the critical nature of regulatory strategy as delineated in the literature but also expand on it by detailing how such strategies are operationalized and valued in the investment decision-making process.

Furthermore, the findings highlight a key recommendation for medical device entrepreneurs and innovators: the integration of regulatory considerations must be both early and adaptable, tailored to the specific developmental stage and unique challenges of the technology in question. This strategic integration enables a more informed approach to navigating the regulatory landscape, enhancing the attractiveness of medical device ventures to investors who are increasingly discerning in their evaluation of regulatory strategies and their implications for market access and long-term viability.

In summary, the study's findings, drawn from both literature and direct investor insights, underscore the nuanced and critical role of regulatory strategies in influencing investment decisions within the medical device industry. They contribute to a more nuanced understanding of how regulatory considerations are integrated into the broader strategic framework of medical device innovation, commercialization, and investment, offering valuable lessons for entrepreneurs, investors, and regulatory professionals alike.

The Problem. This study addressed the challenge entrepreneurs in regulated industries face in raising sufficient investment capital due to regulatory burdens, particularly in the medical device industry. These regulatory requirements pose risks of time, money, and uncertainty, discouraging investor support. The lack of a standardized benchmark for evaluating investment risk from regulatory compliance further complicates the situation. The study addressed the variables contributing to medical device regulatory uncertainty and identified best practices in regulatory strategy based on industry professionals' experiences. It sought to fill a gap by identifying factors that contribute to regulatory strategy success and regulatory uncertainty, providing a benchmark for innovators and investors to evaluate regulatory strategies for new medical device market entry projects in the United States.

The findings of this research directly address the core problem outlined in the study by elucidating the multidimensional strategies required to navigate the regulatory and investment landscape in the medical device industry. The research highlights the critical importance of financial strategy and regulatory economics, underscoring the necessity for strategic financial planning and understanding the economic implications of regulatory compliance to attract and secure investment capital. The themes of Agile Regulatory Strategy Development and Mastering Regulatory Strategy emphasize the development of adaptable, informed strategies and proactive planning to manage the uncertainties and risks associated with regulatory compliance, thereby making ventures more attractive to investors. Strategic Knowledge Integration and Proactive Regulatory Engagement advocate for the integration of specialized expertise and early engagement with regulatory bodies, proposing solutions to the problem of a lack of standardized benchmarks for investment risk evaluation. Furthermore, Collaborative Regulatory Ecosystem and Systems Integration themes speak to operational challenges, suggesting that a coherent

approach integrating business operations with regulatory strategies can mitigate risks related to time, money, and uncertainty. Finally, themes like Balancing Innovation with Regulatory Requirements and External Variables, such as Supply Chain Considerations, address the balancing act between innovation and compliance, offering insights into managing external factors that impact regulatory strategy success. Altogether, these themes provide a comprehensive framework for overcoming the barriers to regulatory strategy success, aligning closely with the study's problem statement by offering actionable insights for navigating the complex regulatory environment in the medical device sector.

Summary of the findings

The study employed a qualitative case study approach that delved into identifying and understanding the best practices essential for the success of regulatory strategies within the medical device industry. The root of this research lies in its exploration of the various factors that contribute significantly to the development and implementation of effective regulatory strategies, which are pivotal for the commercialization of medical technologies and attracting necessary capital investments. The backdrop of this study was set against the complex regulatory landscapes that medical device innovators navigate, emphasizing the need for strategic finesse to ensure successful market entry and sustainable business growth in this highly regulated sector.

To anchor the study, the researcher conducted semistructured interviews with a diverse group of participants, including regulatory professionals directly engaged in the medical device industry and investors who bring a financial perspective to the topic of regulatory strategy. This methodological choice allowed for a multi-dimensional exploration of the topic, aiming to capture a holistic view of the practices deemed successful in regulatory strategy development and execution. The use of purposive and snowball sampling techniques was vital in this context,

as it facilitated the inclusion of a broad spectrum of insights and experiences, enhancing the study's depth and relevance. This recruitment strategy, while initially challenging, eventually led to the attainment of data saturation, signifying that no new themes or insights emerged from the interviews, thus ensuring the comprehensive coverage of perspectives relevant to the study's objectives.

The thematic analysis yielded 12 salient themes that together paint a detailed picture of the landscape surrounding medical device regulatory strategy success. These themes span across financial planning and regulatory economics, emphasizing the crucial role of strategic financial foresight in navigating regulatory pathways and attracting investment. Agile regulatory strategy development and proactive regulatory engagement with the FDA emerged as vital for adapting to the dynamic regulatory environment and mitigating potential roadblocks. Strategic knowledge integration, collaborative regulatory ecosystems, and systems integration highlight the importance of leveraging expertise, fostering collaborative networks, and employing efficient systems to enhance regulatory processes. Balancing innovation with regulatory requirements and managing development dynamics underscore the challenges of aligning product innovation with stringent regulatory standards. Strategic leadership efficacy, regulatory uncertainty, and supply chain considerations were identified as pivotal in steering regulatory strategies toward success, addressing external uncertainties, and navigating supply chain complexities. These themes collectively underscore the multifaceted nature of regulatory strategy in the medical device industry, stressing the importance of a comprehensive, informed approach that integrates financial, operational, product, leadership, and external considerations for achieving success in the regulatory landscape.

The findings directly addressed the five research questions, providing deep insights into the best practices that facilitate the success of a regulatory strategy. The thematic analysis identified variables such as strategic financial planning, agile regulatory strategy development, and proactive engagement with regulatory bodies as critical to the effectiveness of regulatory strategies. These variables ensure that regulatory strategies are not only compliant but also strategically aligned with both market demands and regulatory expectations, facilitating smoother market entry. The findings emphasized the importance of a clear regulatory pathway and strategic risk assessment from the outset, highlighting how these aspects influence investor confidence. The ability to articulate a coherent and convincing regulatory strategy, coupled with a robust financial plan, directly impacts the likelihood of securing necessary investments by mitigating perceived risks associated with regulatory compliance and market access.

Best practices identified include the integration of regulatory considerations at the early stages of product development, continuous engagement with regulatory bodies, and the adoption of a collaborative approach to regulatory strategy involving cross-functional teams. These practices facilitate a more informed, agile, and comprehensive approach to regulatory strategy development and execution, enhancing the chances of successful market entry and sustained compliance.

The study's findings align with and expand upon current theories and models by emphasizing the dynamic and integrative nature of regulatory strategy. The importance of early and continuous regulatory engagement, strategic financial planning, and collaborative ecosystems provides a nuanced understanding of regulatory strategy as a multifaceted and iterative process rather than a linear or static one. Medical device companies can leverage these findings by incorporating strategic financial planning and risk assessment early in the

development process, fostering proactive and ongoing engagement with regulatory bodies, and adopting a collaborative approach to strategy development. By focusing on these key areas, companies can enhance their regulatory strategy development processes, improve outcomes, and increase the likelihood of successful market entry and investment acquisition.

The study's findings offer valuable insights into the complexities of regulatory strategy in the medical device industry, addressing the initial research questions comprehensively. These insights not only contribute to academic literature but also provide practical guidance for industry professionals, enhancing the strategic planning and execution of regulatory strategies for successful market entry and investment procurement.

Application to Professional Practice

Building upon the findings from the qualitative case study that examined the success factors in regulatory strategies within the medical device industry, it became apparent that navigating the complexities of the U.S. regulatory framework necessitates a comprehensive approach. This section further explored how these insights apply to professional practices, detailing strategic measures that could markedly improve operations within the medical device sector. Furthermore, it intended to investigate additional tactics that organizations might employ to capitalize on the study's findings. Additionally, this discussion will extend into carefully considered recommendations for future research, illuminating potential areas for further exploratory studies.

Improving General Business Practice

The qualitative case study on regulatory strategy success within the medical device industry unveiled a wealth of insights with the potential to significantly transform general business practices. By deciphering the complexities and nuances of effective regulatory

strategies, this study not only navigated through the intricate regulatory landscape but also provided a blueprint for enhancing overall business operations within the medical device sector. The findings from this investigation suggested several key areas where businesses can refine their practices for better potential outcomes.

Integrating Financial Planning With Regulatory Strategy. One of the revelations from the study was the critical role of financial planning in the context of regulatory strategies. The commercialization of medical devices is inherently linked to navigating regulatory pathways successfully, which in turn requires substantial financial investment and risk management. Effective financial planning, as suggested by the study, involves a deep understanding of the costs associated with regulatory compliance, including the expenses of navigating through the approval or clearance processes and maintaining compliance post-market entry.

From an investor's viewpoint, the integration of financial planning with regulatory strategies emerged as a critical element for business success. Investors are keenly interested in how medical device companies manage the financial risks associated with regulatory compliance and market entry. Effective financial planning that considers the costs of regulatory pathways and aligns them with business goals is highly attractive to investors. It demonstrates a company's ability to manage resources efficiently and to navigate the financial implications of regulatory processes.

For businesses, this means adopting a more integrated approach where financial planning and regulatory strategies are developed in tandem. By doing so, companies can ensure that they are not only setting realistic budgets for regulatory activities but also identifying potential financial risks early in the product development process, which can make a company more appealing to investors. This integrated approach allows for better allocation of resources,

ensuring that financial investments in regulatory compliance contribute positively to the overall business strategy, enhancing return on investment and securing the financial viability of the product in the competitive market. By doing so, companies not only safeguard their financial health but also position themselves as savvy operators in the eyes of potential investors.

Fostering Agile Regulatory Strategy Development. The study underscored the importance of agility in developing and implementing regulatory strategies. In an industry characterized by rapid technological advancements and evolving regulatory requirements, the ability to adapt quickly is invaluable. An agile regulatory strategy process enables businesses to respond swiftly to new information, regulatory feedback, and changes in the regulatory landscape. This agility can significantly reduce time to market, a critical factor in achieving competitive advantage.

Investors value agility in regulatory strategy development because it signifies a company's ability to adapt to changing regulatory environments and market demands swiftly. An agile approach reduces the time to market and mitigates risks associated with regulatory compliance, making the company a more attractive investment. Businesses that show they can quickly pivot their regulatory strategies in response to feedback from regulatory bodies or changes in regulations are seen as more resilient and capable of sustaining long-term success.

For general business practice, embracing agility means fostering a culture of continuous learning and flexibility within the organization. Businesses need to invest in systems and processes that allow for quick decision-making and easy adaptation of regulatory strategies. This includes maintaining open lines of communication with regulatory bodies, engaging in early and ongoing dialogues, and being prepared to pivot strategies based on regulatory feedback. This

adaptability not only improves regulatory outcomes but also demonstrates to investors that the company is well-equipped to manage the uncertainties inherent in the medical device industry.

Emphasizing Strategic Knowledge Integration. Another vital insight from the study is the significance of strategic knowledge integration. Successfully navigating the regulatory environment requires a comprehensive understanding of the regulatory processes, guidelines, and requirements. Integrating this specialized knowledge into the broader business strategy is crucial for aligning product development, marketing, and commercialization efforts with regulatory expectations.

Improving general business practice in this context involves developing mechanisms for capturing, sharing, and integrating regulatory knowledge across all levels of the organization. This could include training programs, cross-functional teams, and knowledge management systems designed to ensure that regulatory considerations are integrated into decision-making processes. By embedding external regulatory expertise into the fabric of the organization, businesses can ensure that their strategies are both innovative and compliant, thereby minimizing risks and optimizing market success.

Leveraging Regulatory Strategy as a Competitive Advantage. Investors often view a well-crafted regulatory strategy not just as a compliance requirement but as a competitive advantage. A regulatory strategy that efficiently navigates the complexities of the regulatory landscape can expedite product approval or clearance and market entry, providing a significant edge over competitors. From an investor's perspective, companies that can leverage their regulatory strategies to achieve faster market access or to differentiate their products based on compliance excellence are particularly attractive.

To capitalize on this, businesses should focus on developing regulatory strategies that go beyond mere compliance. This involves proactive engagement with regulatory bodies, innovative approaches to meeting regulatory requirements and leveraging regulatory milestones as part of the company's value proposition to the market and investors. By doing so, businesses not only enhance their attractiveness to investors but also strengthen their market positioning and brand reputation.

The findings from this study present a compelling case for businesses in the medical device industry to reevaluate and enhance their general practices. Integrating financial planning with regulatory strategies, fostering agility in regulatory strategy development, and emphasizing strategic knowledge integration can help businesses navigate the regulatory landscape more effectively. The businesses can also achieve greater operational efficiency, market competitiveness, and attractiveness to investors. These improvements in general business practice are not just about regulatory compliance but about leveraging regulatory strategies as a catalyst for business growth and innovation.

Potential Application Strategies

The findings from the study on regulatory strategy success within the medical device industry offer a blueprint for organizations looking to refine their operations and align more closely with investor expectations and regulatory requirements. Leveraging these insights, organizations can develop and implement a range of potential application strategies that not only enhance regulatory compliance but also bolster overall business performance. Below are additional discussions on several potential application strategies drawn from the study's findings.

Integrated Regulatory and Financial Strategy Development. One crucial application strategy is the integration of regulatory planning with financial strategy development.

Organizations can leverage the study's insights by creating cross-functional teams that include members from finance, regulatory affairs, and product development. These teams would work together from the initial stages of product conceptualization to ensure that financial planning accounts for all regulatory aspects, including compliance costs and market entry strategies. This integrated approach allows for a more accurate assessment of the product lifecycle, investment needs, and return on investment, making the company more adept at managing resources and appealing to investors.

Agility in Regulatory Practices. Adopting agility as a core component of regulatory strategy is another significant application strategy. Organizations can implement flexible project management frameworks, such as Agile or Scrum, specifically tailored to regulatory processes. This involves regular review cycles, adaptive planning, and the early and frequent delivery of regulatory milestones, enabling organizations to respond rapidly to changes in regulatory guidance or unexpected feedback from regulatory bodies. Training programs focused on enhancing understanding of regulatory frameworks and fostering a culture of agility can empower employees to contribute more effectively to the regulatory process, enhancing the organization's overall responsiveness.

Leveraging Technology for Regulatory Efficiency. Technology adoption offers a powerful strategy for applying the study's findings. Organizations can invest in regulatory technology solutions (RegTech) that streamline the submission process, track regulatory changes, and facilitate compliance management. Utilizing artificial intelligence and data analytics, companies can predict regulatory trends, identify potential compliance risks, and optimize their regulatory strategies accordingly. By leveraging technology, organizations not

only improve their regulatory efficiency but also free up valuable resources that can be redirected toward innovation and product development.

Strategic Regulatory Knowledge Management. Building a robust regulatory knowledge management system constitutes another pivotal application strategy. This involves creating centralized repositories of regulatory information, guidelines, and best practices accessible to all employees. Training and continuous education programs can be developed to ensure that employees across the organization understand regulatory requirements and how they impact different aspects of the business. By embedding regulatory knowledge into everyday business operations, organizations can ensure that regulatory compliance is a shared responsibility, fostering a culture of compliance and strategic thinking.

Proactive Stakeholder Engagement. Finally, proactive engagement with stakeholders, including regulatory bodies, industry partners, and customers, emerged as a critical strategy. Establishing open lines of communication and collaboration can provide organizations with valuable insights into regulatory expectations and market needs. Participatory approaches to regulatory strategy development, such as involving customers in the early stages of product design or collaborating with industry partners on regulatory innovation, can enhance product relevance, compliance, and market success.

In conclusion, by integrating financial planning with regulatory strategy, fostering agility, leveraging technology, managing regulatory knowledge strategically, and engaging stakeholders proactively, organizations can significantly enhance their operational and strategic capabilities. These application strategies enable organizations to not only meet regulatory requirements more effectively but also to use their regulatory strategy as a competitive advantage, driving innovation, efficiency, and market success.

Summary of Application to Professional Practice

The study on regulatory strategies within the medical device industry illuminated the path for businesses to enhance their operational efficiency and market positioning. Integrating financial planning with regulatory strategy and fostering agility in regulatory processes are paramount, enabling companies to navigate the complexities of compliance while managing resources effectively. This approach, coupled with the strategic integration of regulatory knowledge and leveraging technology, positions companies to respond swiftly to regulatory changes and stakeholder expectations. Emphasizing proactive engagement with regulatory bodies and stakeholders further enriches this strategy, allowing businesses to not only meet but exceed regulatory requirements, thereby transforming regulatory compliance into a significant competitive advantage and driving market success.

Recommendations for Further Study

Based on the comprehensive analysis and insights garnered from the study on regulatory strategies in the medical device industry, several recommendations for further research emerge. These recommendations aim to build upon the foundational work of this study, exploring new dimensions and deepening the understanding of regulatory strategies within the medical device sector and beyond:

Comparative Analysis Across Different Regulatory Environments

Future studies could benefit from a comparative analysis of regulatory strategies across various global markets, such as the European Union, Asia, and emerging markets. Understanding the nuances and challenges specific to different regulatory environments can provide valuable insights for companies looking to expand internationally. The study highlighted the complexity and dynamism of navigating regulatory landscapes, underscoring the need for a deeper

understanding of global regulatory differences. Given the increasing globalization of the medical device market, a comparative analysis becomes essential for developing strategies that can be adapted to various regulatory environments, ensuring that companies can efficiently expand their international footprint.

Long-Term Outcomes of Agile Regulatory Strategies

Investigating the long-term outcomes and effectiveness of adopting agile regulatory strategies would be valuable. This research could focus on measuring the impact of agility on time to market, cost efficiency, and overall business success, providing evidence-based insights into the benefits and potential drawbacks of agile approaches in regulatory compliance. The agility in regulatory strategy development, highlighted as beneficial in this study, raises questions about its long-term effectiveness and impact. Investigating agile regulatory strategies in depth would provide empirical evidence of their benefits, challenges, and best practices, helping companies and regulators to adopt more flexible and responsive approaches.

Role of Artificial Intelligence and Machine Learning in Regulatory Compliance

With the increasing adoption of artificial intelligence (AI) and machine learning in healthcare, further study on their role in enhancing regulatory compliance processes could provide groundbreaking insights. This includes automating compliance monitoring, predicting regulatory changes, and optimizing submission processes. The study's exploration of regulatory strategies and the use of digital tools points to the potential of AI and machine learning to revolutionize regulatory processes. As these technologies continue to advance, researching their application in regulatory compliance and strategy could lead to significant efficiencies and innovations, aligning regulatory practices with the pace of technological advancements.

Stakeholder Engagement and Collaborative Regulatory Approaches

Additional research into the dynamics of stakeholder engagement, including patient advocacy groups, healthcare professionals, and industry partners, in the regulatory process could unveil strategies for collaborative regulation. This might explore how inclusive approaches to stakeholder engagement can influence regulatory success and product acceptance in the market. The importance of integrating various perspectives in regulatory strategy development, an aspect touched upon in the study, suggests that further exploration into stakeholder engagement could yield richer, more inclusive regulatory approaches. Understanding how different stakeholders can contribute to and influence regulatory outcomes could enhance product market access and compliance.

These recommendations for further study not only aim to expand the body of knowledge on regulatory strategies but also address emerging trends and challenges in the medical device industry. By exploring these areas, future research can provide actionable insights for companies to navigate the regulatory landscape more effectively and leverage regulatory market access as a strategic asset.

Reflections

Reflecting upon the study's exploration of regulatory strategies within the medical device industry, I realize that the journey has been profoundly enlightening, both from a personal and professional standpoint. Integrating financial planning with regulatory strategies, embracing agility in regulatory processes, and recognizing the significance of leveraging technology and proactive stakeholder engagement have emerged as foundational pillars for navigating the intricate regulatory landscape. This exploration has not only enhanced my understanding and strategic thinking in this complex field but has also contributed to my personal growth,

challenging me to think critically and adaptively in the face of evolving industry standards and innovations. Incorporating a biblical perspective, the journey resonates with the principle of stewardship—carefully managing resources and knowledge for the greater good, reflecting values of integrity and diligence. As this study paved the way for future research into digital health technologies, global regulatory differences, and sustainability, it reaffirms the importance of continual learning and ethical leadership in the pursuit of excellence and innovation in the medical device industry. This reflection underscores a deep appreciation for the multifaceted nature of regulatory strategy, enriched by a commitment to professional excellence and guided by enduring principles.

Personal & Professional Growth

Reflecting on the journey of conducting this comprehensive study on regulatory strategies within the medical device industry, I found myself at a point of significant personal and professional growth. This research endeavor was not just an academic pursuit but a transformative experience that challenged me to navigate through a maze of personal obstacles and professional commitments. Balancing a burgeoning business while delving into the complexities of regulatory frameworks tested my resilience, time management skills, and dedication to scholarly excellence.

Navigating these obstacles has served as a catalyst for development, sharpening my skills in prioritization, adaptability, and resilience. Professionally, I've gained a deeper understanding of the intricacies of regulatory strategies, an insight that directly benefits my business by aligning our operations more closely with best practices and investor expectations. This study has not only broadened my knowledge but also sharpened my analytical skills, allowing me to approach problems with a more nuanced perspective.

On a personal level, this journey has reinforced the importance of resilience and faith in the face of adversity. Drawing from a biblical perspective, I was reminded of James 1:2-4, which speaks to the value of perseverance through trials, knowing that such testing produces steadfastness. This passage served as a beacon of strength, encouraging me to embrace the challenges as opportunities for growth. It reminded me that personal and professional development often comes through the hardest battles fought and the most challenging mountains climbed.

In conducting this study, I've not only contributed to the academic and professional discourse on regulatory strategies in the medical device industry but have also embarked on a journey of self-discovery and growth. This experience has underscored the interconnectedness of personal values, professional ethics, and scholarly pursuit, shaping me into a more resilient scholar, a more insightful business leader, and a more steadfast individual in both my personal and professional life.

Biblical Perspective

Integrating business functions with a Christian worldview in the study of regulatory strategies in the medical device industry offers a profound dimension of ethical and spiritual considerations. It challenges individuals and organizations to align their practices with values of stewardship, integrity, and servanthood, deeply rooted in Scripture. This alignment enriches the understanding and execution of business activities, ensuring they not only comply with regulatory standards but also contribute positively to societal well-being.

Stewardship. Christian stewardship emphasizes responsible management of the resources God has entrusted to individuals and organizations. As stewards, business owners are called to wisely utilize their talents, technology, and financial resources to innovate within God’s

creation, underpinning their operations with sustainability and ethical considerations. Christian stewardship calls for the prudent management of the manifold resources God has entrusted to us. In regulatory strategies for medical devices, this translates to a steadfast commitment to ensuring that products are not just safe and effective but that they also fulfill their purpose with integrity and without harm. The parable of the shrewd manager in Luke 16 teaches us the value of resourceful stewardship. Jesus said, “The master commended the dishonest manager because he had acted shrewdly” (Luke 16:8 NIV). Although the manager is not lauded for his dishonesty, his shrewdness in managing resources effectively is highlighted as an example to emulate in the context of honest and wise stewardship.

Business owners endowed with talents, technology, and finances are called to steward these gifts wisely in innovation and in the care for God’s creation, grounding their work in sustainable and ethical practices. It's a call similar to the wisdom found in Proverbs: "The plans of the diligent lead to profit as surely as haste leads to poverty" (Proverbs 21:5 NIV). This scripture underscores the importance of thoughtful planning and stewardship in business.

Romans 14:12 highlights our personal responsibility before God: “So then, each of us will give an account of ourselves to God” (NIV). In the context of the medical device industry, this means business practices must be held to a high standard of accountability, ensuring that every action and decision is defensible before God and aligns with His commandments. Stewardship in this light is a dedication to excellence and adherence to moral principles, guaranteeing that the lifecycle of medical devices—from conception to commercialization—reflects a commitment to God’s creation and the human lives that are served.

Integrity. Integrity stands as a cornerstone of Christian ethics, embodying honesty, transparency, and righteousness in all dealings. For businesses navigating regulatory strategies,

integrity means more than adherence to laws; it signifies a deeper commitment to truth and ethical principles, guiding decision-making and interactions with regulators, customers, and the public.

"Better is a poor man who walks in his integrity than a rich man who is crooked in his ways." (Proverbs 28:6 ESV). This wisdom underscores the value of integrity over material gain, urging businesses to prioritize ethical standards and truthfulness in their regulatory strategies. Upholding integrity ensures that the processes leading to product approval or market clearance and release are conducted with honesty, fostering trust and credibility in the industry.

Servanthood. The Christian call to servanthood emphasizes putting the needs of others first, reflecting Christ's example of service. In the business context, this translates to prioritizing patient safety, well-being, and access to essential medical devices. Companies are challenged to view their regulatory strategies through the lens of serving others, ensuring that their products genuinely meet patient needs and enhance the quality of life.

"For even the Son of Man did not come to be served, but to serve, and to give his life as a ransom for many." (Mark 10:45 NIV). Inspired by Jesus' ultimate act of service, businesses in the medical device sector are encouraged to adopt a service-oriented approach, guiding their regulatory endeavors with the aim of serving the global community, especially those in dire need of medical interventions.

Justice. The Bible speaks volumes about the importance of justice in our dealings, advocating for fairness and the protection of those who are most vulnerable. In the sphere of medical devices, this principle urges companies to ensure that their products are accessible to all segments of the population, including underserved communities, and that they do not exploit or neglect any group.

"Learn to do right; seek justice. Defend the oppressed. Take up the cause of the fatherless; plead the case of the widow." (Isaiah 1:17 NIV). This scripture calls for active engagement in justice, challenging businesses to go beyond mere compliance with regulatory standards and actively work towards equitable access to medical technologies. It underscores the responsibility of companies to advocate for and implement practices that ensure their products can benefit everyone, especially those who might not have easy access due to economic or geographical barriers.

Incorporating justice into regulatory strategy means advocating for policies that ensure wide-reaching access to medical devices, striving to lower costs without compromising quality, and engaging in philanthropic efforts to distribute technologies to areas where they are most needed. It involves transparent dealings that prioritize patient safety and well-being over profit, ensuring that no corners are cut in the rush to bring a product to market.

Biblical Perspective Summary. Viewing the business functions involved in regulatory strategies through a Christian worldview instills a sense of higher purpose and ethical responsibility in the operations of medical device companies. Operating under these guiding principles, companies can navigate the regulatory landscape with a moral compass that points towards not just fulfilling legal obligations but also contributing positively to societal health and justice. This approach aligns business practices with the Christian call to love and serve our neighbors, ensuring that the benefits of medical device innovations reach far and wide, embodying the Kingdom's values of righteousness, justice, and compassion. This approach not only supports business practices with Christian values but also enhances the impact of medical devices on society, fulfilling a mission that transcends commercial success and contributes to the healing and flourishing of the global community.

Summary of Reflections

Reflecting on this study's journey through the intricacies of regulatory strategies in the medical device industry, it becomes evident that this was much more than an academic endeavor; it was a pathway to profound personal and professional transformation. Juggling the challenges of a growing business while delving into complex regulatory frameworks tested my resilience and honed my skills in critical and adaptive thinking. This process not only enriched my professional expertise, directly impacting my business by aligning our operations with industry best practices and investor expectations, but also fostered significant personal growth.

The integration of a Christian worldview brought an additional layer of depth to this journey, emphasizing stewardship, integrity, servanthood, and justice as foundational pillars guiding my approach to regulatory strategies. These principles, deeply rooted in Scripture, shaped my understanding of ethical leadership and the importance of prioritizing the well-being of patients and the community. Verses like Romans 14:12, Proverbs 28:6, Mark 10:45, and Isaiah 1:17 not only served as ethical compasses but also as reminders of the responsibility to manage God's creation wisely, act with steadfast honesty, serve others selflessly, and pursue justice diligently.

This reflection underlines a journey marked by challenges and growth, guided by enduring biblical principles. It highlights the interconnectedness of professional excellence and spiritual values, illustrating how integrating a Christian worldview into business practices can elevate the impact of regulatory strategies beyond compliance, contributing positively to societal health and embodying the Kingdom's values of righteousness, justice, and compassion. Through this study, I've not only contributed to the discourse on regulatory strategies but also embarked on a transformative journey of self-discovery, ethical reflection, and growth.

Summary of Section 3

In examining the success factors of regulatory strategies within the medical device industry, this study conducted an in-depth qualitative analysis through semistructured interviews with industry professionals and investors. These interviews revealed key themes such as financial planning, agile regulatory strategy development, and strategic knowledge integration as pivotal for effectively navigating the complex U.S. regulatory environment. The interview process yielded insights that addressed each of the research questions. It also highlighted the general problem that entrepreneurs face in securing investments due to regulatory challenges in the medical device industry. In addition, the study addressed the specific problem of a lack of standardized benchmarks for assessing investment risk related to regulatory market access. The findings underscored the necessity of integrating comprehensive financial oversight with regulatory planning, advocating for an agile approach that adapts swiftly to regulatory changes and emphasizes the importance of strategic knowledge dissemination within organizations. Future research recommendations include exploring regulatory strategies across different markets and the role of emerging technologies in regulatory compliance, aiming to deepen understanding and enhance strategic applications in medical device commercialization. Reflecting on the study, the investigator shared personal and professional growth experiences, emphasizing the challenges and learning opportunities encountered throughout the research process. The study not only contributed to the academic and practical knowledge of regulatory strategies but also fostered a deeper personal understanding of navigating regulatory frameworks and aligning operations with best practices.

Summary and Study Conclusions

This study embarked on an exploration of the critical components that define successful regulatory strategies within the medical device industry, offering a qualitative analysis of the factors that influence the development and execution of effective regulatory strategies in the U.S. medical device sector. By delving into the personal experiences of regulatory affairs professionals and investors, the research unearthed several key themes pivotal in shaping regulatory strategy success. Operational factors, including financial planning, business process management, and quality management systems, emerged as foundational, alongside the significance of leadership in steering organizations through regulatory pathways and the importance of product design in meeting compliance and market needs. Furthermore, external factors such as regulatory uncertainty and supply chain considerations were identified as critical elements influencing the trajectory of medical device commercialization, with the study also highlighting the role of business ecosystems in bolstering regulatory strategy success.

The findings contribute significantly to both academic and professional understandings of medical device regulatory strategies, providing a foundation for further research and offering actionable insights for practitioners. For entrepreneurs and regulatory professionals, the importance of early and strategic planning, comprehensive quality management, and engagement with the broader business ecosystem was underscored. Investors, too, gain a clearer understanding of the intricacies of regulatory strategy, enhancing their ability to assess and mitigate risks associated with medical device innovation.

The study concluded that successful regulatory strategy in the medical device industry is a multifaceted endeavor influenced by operational excellence, strategic leadership, and proactive engagement with external regulatory and market dynamics. It highlighted the necessity of

adopting a holistic approach to regulatory planning, integrating product design, quality management, and business strategy from the outset. Looking forward, the research opened avenues for further exploration into the impacts of emerging technologies, global regulatory trends, and evolving market demands on regulatory strategy success, suggesting that future studies could also examine the role of digital transformation in optimizing regulatory processes and enhancing compliance efficiency.

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Appendix A: Recruitment Letter

[Insert Date]

[Recipient]

[Title]

[Company]

[Address 1]

[Address 2]

[Address 3]

Dear [Recipient]:

As a graduate student in the School of Business at Liberty University, I am conducting research as part of the requirements for a Doctorate in Business Administration (DBA). The purpose of my research is to explore the various factors involved in developing and implementing a successful regulatory strategy and best practice in the U.S. medical device industry, and I am writing to invite you to participate in my study.

If you are a mid- to senior-level manager or director either in your current or recent (within the last 5 years) job functions and have participated in the development or execution of regulatory strategies for medical devices in the United States in the last 5 years, or if you are an investor, project financial sponsor, or a venture capitalist who has been involved in the evaluation, funding, or capital raise for a medical device commercialization project in the last 5

years and are willing to participate, you will be asked to complete an in-person, telephone, or email interview, and, if necessary, review and clarify particular research discussions from the original interview transcript. The initial interview should last between 20-30 minutes, and you may be contacted via phone call, text message, or email to answer follow-up clarifying questions, which would be minimal if necessary. Your name and other identifying information will be requested as part of your participation, but the information will remain confidential.

To participate, please contact me at xxx-xxx-xxx or xxx@xxx.xxx to review the screening guide and schedule an interview.

Attached to this invitation letter, I have included a consent form that contains additional information about the research study. Following the participation screening process, please review and sign the consent form and return it to me in-person at the interview or via email as a .pdf file to xxx@xxx.xxx at some point before the scheduled interview.

I thank you in advance for considering your participation in this interesting and informative research project. I look forward to learning about your experiences with medical device regulatory strategy.

Best regards,

Jonathan Ward

Appendix B: Interview Screening Guide

Time of screening:

Date/Place:

Interviewer:

Participant:

Introductory Statement: The purpose of my research is to explore the various factors involved in developing and implementing a successful regulatory strategy and best practice in the U.S. medical device industry. The following screening questions were designed to ensure that your participation in today's interview satisfies the study's rigorous research requirements.

Questions for primary data sources (regulatory professionals):

1. Are you an adult over the age of 18?
2. Are you a mid- to senior-level manager or director either in your current or recent (within the last 5 years) job function?
3. Have you participated in the development or implementation of regulatory strategies for medical devices in the United States in the last 5 years?

Questions for secondary data sources (investors and venture capitalists):

1. Are you an adult over the age of 18?
2. Are you an investor, project financial sponsor, or a venture capitalist who has been involved in the evaluation, funding, or capital raise for a medical device commercialization project in the last 5 years?

Concluding statement: Thank you for participating in this screening and your interest in this research topic. You (do)/(do not) satisfy the study's requirements. (1) I look forward to learning from you and about your experiences in this area of study. (2) I'm sorry for the inconvenience, but you do not meet the study's requirements. Thank you again for your time!

Appendix C: Informed Consent Form

Title of the Project: Best Practices Associated with Medical Device Regulatory Strategy Success: A Case Study

Principal Investigator: Jonathan Ward, Doctoral Candidate, Liberty University School of Business

Invitation to be Part of a Research Study

You are invited to be in a research study of the regulatory strategy development and implementation process for the U.S medical device industry. You were selected as a possible participant because you meet the following criteria: you are a mid- to senior-level manager or director either in your current or recent (within the last 5 years) job functions and have participated in the development or execution of regulatory strategies for medical devices in the United States in the last 5 years. Or, you are an investor, project financial sponsor, or a venture capitalist that has been involved in the evaluation, funding, or capital raise for a medical device commercialization project in the last 5 years. Please read this form and ask any questions you may have before agreeing to be in the study.

Taking part in this research project is voluntary.

Please take time to read this entire form and ask questions before deciding whether to take part in this research.

What is the study about and why is it being done?

The purpose of this study is to explore the variables that contribute to medical device regulatory strategy best practices and regulatory success in the medical device industry. Successful regulatory strategies are essential to the eventual commercialization of medical technology. Innovators and entrepreneurs must address and integrate a number of factors into the

strategic process in order to achieve successful product launches. The data collected will allow the researcher to identify emergent themes associated with regulatory strategy success. A study of regulatory strategy design and implementation best practices used by regulatory professionals will provide insight for product development teams as well as potential project financial sponsors and investors considering new commercialization opportunities.

What will happen if you take part in this study?

If you agree to be in this study, I will ask you to do the following things:

1. Interview: You will be asked to complete a 20- to 30-minute interview in-person, via telephone, via internet communication portal (e.g., Webex, Zoom, etc.), or via email. Interactive interviews will be scheduled at your convenience. These interviews will be recorded to ensure responses are reported accurately. If an interview can only be accommodated via email correspondence, I will email you the interview questions for completion and email return at your earliest convenience.
2. It is possible that I may need to reach out to you to clarify specific experiences or information based on the transcripts and my notes. I would ask that you make yourself available at your convenience to facilitate follow-up discussions at your preferred communication method (e.g., phone call, email, text message, in-person). Interactive interviews will be recorded for reporting accuracy.
3. Complete follow-up transcript review of the original interview. Follow-up transcript review should take no more than approximately 5 minutes of your time.

How could you or others benefit from this study?

Participants should not expect to receive a direct benefit from taking part in this study.

Benefits to society include improving regulatory strategy development and implementation which may, in turn, improve the level of success in new product launches and availability to the medical community.

What risks might you experience from being in this study?

The risks involved in this study are minimal, which means they are equal to the risks one would encounter in everyday life.

How will personal information be protected?

The records of this study will be kept private. In any sort of report I might publish, I will not include any information that will make it possible to identify a subject. Research records will be stored securely, and only the researcher will have access to the records.

- Participants will be assigned a pseudonym. In-person interviews will be conducted in a location where others will not easily overhear the conversation.
- Data will be stored on a password locked computer and may be used in future presentations. After three years, all electronic records will be deleted.
- Interviews will be recorded and transcribed. Recordings will be stored on a password locked computer for three years and then erased. Only the researcher will have access to these recordings.

How will you be compensated for being part of the study?

Participants will not be compensated for participating in this study.

Is study participation voluntary?

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Liberty University. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

What should you do if you decide to withdraw from the study?

If you choose to withdraw from the study, please contact the researcher at the email address/phone number included in the next paragraph. Should you choose to withdraw, data collected from you will be destroyed immediately and will not be included in this study.

Whom do you contact if you have questions or concerns about the study?

The researcher conducting this study is Jonathan Ward. You may ask any questions you have now. If you have questions later, you are encouraged to contact him at xxx-xxx-xxxx or xxx@xxx.xxx. You may also contact the researcher's faculty chair, xxxxxxxxxxx, at xxx@xxx.xxx.

Whom do you contact if you have questions about your rights as a research participant?

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher, **you are encouraged** to contact the Institutional Review Board, xxxxxxxxxxxxxxxxxxxxx or email at xxx@xxx.xxx.

Disclaimer: The Institutional Review Board (IRB) is tasked with ensuring that human subjects research will be conducted in an ethical manner as defined and required by federal regulations. The topics covered and viewpoints expressed or alluded to by student and faculty researchers are those of the researchers and do not necessarily reflect the official policies or positions of Liberty University.

Your Consent

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. You will be given a copy of this document for your records. The researcher will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I have read and understood the above information. I have asked questions and have received answers. I consent to participate in the study.

☐ The researcher has my permission to audio-record/video-record me as part of my participation in this study.

_____

Printed Subject Name

_____

Signature & Date

Appendix D: Interview Guide

Best Practices Associated with Medical Device Regulatory Strategy Success: A Case Study

Time of interview:

Date:

Place:

Interviewer:

Participant:

Introductory Statement: The purpose of this interview is to learn how regulatory affairs professionals and other stakeholders in the medical device industry perceive the various factors involved in developing and implementing a successful regulatory strategy. The study of regulatory strategies and best practices should help organizations and individuals to 1) identify systemic and leadership organizational gaps associated with successful or unsuccessful regulatory strategies, 2) identify and address important risk factors related to product characteristics prior to strategy implementation, 3) compare proposed projects and investment opportunities against risk factor priority scales to judge potential regulatory strategy performance, and 4) reduce the uncertainty capitalists associate with unpredictable returns on investment.

Questions (For primary sources, use section 1; for secondary sources, use section 2.):

Section 1 - Primary data source (regulatory professionals)

1. What has been your role in developing and/or implementing regulatory strategies for the commercialization of medical devices for the U.S. marketplace?
2. Could you please describe your experience or involvement in regulatory project budgeting and fund raising?
    a. What elements of the regulatory strategy do you think contribute most to successful fund raising or capital investment in a new product development project?
    b. What challenges have you encountered when attempting to acquire the funds necessary to implement regulatory strategies in your organization?
3. What advice would you give to new product development teams, entrepreneurs, and fellow regulatory professionals involved in developing and implementing regulatory strategies as they prepare budgets and seek to secure capital investments?

Regulatory Strategy Process

1. Could you please describe regulatory strategy process at your organization (e.g. activities, stakeholders, data collection, documentation outputs, etc.)?
2. Could you please describe an example of a regulatory strategy you have developed or executed specifically for a U.S. medical device commercialization project?
3. From your experience, are there any factors you encounter during the strategy development and implementation process that cause you to make revisions to a strategy?
    a. Could you describe an example of when a follow-up strategy or modification to an existing strategy was required?
4. What elements of the regulatory strategy process are most challenging in your organization?

5. What elements of the process contribute most to regulatory strategy success?
6. Is there anything you would change about the regulatory process at your organization?
    a. Why is that?

Operational Factors

1. What type of business ecosystem or work environment is most beneficial for the development and implementation of regulatory strategies? (e.g. collaborative, resistant, engaged, apathetic, innovative, etc.)?
    a. From you experience, how does that business ecosystem effect the outcomes of regulatory strategy development and implementation?
2. Please describe your recommended approach to the requirements associated with managing business processes and quality systems.
3. From your perspective, how does the development or implementation of a regulatory strategy affect other business processes (e.g., marketing, design and development, production, post market surveillance, etc.)?

Leadership

1. How would you describe the different stakeholder engagements you have experienced during the regulatory strategy development and implementation process?
2. Please explain when and how leadership at your organization gets involved with the development or implementation of regulatory strategies.
3. How would you describe your organization's leadership's commitment to and understanding of the medical device regulatory strategy process?
4. Is there anything you wish your leadership team did differently to support the regulatory strategy process?

Product Design

1. What elements of product design present challenges when developing a regulatory strategy?
2. How would you describe the impact device complexity and innovation has on the development and implementation of regulatory strategy?
3. How does the regulatory strategy process change when you consider different device risk classifications (e.g., Class 1, Class 2, Class 3, etc.)?
4. Based on your experience, at what point in the design process is it most appropriate to develop a regulatory strategy?
5. How do modifications made to a regulatory strategy in later design stages impact the successful implementation of a strategy?

External

1. What external elements, or things outside your control, prove most challenging when attempting to design or implement a regulatory strategy?
    a. How do you address those challenges?
2. How would you describe your experience with the U.S. Food and Drug Administration (FDA) with respect to the development or implementation of regulatory strategies?
    a. What elements of this interaction surprised you?
3. Have you been involved in an FDA inspection associated with a premarket application?
    a. How would you describe that experience?
4. How would you describe the FDA's level of transparency regarding their expectations regarding premarket activities (presubmission meetings, regulatory applications, inspections, etc.)?

5. How do regulatory costs imposed by the FDA impact your organization's decision to pursue a particular regulatory pathway?
6. What advice would you give to new product development teams, entrepreneurs, and fellow regulatory professionals involved in developing and implementing regulatory strategies with respect to engagement with the FDA?

Section 2 - Secondary data source (investors and venture capitalists)

1. What has been your role in assessing and evaluating potential investment opportunities for new product development projects in the context of the U.S. medical device industry?
2. From your perspective, how influential is a regulatory strategy when it comes to securing capital investment for new product development?
    a. At what stage in the development process should an entrepreneur or innovator have developed a regulatory strategy?
    b. Relative to developing regulatory strategies, what challenges do entrepreneurs and innovators face when attempting to secure the funds necessary to implement proposed regulatory strategies?
3. What advice would you give to new product development teams, entrepreneurs, and regulatory professionals involved in developing and implementing regulatory strategies as they prepare budgets and seek to secure capital investments?

Regulatory Strategy Process

1. How would you describe the level of importance of having an established regulatory strategy when a project team or innovator seeks funding or investment?
2. What concerns you the most about how project teams or entrepreneurs development and implement regulatory strategy?

Operational Factors

1. What type of business ecosystem or work environment is most attractive to you as an investor in medical device technology projects?
2. From your perspective, how does the business ecosystem or work environment affect the success or failure of regulatory strategy design and implementation?

Leadership

1. What type of leadership do you look for when considering investing in or sponsoring a medical device commercialization project?
2. How do those leadership characteristics influence the design and implementation of a regulatory strategy?

Product Design

1. What product design factors are most attractive to you as an investor of medical device technology?
2. How do those design factors appear to influence the success or failure of regulatory strategy design and implementation?

External

1. What is your perception of the Food and Drug Administration (FDA)?
2. From your perspective, what value (if any) does early engagement with the FDA bring to a medical device commercialization project?
3. Are there any external factors (things outside the control of an entrepreneur or project team) that appear to impact the success or failure of a project requiring regulatory strategy?

Concluding statement: Thank you very much for your participation in this interview. I assure you that your confidentiality is of the utmost importance during this process. I will contact you if I have any questions regarding this interview once the information has been transcribed.

Appendix E: Recruitment: Follow Up

[Insert Date]

[Recipient]

[Title]

[Company]

[Address 1]

[Address 2]

[Address 3]

Dear [Recipient]:

As a graduate student in the School of Business at Liberty University, I am conducting research as part of the requirements for a Doctorate in Business Administration (DBA). Last week an email was sent to you inviting you to participate in a research study. This follow-up email is being sent to remind you to respond if you would like to participate and have not already done so. The deadline for participation is [Date].

Participants, if willing, will be asked to you will be asked to complete an in-person, telephone, or email interview, and, if necessary, review and clarify particular research discussions from the original interview transcript. The initial interview should last between 20-30 minutes, and you may be contacted via phone call, text message, or email to answer follow-up clarifying

questions, which would be minimal if necessary. Your name and other identifying information will be requested as part of your participation, but the information will remain confidential.

To participate, please contact me at xxx-xxx-xxxx or xxx@xxx.xxx to review the screening guide and schedule an interview.

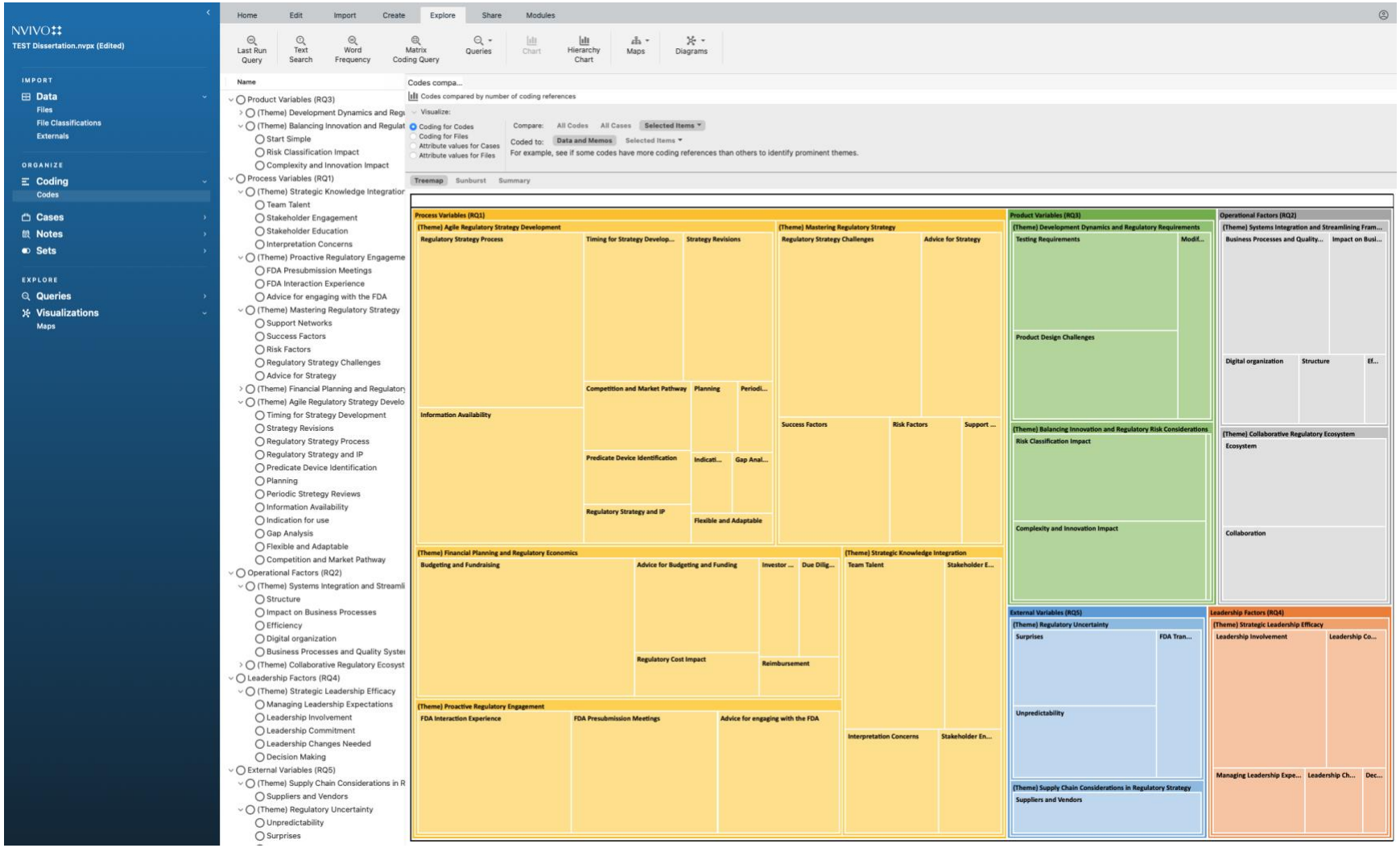
Attached to this invitation letter, I have included a consent form that contains additional information about the research study. Following the participation screening process, please review and sign the consent form and return it to me in-person at the interview or via email as a .pdf file to xxx@xxx.xxx at some point before the scheduled interview.

Sincerely,

Jonathan Ward

Doctoral Candidate

Appendix F: Screenshot From NVivo 14 with Thematic Analysis and Coding Result



Appendix G: IRB Exemption

[External] IRB-FY21-22-607 - Initial: Initial - Exempt

[redacted]

[EXTERNAL EMAIL: Do not click any links or open attachments unless you know the sender and trust the content.]

LIBERTY UNIVERSITY.
INSTITUTIONAL REVIEW BOARD

December 8, 2022

[redacted]

Re: IRB Exemption - IRB-FY21-22-607 BEST PRACTICES ASSOCIATED WITH MEDICAL DEVICE REGULATORY STRATEGY SUCCESS: A CASE STUDY

Dear [redacted]

The Liberty University Institutional Review Board (IRB) has reviewed your application in accordance with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulations and finds your study to be exempt from further IRB review. This means you may begin your research with the data safeguarding methods mentioned in your approved application, and no further IRB oversight is required.

Your study falls under the following exemption category, which identifies specific situations in which human participants research is exempt from the policy set forth in 45 CFR 46:104(d):

Category 2.(iii). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Your stamped consent form(s) and final versions of your study documents can be found under the Attachments tab within the Submission Details section of your study on Cayuse IRB. Your stamped consent form(s) should be copied and used to gain the consent of your research participants. If you plan to provide your consent information electronically, the contents of the attached consent document(s) should be made available without alteration.

Please note that this exemption only applies to your current research application, and any modifications to your protocol must be reported to the Liberty University IRB for verification of continued exemption status. You may report these changes by completing a modification submission through your Cayuse IRB account.

If you have any questions about this exemption or need assistance in determining whether possible modifications to your protocol would change your exemption status, please email us at [redacted]

Sincerely,

[redacted]
Administrative Chair of Institutional Research
Research Ethics Office