EFFECTIVE STRATEGIC DECISION-MAKING STRATEGIES FOR PLANT MANAGERS IN PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURING IN MODERN DAY PUERTO RICO: A QUALITATIVE CASE STUDY

by

Cherisa Jerez

Doctoral Study 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

This qualitative, collective case study covers the experience of strategic decision making in a pharmaceutical and medical device manufacturing environment in Puerto Rico during the current economic crisis. The medical device and pharmaceutical manufacturing industry in Puerto Rico was selected because of the tax expirations targeting this specific industry and the predominance on the island this industry represents in the manufacturing environment. Despite Puerto Rico's dominance in medical device and pharmaceutical manufacturing over the past 60 years, the current financial and government crisis poses a significant threat to executive level commitment toward maintaining operations on the island. Research questions focused on plant manager's experiences and perspectives regarding the strategic decision-making process. Participant interviews included executives indirectly overseeing regulated facilities in Puerto Rico, four plant managers for medical device facility on the island and representatives of their direct staff, a former global operations leader for the pharmaceutical industry, and an economic representative in Puerto Rico. The interviews in conjunction with direct observation and document reviews of the four facilities provided the qualitative data used to develop a guideline of specific strategic decision making factors for future plant managers on the island and the results of the impact the external environment on the island is having on plant managers. The study concludes with recommendations for future research and application. The intent of the recommendations is to support continued manufacturing growth on the island.

Key words: Puerto Rico's economic crisis, strategic decision-making, plant managers in Puerto Rico

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Dr. Edward Moore

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Dedication

This work is dedicated to my beloved grandmother, Dr. Irene Liberman, whose tenacity, passion, and genetically passed stubbornness made me a much better woman than I'd ever imagined I could be. Thank you for demonstrating that becoming a "Dr." was not out of reach, regardless of the circumstance. Your example of hard work and resilience bears fruit in my life every day.

I would also like to dedicate this work to my grandfather, Jim Mulligan and his wife Laurie Mulligan, for inspiring me through the power of literature at an age where my mind was open to all possibilities. Thank you for introducing me to the power of words and storytelling. Your influences have shaped my destiny.

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Section 1: Foundation of the Study

The economy of Puerto Rico has undergone a significant level of economic instability, resulting from government investment decisions. This, in turn, led to the fiscal turmoil and increased pressure from the U.S. Treasury to address the problem of financing protections for America's largest, yet deeply bankrupt territory (Long, 2017). The proposed solution began with the implementation of the Puerto Rico Oversight, Management and Economic Stability Act (PROMESA) signed into law on June 30, 2016 (Long, 2017). The implementation of a government oversight debt restructuring solution, in conjunction with the average two percent population reduction of working-age adults that the island is facing each year ("A Crippling Blow," 2017), combined to generate an economic environment plagued with challenges toward sustainability and long-term growth.

The government economic crisis poses a unique level of challenges on local business leaders as they determine their strategic direction methodology and the approaches they employ as part of the strategic decision-making process. This is a unique challenge for plant managers responsible for the operations of pharmaceutical and medical device manufacturing facilities – an industry that has already significantly suffered locally, because of the changing tax laws, particularly the repeal of Section 936 in 1996 and its associated 10-year phase out (Pantojas-Garcia, 2016). This research followed how the newfound environment in Puerto Rico is shaping the decision-making strategies of these specifically identified leaders. It also provided examples of strategic decision-making strategies that are enabling operations to continue successfully despite the external environmental pressures. The intent of the research was to apply a case study approach and conduct interviews and an onsite observation of plant managers overseeing either a pharmaceutical or medical device manufacturing facility in Puerto Rico to identify the

demonstrated strategies these leaders employed during the strategic decision-making process despite the environmental turmoil that surrounds them. In addition, the research provided insights into areas of leadership, strategic focus, and economic interest that should be further evaluated when considering future growth and expansion in Puerto Rico.

Background of the Problem

The government crisis. The Puerto Rico Commonwealth reached its economic breaking point, unable to operate without US government intervention, incurring an unsustainable debt burden amidst a series of crippling economic policies (Park & Samples, 2017). The economy is struggling to sustain the provisions necessary to provide governmental services such as education and healthcare and their associated costs, in addition to the pension debts and standard operational costs of running the government (Park & Samples, 2017). The economy of Puerto Rico is in crisis as it faces another year in decline, the ninth consecutive year in the last 10 that the island has suffered economically (Slavin & Shields, 2017). These underlying themes are prevalent across all the recent literature being published regarding the Puerto Rican debt crisis as it is considered the largest municipal bankruptcy ever in the history of the world, affecting over 73 billion dollars of debt (Colon, 2015).

This crisis can be summarized as a result of Puerto Rico's primary strategy to issue bonds as a method for cash influxes without the necessary planning in place to determine how to pay them back once they mature. As evidence, the bonds, upon reaching maturation, became degraded to junk status in 2014 (Wolf, 2016) and forced Puerto Rico out of the financial markets. This, in turn, forced the island's governmental leaders to take a hard look at their realities as bonds preparing to materialize could not be paid without serious disruptions to the most basic needs, such as the education and healthcare of the Puerto Rican people (Block, 2017). In addition

to the strains of the large sums of debt, Puerto Rico's inability to access the bankruptcy code and the bonds backed by Constitutional protections (Colon, 2015) further forced the island to consider impacting its citizens in their most sensitive facets of life. Public transportation, education, and healthcare all became potential casualties in the all too serious risks of total governmental shutdown (Block, 2017).

In June of 2016, the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) was enacted requiring that the island's government work with external creditors to obtain debt relief. The details on exactly how it would come to fruition are still unfolding as an oversight board and the island's leaders continue to negotiate the provisions and the details (Park & Samples, 2017). The question now remains, as Puerto Rico works under the guidance of the oversight board, how to begin aligning payments and schedules of the maturing bonds in conjunction with the reestablishment of the Puerto Rican economy (Park & Samples, 2017).

The island once enjoyed economic prosperity and stability as it offered unique tax incentives and an educated labor force readily available to support foreign direct investment. Pantojas-Garcias's (2016) highlighted the island's prosperity, particularly, during 1976 – 1996 in which U.S. direct investments in Puerto Rico were the highest in the world and led Puerto Rico to become the most "highly industrialized non-independent territory in the Caribbean" (p. 59). Its geographical position from a transportation and logistics perspective as well as its economic position aligned with the United States' markets and served as an enticement for companies and investors around the world. Sadly, the posturing is now a memory, a far cry from today's current perception of the island's offerings. Now, Puerto Rican business leaders are challenged to develop ways to re-entice investment and trust in the economy's ability to provide a strong return on investment and identify a path to profitability going forward.

Manufacturing in Puerto Rico. The pharmaceutical and medical device manufacturing industry has represented the largest portion of manufacturing in Puerto Rico since the 1950s and has also suffered the greatest decline because of multiple governmental interventions (Gerow, 2014). The plant manager's perspective also aids in the reconciliation of the local community, the corporation themselves, and the outside investors. McNeal (2017) identified authors such as Alexa S. Dietrich that have described pharmaceutical corporations in Puerto Rico to be neither good neighbors nor responsible citizens with little to no interest in corporate citizenship. A case-study exploring the aspects of integral decision making from local manufacturing leaders will provide additional research as to how plant managers assess these types of perceptions in the strategic decision-making process and reduce the risk of further plant closures on the island. The research associated with interviewing and observing successful plant managers, whereby successful is defined as their ability to maintain fully operational factories on the island, amidst the increase in plant closures, will serve as beneficial to others seeking strategies for long term sustainment on the island.

The need for effective strategic decision making. Local governmental organizations such as Puerto Rico's *Hacienda* organization are expanding the number of facilities that are processing private vehicle exportation in order to manage the increasing volume of vehicles and their corresponding owners that are leaving the island. This crisis is real, and the population of Puerto Rico is significantly declining because of this mass exodus (Vincens-Feliberty & Ricketts, 2016). More and more manufacturing plant leaders are tasked to maintain competitive positions while continuing to operate in Puerto Rico. The available research highlighting reflections and the experience of those in a similar demographic will prove useful in developing best-practice strategies for other leaders still operating on the island or those looking to enter the

local economy. It is the research that will tie operational success in Puerto Rican manufacturing facilities to the strategic decision-making strategies employed by its leadership that can serve to provide a framework for a potential path forward.

Problem Statement

Local medical device and pharmaceutical plant managers are critical leaders in driving the financial performance of the local economy on the island. They serve to provide strategic direction to facilities employing the top private middle-class industry on the island (Soto-Rodriguez, 2014). If they are unsuccessful in the sustainment and further development of jobs in the local economy, the island will continue to suffer mass emigrations and plant closures. With the onset of the recent economic crisis, Puerto Rico is undergoing one of the largest mass emigrations since the 1950s (Vincens-Feliberty & Ricketts, 2016).

The general problem to be addressed in this case study is the large volume of manufacturing plants closing their operations in Puerto Rico. Statistics show significant job losses on the island, as a result of manufacturing facility closures, particularly in the areas of medical device and pharmaceutical manufacturing (Vega-Rosado, 2011). This has long-since served as Puerto Rico's top local industry, both in job volume as well as competitive pay (Vega-Rosado, 2011). According the McGinley's (2017) article on drug shortages following Puerto Rico's Hurricane Maria crisis, the drug manufacturing industry alone, represents 72% of Puerto Rico's 2016 exports. In addition, Colon and San Miguel (2016) pointed out that the general perception of investors believed Puerto Rico (and its corporate leaders) must tackle their economic and fiscal debt structures with transparency and with the purpose of re-establishing credibility with the public. The specific problem to be addressed is lack of strategic decision-making strategies available driven by Puerto Rico's critical manufacturing leaders, specifically in

the medical device and pharmaceutical manufacturing environments. The specific problem to be addressed is lack of strategic decision-making strategies available driven by Puerto Rico's critical manufacturing leaders, specifically in the medical device and pharmaceutical manufacturing environments. One primary method to reduce the closure of unprofitable factories and regain the trust of stakeholders is to identify successful strategic-level decision making strategies these leaders must deploy in order to regain the stability and profitability of their operations and reduce the risk of closure.

Purpose Statement

The purpose of this qualitative case study is to increase the empirical knowledge of strategic decision-making strategies demonstrating successful operations in the volatility of Puerto Rico's economic and governmental crisis and reduce further economic impacts on the island tied to plant closures. More specifically, the intent of this investigation was to develop the connection between the medical and/or pharmaceutical plant manager's strategic decision making and operational planning process and a successful plant operation more clearly understood. The specific population selected was determined to understand the unique needs and demands of the strategic decision-making process when faced with Puerto Rico's current economic instability.

This case study focused on select Puerto Rican plant managers having recently completed the strategic operating plans underneath the umbrella of a bankrupt government and provided insights into the elements the Puerto Rican economic crisis is having on the overall decision-making process. This provided a framework for the development of a more relevant process for strategic decision making for other leaders in comparable circumstances on the island and use scholarly research as a method to improve business practices (Creswell, 2009).

Nature of the Study

The research method selected was a qualitative analysis. Merriam and Tisdell (2016) described qualitative researchers as individuals that are interested in "understanding how people interpret their experiences, how they construct their worlds, and what meaning they attribute to their experiences" (p. 6). The focus of the research was to explore and understand the experiences of a specific population of business leaders in Puerto Rico. Qualitative analysis is a method for the researcher to understand how the specific population being studied, in this case manufacturing plant managers, are interpreting their unique experiences during an economic event that is the first of its kind on such a grand scale.

Discussion of method. Creswell (2012) identified three types of research methods include quantitative, qualitative, and mixed methods. The quantitative method is based on the application of linear modeling of independent relationships or the ability to measure, typical using an instrument, variable that may be mathematically or statistically analyzed (Goertzen, 2017). In the case of the research for leaders in Puerto Rico, the study was to be based on real time observations and findings associated with the interpretive conclusions of the research. There were no direct numerical correlations to be ascertained by the observations, making a quantitative approach incompatible to the method of study.

The mixed methods approach required a study that combines the elements of both the qualitative and quantitative approaches (Yin, 2016). This study is philosophical in nature with philosophical assumptions that are addressed through the combined approaches of both qualitative methods and quantitative methods (McKim, 2015). As the purpose and proposed design element of this research did not have a quantitative element, the mixed method approach was incompatible with the selected method.

The research method selected was a qualitative analysis. Merriam and Tisdell (2016) described qualitative researchers as individuals that are interested in "understanding how people interpret their experiences, how they construct their worlds, and what meaning they attribute to their experiences" (p. 6). The focus of the research was to explore and understand the experiences of a specific population of business leaders in Puerto Rico. The research allowed for the study to be formulated around the concepts of words and open-ended questions (Creswell, 2012). Qualitative analysis allows the researcher to understand how the specific population being studied, in this case pharmaceutical and medical device manufacturing leaders and local economic representatives in Puerto Rico, are interpreting their unique experiences during an economic event that is the first of its kind on such a grand scale.

This method was selected to gain understanding through direct observation and first-hand interviews with participants directly affected by the affectual environment within the strategic decision-making process. Because the object of the investigation can be classified within the boundaries of a very specific population and a delimitated focus area, the case study was the most well-suited research method (Stake, 2005). In addition, Yin (2016) described qualitative research as a methodology that seeks to establish cause and effect relationships through the adherence of value free measures. The very nature of this study's focus on verbal interpretation, real time observations, and a focused population met the criteria across multiple experts as a qualitative study.

Discussion of design. Other methods of qualitative research include narrative research, phenomenology, and ethnography. In the case of narrative research, the researcher is taking the role of a narrator and telling a story based on observations and research (Creswell, 2009), which would not have aligned with the objective of this research as the approach was not to tell a story

but to draw conclusion of a causational relationship between non-numerical associations. The strategic decision-making process did not provide enough evidence to support a phenomenon, which is considered the basis of a qualitative study designed with a phenomenological approach (Yin, 2016). According to Merriam and Tisdell (2016), the ethnography is focused on an entire cultural group. This did not align with the small and culturally varied group selected for this specific research.

In the case of understanding the cultural implications and the real-time experiences of those leading business during the economic crisis, the research was conducted by interviewing key participants, such as those in critical roles for executive decision making in Puerto Rican manufacturing. This supported Creswell's (2012) description of an in-depth exploration of a system bounded by very specific criteria or boundaries. The boundaries in this case is both the industry, the location, and the current period with which the research is being conducted.

The intent behind this experience was to capture firsthand information that lead to obtaining an essence of the human experience, in this case, the plant-level leaders as primary decision makers as well as a sampling representative of their staff. The goal of the research was to help support a cause and effect relationship – the strategic decision-making approaches of these leaders and the successful operations of their factories in Puerto Rico. The very nature of creating this alignment without numerical data, further supports Yin's (2016) description of a qualitative study whereas the specifics boundaries identify it as a case study. In addition, interviews conducted with higher level regional leaders responsible for operations in Puerto Rico would allow for additional insights and the triangulation of findings across the varied participants. Lastly, interviews expanding into areas of government representatives provides additional human experience and insights of the government bankruptcy in Puerto Rico from a

unique vantage point. Obtaining the essence of the human experience for a specified purpose with a uniquely identifiable population is representative of a qualitative case study (Creswell, 2009).

Summary of the nature of the study. Merriam and Tisdell (2016) stated that qualitative studies are inductive in nature and center on the researcher's observations and findings as a method to induce or support a type of theory or create a new one. In the case of this observation, a case study design is structured so that the researcher selects a pre-designed group of participants – in this case plant level managers, fully responsible for the successful operations and management of medical device or pharmaceutical manufacturing on the island of Puerto Rico. These manufacturing plant level managers in the medical device and/or pharmaceutical industry, were selected because of their demonstrated ability to integrate effective strategic decision-making models and operational planning to continue their operations. Moreover, they have done this in an industry at high risk for continued operations in Puerto Rico because of the lost tax incentives. In addition, the plant managers in the medical device and pharmaceutical industry are required to manage profitability and sustainability in an environment with new burdens placed on them by the new fiscal government crisis.

The research and data for the case study were based on the interviews and observations of economic representatives that gave further support and insight to the government instability on the island as well as the plant managers, manufacturing executives, and plant staff as they navigated through the strategic decision making process considering these multiple external challenges and maintained a competitive advantage for operations in Puerto Rico.

Research Questions

This study explored strategic decision-making strategies needed to successfully operate in the volatility of Puerto Rico's economic and governmental crisis and reduce further economic impacts on the island tied to plant closures. Strategic decision making is a topic of research that is broadly studied, particularly when considering causation and the associated approach in strategic decision-making (Reymen et al., 2015). The researcher sought to explore the decision-making strategies plant managers in manufacturing were using to maintain a competitive environment in Puerto Rico. This information could be valuable to other plant managers on the island that are at risk of a plant closure due to the island's environment instability and desire to learn from other leaders that have successfully continued their operations. To support and uphold the value of this study, the following research questions were utilized:

1. What decision-making strategies did the plant managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico?
2. What impact did the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have on the strategic decision-making process?

Conceptual Framework

The conceptual framework for this study was built upon the premise that strategic decision making is directly correlated to the overall success and sustainability of an operation (Peterlin, Pears, & Dimovski, 2015; Schneider & Jones, 2017; Self, Self, Matuszek, & Schraeder, 2015). Strategic decision making is a direct result of the leader's determinations of their current environment and the pathway forward. This implies that strategic decision making

may be heavily influenced by a leader's individual experiences, perceptions and judgements. The affective events theory (AET) is a study based on the correlation of the role emotion has on the evaluative judgement, or further described as the relationship between an individual's behavior and their unique experiences (Ashkanasy, Humphrey, & Quy, 2017). Weiss and Cropanzano (1996) described the unique departure of AET from traditional theories as it is grounded in the "structure, causes, and consequences of affective experiences at work" (p. 11) and how the decision-making process of people are affected by the events that occur in that same workplace. Because the purpose of this study was to better understand the strategies used for the strategic decision-making process executed by leaders in Puerto Rico amidst the crisis events, AET was selected to ground the associated research.

Discussion of affective experiences theory. According to Page (2016) the AET is best described as a theory founded on the principle of human behavioral impacts driven by the affective experiences at work. These affective experiences would essentially lead to an emotional reaction that would in turn, influence an individual's behaviors and attitudes. AET directs the focus away from the features of the work environment and restructures the focus toward events as the primary cause for the affective reaction (Weiss & Cropanzano, 1996).

Similarly, Neumann (2017) posited that research in strategic management and associated decision making is shifting from traditional focuses on analytical models and trending toward theories focused more on cognitive and behavioral strategies. Neumann (2017) highlighted the research of Hodgkinson and Healy as pioneers in addressing the joint effects of cognition and emotion in the strategic decision-making process.

Hodgkinson and Healy (2011) summarized the studies of neuro-economics, distinguishing between emotional and analytical operations in the brain and the varying decision-

making results that can occur when the brain is utilized in both the "cold" cognitive functional capacity as well as the "hot" emotional mode. The studies continue to demonstrate the growing research validating that affect and emotion are serving as an integral portion of cognition and decision making and tying together the action of feeling with decision making and action (Ashkanasy et al., 2017).

Ultimately, the basis of strategic decision making will be impacted by the cognition and emotion of the decision maker. Schneider and Jones (2017) posited that leader's behaviors and actions will generate results over a period, stemming directly from the results of their decisions and the relationships with the people in their organizations. A key focus of AET is to understand the relationship effects at work will have on the leader's decision-making strategy in order to create an awareness and best manage the overall results of those core strategic decision (Page, 2016).

Discussion of relationships between concepts. AET relates to this study because several researchers on leadership, decision-making, and organization behavior are now emphasizing the importance of emotions and attitude on cognitive outcomes. In addition, the current conditions in Puerto Rico can be characterized as traumatic for the leaders that are faced to continue driving a profitable and sustainable operation on an island severely impacted by environmental, economic, and geo-political upheavals unseen ever before. According to Peterlin et al. (2015), contemporary leadership and its associated strategic decision-making platforms require the engagement of leaders and their engagement with the community as a stakeholder, defined more specifically as a stakeholder consisting of government, educational organizations, profit and non-profit entities. The challenges for more contemporary leaders, particularly those in the current crisis environment Puerto Rican leaders operate in, mandates that these leaders are aware of what

traits are affective predisposition and identify the predominant likelihood resulting from the manifestation of those traits (Weiss & Cropanzano, 1996). This is especially true when faced with the task of strategic decision making.

Summary of the conceptual framework. AET informed the expectations of this research in two foundational ways. First, the underlying assumption that affective events have a direct correlation to emotional appraisals and will impact the decision maker's strategies as it relates to strategic decision making (Page, 2016). Decision-making will be directly defined by the affectual experiences in the workplace. The primary research question of this study was: What decision-making strategies did the plants managers integrate into the strategic decision-making process to support a successful outcome in a manufacturing operation in Puerto Rico? This question is based on a direct correlation between the strategies employed by the operational leadership during the strategic decision-making process and the successful sustainability of the manufacturing operation in Puerto Rico.

In addition, this question grounded in AET assumed that an affective event taking place in the workplace in Puerto Rico by the highest, local level leader, would have a positive reaction to the strategic decision-making process (Neumann, 2017; Page, 2016; Weiss & Cropanzano, 1996), thereby driving positive financial results and avoiding the risk of a site closure. Secondly, the second research question researching the impact the external environment, such as the government bankruptcy or the expiration of the island's tax incentives had on the strategic decision making process, determines the nature of the affective event on each plant manager and the translating results of their interpretation into their strategic decision making strategy (Neumann, 2017; Page, 2016; Weiss & Cropanzano, 1996).

Lastly, the purpose of this study was to provide leaders currently leading operations in Puerto Rico available research and published finding on the inputs to the strategic decision-making process, resulting in a sustainable operation. The idea that the actual events occurring around them will impact the strategic level decisions they are required to make about the future of the operation is grounded in AET, in turn, providing a sound framework for the reliability of the study.

Definition of Terms

The focus of this research was the strategic decision-making strategies made my plant managers associated with the successful sustainment of operations for medical device and pharmaceutical manufacturing in Puerto Rico during its current crisis environment. The following definitions are provided to provide clarification of the terms intended use in the study:

Affective events theory: A theory focused on the structure, causes, and consequences of affective experiences at work (Weiss & Cropanzano, 1996).

Plant manager: Middle manager operating at the intermediate level of the corporate hierarchy, directly responsible for the profit and operation of a manufacturing facility (Smith, Plowman, & Duchon, 2010).

Assumptions, Limitations, Delimitations

Assumptions. There were two important assumptions associated with this study. First, it was assumed that the researcher would receive honest and introspective data from the participants based on their most recent experiences with the site's strategic decision making and operational planning sessions, this supports Stake's (2005) definition of qualitative research as interpretative research dependent upon observer's defining and redefining the meanings of what they say and hear.

To help ensure the use of the most recent experience, the interview questions were designed to specifically reference the most recent sessions. Regarding honest and introspective feedback, the researcher provided assurance of confidentiality in the original request to participate and allowed from the withdrawal of the study without any ramifications. Second, it was assumed that the plant managers' interviewed were integral participants and not just casual observers or indirect facilitators of the strategic decision making and operational planning process. This ensured that the representative sample of plant managers represents the greater population of other plant managers serving as strategic decision makers for their facilities, providing an adequate representative sample for qualitative research (Simon, 2011).

Limitations. Melamed and Robinson (2019) addressed the limitation of a single case study as a tool more appropriate for the generation of hypothesis versus the development of scientific theory. One approach Stake (2014) highlighted to manage this constraint was to choose a sample population with close attributes to the greater population. In this exploratory case study, the sample population of four plant managers operating in medical device and/or pharmaceutical manufacturing in present day Puerto Rico was specific enough of a population to address the overall problem statement.

Limitations were also associated with the presumably short period plants had been operating under the new crisis environment. Although the initial default of a government crisis began in 2015 (Pierluisi, 2015), the oversight board controlling the island's budget via the enactment of the Puerto Rico Oversight, Management, and Economic Stability Act was incorporated in 2016 ("A Crippling Blow," 2017), establishing, a minimum of three periods of strategic decision making sessions prior to the induction of this research.

Delimitations. Simon (2011) described the delimitation as an area that will develop the specific boundaries and criteria of the study. The scope of the research was targeted specifically to the pharmaceutical and medical device manufacturing industry. Other types of industries, such as the hospitality industry, were not considered for the purpose of this research.

The plant managers interviewed and observed for this case study directly oversaw plants in Puerto Rico. Plant managers also responsible for plants outside of the island, in addition to the plants in Puerto Rico, were also considered. For the purposes of strategic planning, the case study specifically analyzed decision making strategies and practices revolving around the current and previous annual operation for their respective site.

Significance of the Study

Reduction of gaps. The significance of the research is that the information obtained may reduce the gap in knowledge current Puerto Rican manufacturing leaders have regarding impacts the economic environment on their strategic decision-making process. In addition, the research provided insight into successful approaches in decision making amidst the current economic challenges in Puerto Rico. Bonilla (2018) professed that since Hurricane Maria, nearly 300,000 Puerto Ricans have left for Florida alone. This is contributing to the proposed forecast of a near 25% reduction of the island's total population by 2020 (Bonilla, 2018). Today's manufacturing leaders on the island are continuing to maintain a successful operation and adjust their strategic planning as a direct result of the external environment. This knowledge assists other plant managers in Puerto Rico challenged with creating and maintaining a competitive environment as well.

The exploratory research can also be used to help executive leaders with multi-plant responsibility determine whether Puerto Rico can serve as a viable location for future

manufacturing needs as they review the newly available research on the strategic decision-making approaches modeled in Puerto Rico. Lastly, the research provides a timely and relevant analysis with respect to current operations in this new crisis era in Puerto Rico and provides data that will help assess the value of continued investment and operational sustainment of plants currently operating on the island.

Implications for biblical integration. The biblical framework for this study mainly consisted of the biblical story of Jonah and his obedience to adhere to the Lord's command and save the land from the destruction that many deemed it had deserved. The findings of this study dealt closely with the impact of a leader on the organization, which would, in turn, provide a blessing and a favorable course to Puerto Rico, determining a similar parallel to Jonah's impact on the city of Nineveh and its future. The implication of the findings in relation to the biblical framework further support the Lord's calling on us as individuals or as a collective group to intervene, at times, in order to "save the land."

The story of Jonah. The Bible shares the story of Jonah in which God specifically selected his chosen one, Jonah, to the Assyrian city of Nineveh to prophesy there despite its very bad reputation for corruption and sin. Initially Jonah was opposed to the idea of doing anything to save the city with such a bad reputation, but the will of God prevailed, and Jonah found himself freed from the belly of a large fish in order to execute his promise to God. His prayer when stating, "But I, with shouts of grateful praise, will sacrifice to you. What I have vowed I will make good. I will say, 'Salvation comes from the Lord.'" (Jonah 2:9, NIV) is a testament to the obedience the Lord will bless as those leaders on the island called by him to restore are faithful to their calling.

After proclaiming that in 40 days the city would be destroyed, the Ninevites repented and God had compassion on them and did not destroy them. God was able to see a greater good in these people far beyond what they could see for themselves, until the time had come for it to be revealed. “When God saw what they did and how they turned from their evil ways, he relented and did not bring on them the destruction he had threatened” (Jonah 3:10, NIV). He offered salvation and protection as a direct result of their repentance. In a similar manner, Puerto Rico’s government has the opportunity to veer from their sinful ways of instant financial gratification through irresponsible borrowing and the Lord can bless the economy through the prosperity and success of its local infrastructure.

Some may question whether the time is coming for Puerto Rico to be reviewed by God and offered up for destruction or depending on their willingness to repent, a second chance at prosperity and abundance. Like the story of Jonah, Puerto Rico, like Nineveh is undergoing a transition and time for reflecting, evaluation, and a potential radical change that can only help to improve the economic conditions on the island and re-grow a new economy. Now more than ever, Puerto Rico, like Nineveh needs our Lord’s intervening and protective hand to help open economic doors that can help reduce the amount of suffering on the island today.

Relationship to field of study. The cognate this research applies to is International Business. Despite being a territory of the United States, Puerto Rico’s independently run government provides a wealth of opportunity toward understanding the benefits of manufacturing abroad in an international setting. Its prominent use of a different language (despite English also serving as an official language of Puerto Rico) and cultural differences serves to encompass the realities and challenges of international business.

Researching manufacturing growth and sustainment opportunities and their operation in other countries or territories is the core, foundational, research question for those involved in international business (Smith et al., 2010). Manufacturers are plagued with the cost/benefit analysis of sustaining an operation abroad or manufacturing domestically. The effective strategic decision-making strategies for plant managers are a fundamental topic of understanding cognitive and emotional implications toward decision making in manufacturing operations which often serve as a company's core operation (Jarmolowicz, Reed, DiGennaro, Florence, & Warren, 2016).

Summary of the significance of the study. International business was a prevalent topic throughout this research paper as the research centered on the history of the island's manufacturing environment as well as the associated risks to potential growth, development, and sustainment opportunities in Puerto Rico. Research was focused on the primary drivers for expansion and sustainment in an international business setting, specifically the island of Puerto Rico. This study will lead to available research for the leaders currently in Puerto Rico seeking an opportunity for growth and sustainment initiatives or those companies looking to expand abroad into Puerto Rico.

A Review of the Professional and Academic Literature

Globalization created a smaller and smaller world with respect to the economic exchange of goods and services. Governments and regions once restricted to physical boundaries now use the power of fast-growing logistics networks and the information superhighway to reach customers all around the world. In terms of the provision of demanded goods, companies are now able to consider offerings from differing countries all around the world as a potential target area for the manufacturing of their products. It is no longer necessary for companies to consider

close physical proximity as a key indicator for manufacturing cost advantages. In the new highly connected world, other factors such a local cultural implications and government stability become the prevalent factors for foreign direct investment in the local area.

In the case of investment in the Caribbean, Puerto Rico was once categorized as an area providing a strategic advantage, particularly for the medical device and pharmaceutical industry which currently houses approximately 30 medical device manufacturing facilities producing everything from pacemakers and defibrillators to advanced cancer diagnostics ("Industry takes a hit," 2017). Puerto Rico provided U.S. corporations an opportunity to capitalize on specific benefits such as an educated, low-cost labor force and plentiful tax exemptions which remained available from 1976 until 2006, at which point a 10-year phase out was announced (Feliciano, 2018). These financial incentives for setting up manufacturing capabilities on the island initially created long term commitments between US pharmaceutical and medical device companies. These tax incentives also served Puerto Rico, aiding in the development of a standard and prominent industry on the island that would represent a part of the island's demographic and factor into their identity in the economic sector. Following the expiration of the industry's tax incentives, the pharmaceutical industry still accounts for 72% of the islands exports (McGinely, 2017).

This industry also led to the development and formulation of "home-grown" manufacturing leaders on the island, leaders that quickly developed integral skill sets in terms of navigating business objectives in both English, to appease upper management, and Spanish, to relate to the majority workforce. These leaders also understood the intricacies of a quality-essential focus for goods produced in the pharmaceutical and medical device arenas, in addition to the International Organization of Standards (ISO) 9001, which manages the enterprises

entering foreign markets considering an expansion of exports and covers the requirements prevalent in the manufacturing industry (Civcisa, 2018).

Challenges for Puerto Rico quickly arose as the tax incentive periods came to an end. The laws changed and the incentives for American and European business leaders immediately ceased. With the removal of widespread financial benefits, executives were forced to face the reality of high unemployment rates, economic instability, poor infrastructure specific to local utilities, and a quickly rising inflation rate (Feliciano, 2018). With a perfect storm of economic factors, Puerto Rico immediately began sliding into a recession as companies began closing the factories on the island and redeploying their operations elsewhere (Feliciano, 2018). The culmination of various factors occurred with the economic collapse associated with the Puerto Rican government bankruptcy, a financial crisis never seen in the history of the US municipal bond market (Velez-Serrano, 2018).

Amidst the economic rubble, the remaining pharmaceutical and medical device facilities still operating on the island and their associated plant managers were posed with new challenges as they faced a local economy unbeknownst to their predecessors in a governmental crisis the island had never known before. Strategic decision-making became essential as these leaders were forced to evaluate each long-term step forward and its associated implications. In the remaining sections, the history of the pharmaceutical and medical device establishment on the island will be reviewed, as well as the demographics of the island to include all the current offerings that strive to make it the competitive manufacturing center it once was.

The literature review will consist of the history and facets of the economic crisis as well as its direct implication on the local manufacturing industry. The impact to the local manufacturing site leader will be reviewed as it pertains to their role within the organization. In

addition, the research will review Miltenburg's model for manufacturing strategy in order to determine its applicability and adaptability for local plant managers in Puerto Rico seeking to maintain a competitive advantage (Miltenburg, 2009) to include the relevance and recent applications of this model in the successful integration of manufacturing strategic decision making.

Lastly, the literature review will analyze the concepts of strategic decision-making and the associated strategic decision-making models and their inception into overall leadership strategy. The affective events theory (AET), a theory based on the relations between human emotion and their experiences in the workplace (Vahtera, Buckley, & Aliyev, 2017) will be reviewed to draw a direct correlation to the theory of AET and its implication in strategic decision making.

Manufacturing in Puerto Rico. Puerto Rico's beautiful landscapes are not only encompassed by the warm breezes of the tropical Atlantic Ocean and Caribbean Sea but scattered throughout the 78 municipalities on its lush green tropical lands are the looming (and in some cases fully operational) industrial manufacturing infrastructures of some of the world's most advanced technologies in medical device and pharmaceutical manufacturing. As of 2017, the island continued to house over 30 pharmaceutical manufacturing centers and nearly an equivalent amount of medical device manufacturing facility, although this represented a nearly 50% decline in manufacturing operating on the island in conjunction with a population decline of nearly 400,000 people from 3.8 million to 3.4 million from 2016 to 2017 (Rawlins, 2018). This decline represented many of Puerto Rico's skilled labor force (Rawlins, 2018), further supporting a need to actively engage in research and development strategies that would assist in igniting the island's eroding economy.

In this case, the research begins at the origins of the island's once promising period, where a surge in manufacturing was driven through the inception of tax laws that allowed companies to avoid local state and US federal taxes on profits originating from Puerto Rico-based manufacturing, to include an exemption from US duties once the manufactured goods were imported back to the mainland (Rawlins, 2018). It launched an entire demographical change for an island, a US territory, that had only recently been allowed to undergo its first democratically elected governor in 1949 and established its own constitution in 1952 (Tartakoff, 2014). The inception of these manufacturing tax incentives would begin to shift the small US territory toward a trajectory of becoming an industrial driven society.

The industrial age and its development of a target group. This promoted growth of industry on the island began in the 1950s, following mass emigrations from the island and a near governmental collapse (Tartakoff, 2014). The mid-century leaders in Puerto Rico began to shift from an agricultural economy to an industrial one, with the government at its epicenter of decision making and serving as the designer of a future-focused industry. This strategy led to the creation of 52, state-owned enterprises that operated in a manner which created a monopoly of management in the immediate area and required the local government to focus and invest all of its resources in this particular industry – the capital-intensive investment of pharmaceutical and medical device manufacturing (Soto-Rodriguez, 2014). These governmental investments, in addition to heavy tax incentives provided by the local government allowed US manufacturers to exempt up to 100% of their revenues; in some cases, for periods ranging between 10 and 25 years (Soto-Rodriguez, 2014).

The newly emplaced tax incentives enticed many from the pharmaceutical and medical device industries to penetrate the island in anticipation of cash incentives unavailable anywhere

else in the world (Soto-Rodriguez, 2014). Other benefits such as proximity to the United States as well as Puerto Rico's status as a US territory also served as strategic advantages for executive leaders to invest on the island as a long-term strategy. Manufacturing high-margin products such as pharmaceuticals and medical devices would quickly become even more profitable as companies were able to circumvent traditional tax liabilities simply by producing them in Puerto Rico (Caraballo-Cueto & Lara, 2017).

Section 936 of the Tax Reform Act of 1976. Highlighted as one of Puerto Rico's most integral economic and development tools, Section 936, added during the Tax Reform Act of 1976, maintained a 100% tax credit for US Corporations and essentially eliminated tax payments to the United States on income derived from operations in a qualified possession, such as Puerto Rico and the US Virgin Islands (DiPiero, 1997). This credit applied to both passive income (up to 25%) such as those associated with trade and business activities in which the taxpayer did not materially participate, as well as active income (up to 75%), in which the taxpayer was a material participant (DiPiero, 1997). In addition, prior to the 1996 amendment, the section also allotted for tax credits for both US and Puerto Rican tax returns on income attributable to intangible property licensed to a Section 936 corporation and available for investment in Puerto Rico (DiPiero, 1997), causing a significant dependency on these incentives to grow the economy and the infrastructure of the small island into a manufacturing powerhouse.

Congress eliminated Section 936 in 1996 via a 10-year phase out, through the Small Business Job Protection Act (SBJPA) as a response in increasing tax revenues to offset the tax incentives the SBJPA would provide US mainland small businesses and as a direct justification that the job creating benefits did not justify the loss in revenues (Feliciano, 2018). This was extremely detrimental to the Puerto Rican economy as 98.8% of the one billion dollars in tax

credits awarded under Section 936 were given to corporations located in Puerto Rico, with 69% of them represented within the manufacturing industry totaling 368 returns (Feliciano, 2018). This approximates to $1.9 million in tax credit per individual return or $167.2 million for the 88 returns classified as chemicals and allied products (pharmaceuticals) and $78 million for the instruments and related products returns (medical devices) over the course of 20 years.

Infrastructure in Puerto Rico following Section 936. By the late 20th century companies such as AstraZeneca, Bristol-Meyers, Merck, Amgen, and Pfizer, to name a few, were all established in the local manufacturing environment and producing some of the world's greatest medicines and medical device technologies. In 2017 the pharmaceutical industry alone, represented approximately 50% of the island's manufacturing output and 25% of the island's gross domestic product ("Industry takes a hit," 2017). This, in turn, led to the economic prosperities during the last years of the 20th century and the early years of the new millennium, where Puerto Rico manufactured approximately 20% of the critical medicines supplied around the world (Vega-Rosado, 2011). This competitive advantage marked by reputation and physical footprint in the region created a highly competitive and uniquely Puerto Rican driven industry and, in turn, a need for top talent to lead these facilities.

Unique aspects of the regulated manufacturing environment. The medical device and pharmaceutical industries are heavily regulated industries and as such have uniquely stringent and heavily documented process controls in a very discipline-oriented environment (Handley & Gray, 2015). Document control is essential in these environments and requires facility leaders or plant managers to have a clear understanding of the quality-related implication strategic changes can have on the plant and its support staff. It is not unusual for top executive leaders in both industries to strongly hesitate placing a plant manager in charge of a manufacturing facility if

they do not have a strong background in the medical device and pharmaceutical industry (Baquero & Longobardi, 2014). Despite a strong resume, or a series of successes in their career, the need for experience with the intricacies of the regulated industry tend to become a non-negotiable requirement.

Most leaders that have worked in pharmaceutical and medical device manufacturing are familiar with the term cGMP. This is an acronym that refers to the term *current good manufacturing practice*, which are regulations enforced the US Food and Drug Administration (FDA; Jain & Jain, 2017). These regulations provide a standardized set of minimum guidelines that must be adhered to in the pharmaceutical and medical device manufacturing industries in order to ensure the quality of the product being produced in the factory (Jain & Jain, 2017). Most importantly, by having the guidelines in place, the likelihood of a consumer or the general public being negatively impacted as a result of poor quality is strongly reduced.

Some of the requirements of adherence to the cGMP regulations include adherence to defined hygienic standards, validation of tooling and equipment, minimization and mitigation of variation in controlled activities, as well as strong adherence to change control procedures and documenting training effectiveness (Geyer, Sousa, & Silveira, 2019). Each of these items are audited frequently and the companies operating under a regulated environment invest heavily in ensuring top-rated quality professionals are always monitoring and enforcing a compliant environment.

The knowledge of what it takes to adhere to these specific regulations and a documented history of successfully enforcing these practices are very valuable to companies seeking experienced leaders in these areas as demonstrated in Lowe's (2012) article on recruitment for leaders in the biotech industry in the South. Therefore, much to a local recruiter's frustration,

medical device and pharmaceutical executives are often unlikely and unwilling to hire or even consider plant managers with plant management experience but without experience in the local industry (Lowe, 2012).

This type of advanced experience tends to be unique to the medical device and pharmaceutical industries. In most other manufacturing industries, many would still consider the workforce, somewhat of a blue-collar workforce. Papke Shield and Malhotra's (2008) article on the manufacturing managers perceptions of functional power and strategic decision-making highlights that the manufacturing managers often perceive a certain level of inadequacy of knowledge regarding the production and operational environment among its key executive leaders which further impacts the bottom line. As more and more companies are requiring manufacturing and assembly to the delivery of their goods, more and more executive leaders are becoming exposed to this industry and understanding the source and value to the customer of the quality experience built into the items manufacturability.

Infrastructure of leadership in a manufacturing facility. While each company and their general manufacturing organizational chart will be tailored for each specific company, there are, in general, key positions required to successfully operate a manufacturing center in a regulated industry. The primary leadership role in the factory is the plant manager, who is fully accountable for the financial performance of the factory and serves to lead the team, providing guidance, vision, and direction toward the areas for continuous improvement. The expectation is that with each fiscal year, the plant manager analyzes the financial performance of the site and determines the areas for added efficiencies as well as required capital investments for future growth and sustainment.

In addition to the plant manager, the plant staff normally consist of managers or director level leaders of quality, engineering, operations, environmental, health, and safety (EHS), human resources, finance, and supply chain. Each of these leaders serve as subject matter experts in their respective fields and are tasked to both manage the activities and directions of their subsequent departments as well as provide guidance and expertise to the plant manager with respect to the leader's overall vision for the site (Gurkov & Saidov, 2017). In the case of medical device and pharmaceutical manufacturing, the level of complexity for each of these leaders and the expertise needed is further enhanced by the guiding principles and regulations of the current good manufacturing practices (cGMPs) which are put in place to ensure the overall safety and protection of the final consumer (Jain & Jain, 2017).

Challenges for plant managers in the current environment. Local leaders in Puerto Rico, particularly those responsible for running pharmaceutical and medical device manufacturing plants, should be provided access to a decision-making model that allows them to consider local incentives and considerations which may offset risks associated with government instability. Manufacturing continues to evolve onto a larger and more complicated global framework. Enderwick and Buckley's (2019) article on the global factory continues to emphasize the reality of today's global manufacturing players such as Apple and Foxconn as an example of the collaborative ventures that are essential to the survival of today's manufacturing environment. The article highlights the collaborative partnership these two companies exemplify in order to manage the determinant of governance structures and serve to demonstrate the minimum capabilities manufacturing facilities need in order to retain a competitive edge within the international business setting (Enderwick & Buckley, 2019).

Manufacturers in Puerto Rico reaped the benefits of government intervention through the development of tax incentives for the US manufacturers. Local manufacturing leaders could easily correlate the growth of pharmaceutical and medical device manufacturing on the island over a 30-year period to the government interventions that incentivized the industry. Local manufacturing leaders could easily correlate the growth of pharmaceutical and medical device manufacturing on the island over a 30-year period to the government interventions that incentivized the industry. Puerto Rico has a very long history of granting significant tax exemptions, particularly in the areas of business in order to attract foreign investors. Examples include laws such as Act 20 - The Export Services Incentives Act, Act 22 – The Individual Investor Act, and Act 273 – The International Financial Center Incentives Act (Sampas, 2015). Each of these acts, all enacted since 2012, were designed to attract investment on the island. Unfortunately, as Puerto Rico's recent history has proven, these newly devised tax strategies have not always boded well for the local community. It is because of this that plant managers, the island's operational leaders, are forced to view a strategic future under the eyes of a very different lens then the traditional American operations manager.

The case for Puerto Rico is unique, particularly now with the vast amount of media coverage and economic speculations about the island's potential instability for continued investment. In Kisfalvi and Pitcher's (2003) article on the influence of the CEO, it was noted that more and more studies are showing a causal relationship between top management teams and the strategic decision making process. However, the article goes on to mention the criticality of the emotional responses by the top leader on the team who must be willing to enforce debate and an open forum for discussion. In the absence of open dialogue, the benefits of strategic decision making can be severely limited. In addition, there is the value of managing cognitive conflict in

these discussions, where the conflict arises from a perception of disagreement regarding the specific content, rather than affective conflict, in which interpersonal tensions and personality differences drive the majority of the conflictual behaviors (Vahtera et al., 2017).

Managing both factors in the development and execution of strategic decision making will essentially be the responsibility of the plant manager in a manufacturing setting. The crisis in Puerto Rico will only end when independent organizations, such as the manufacturing facilities continuing to operate on the island are able to rise up and serve as a beacon for economic stability to the local population. In order for these organizations to rise, they need the power of a strong management team, requiring leadership practices at an entirely new level.

Puerto Rican demographics, the people and the industry. Many are surprised by the size of the industry on the island. The reality of those living on the island includes nearly complete importation of food as the agricultural industry on the island suffered when the economic rewards came from the available industrial sectors on the island, also known as the Dutch Disease in reverse (MacEwan, 2017). There simply was no incentive to grow food and invest in agriculture when the opportunities to work and earn a decent living in manufacturing were plentiful and spread throughout the small island (MacEwan, 2017).

The educated workforce. Puerto Rico is a vastly diverse island with a skilled population and a higher-than-average educated population with greater than 24% of people over 25-years-old earning a bachelor's degree compared to 30% in the United States (MacEwan, 2017). The island offers over 70 distinct colleges and universities with bachelor and master's level degree programs. The University of Puerto Rico, established early in the 20th century, has more than 11 campuses across the island and has served more than 60,000 students during its tenure on the island (Dow, 2015). It is also well-known for its engineering programs, particularly its

prestigious University of Puerto Rico (UPR), Mayaguez campus rated 925 out of the world's top 1000 universities in 2016 per the *Center for World University Rankings*, which rates the leading universities each year in 60 different countries. While it is not predominantly known for as a research center, it has been the provided the majority professionals on the island in the distribution of professional engineers and scientists (Mervis, 2017). The statistics continue to represent Puerto Rico's commitment both to excellence in engineering as well as maintaining an educated and available workforce.

Frey and O'Neill-Carrillo's (2008) article on engineering ethics in Puerto Rico highlights the view of engineers in Puerto Rico as champions of social justice and reformers empowered to use their skills and training to "formulate ethical problems and design value realizing solutions" (p. 418). This further reiterates the perceptions and valuation that the Puerto Rican culture places on the engineering professionals on the island and their roles in leading the next generation of manufacturing growth and development of the local economy.

The characteristics of the workforce. Puerto Rico continues to suffer from high unemployment rates despite the low cost of education. The needs of the market are far exceeded by the availability of degreed professionals on the island. From 1990 to 2017, Puerto Rico's unemployment rate averaged between a high of nearly 19% to a low, in the early 2000s, of nine percent (Rawlins, 2018). These statistics further erode the future opportunities for working professionals and continue to contribute the recent mass exodus Puerto Rico has experienced over the last 10 years (Vincens-Feliberty & Ricketts, 2016).

Puerto Rico's workforce is demographically similar, but still strikingly unique with respect to its cultural interpretations of what work means for the individual. The laws in Puerto Rico, both federal and local laws, affect labor practices to those employees reaching and

exceeding the age of 40, therefore, 40 is considered the milestone and a “line in the sand” between the older worker and the younger worker according to a study that was conducted regarding generational gaps in the workplace (Soto & Lugo, 2013). Overall, the finding of the study determined a great deal of openness and willingness to collaborate in the workplace in order to improve the experience for the team, based on the responses among the Puerto Rican participants of the survey (Soto & Lugo, 2013).

The concept of US imperialism. US involvement in Puerto Rico’s economic design and infrastructure has been the crux of, what many local citizens would deem, the epitome of the island’s dependence and downfall. Diane Dick’s article (2015) on the US tax imperialism in Puerto Rico reflects a widely held sentiment on the island which deems the economic disadvantages on the island to be a direct result of colonial system the US tax laws have served to enforce. This has been further supported by Puerto Rico’s ambiguous political status and lack of bankruptcy law support for restructuring public debts as evidence of enforcing Puerto Rico’s dependency on the United States (Dick, 2015).

On the other hand, some economists would argue that these “political collaborations” have also served the local island economy well, as the US has maximized the use of available tax incentives and invested millions of dollars on the island in permanent infrastructures (Liard-Muriente & Schenck, 2018). The US Treasury and American capital markets have also developed commerce unavailable otherwise and served to support the demand for skilled engineers, business leaders, and other high-paying professions as a result of their significant investments on the island (Liard-Muriente & Schenck, 2018). The ongoing debates remain as visible as the political party divisions on the island where some believe strongly in Puerto Rico’s entitlement to statehood, while the opposition stands for complete independence.

Puerto Rico's economic crisis. In 2015 the island of Puerto Rico, a small mass of land in the Atlantic, measuring only 3,420 square miles, created ripples across the world's economic infrastructure as it failed to initiate payments from money's borrowed through the bond markets and threatened to become the first ever US state and/or territory to declare bankruptcy as well as the largest municipal filing bankruptcy in history ("A Crippling Blow," 2017). This type of government instability began to cause executive leaders with deep investments in Puerto Rico to question whether or not the risk was too high to continue with their investments, particularly in the areas of manufacturing, where the infrastructure and annual costs can be directly associated with government stability and tax payments ("A Crippling Blow," 2017).

History of the crisis. In 2014, Puerto Rico enacted a local legislation called the Puerto Rico Public Corporation Debt Enforcement and Recovery Act. This was a controversial step toward obtaining a form of bankruptcy protection for the island's municipalities (Colon, 2015). After many years of raising capital through the sales of bonds, the bond maturation dates arrived and the government's liabilities and the backing that they held threatened to destroy the infrastructure of government services on the island (Colon & Vilarino, 2014).

Puerto Rico declared its financial position an economic crisis upon the forced realization that it was facing approximately 72 million dollars in public debt, roughly the equivalent to the island's gross domestic product (GDP; Colon, 2015). Furthermore, three corporations – Puerto Rico's electric power authority (PREPA), the highway and transportation authority (PRHTA), and the water and sewer authority (PRASA) represented 20 billion (Pierluisi, 2015) with no possibility for bankruptcy protection.

In 1984, following 36 years of liberty to authorize the municipalities to manage their debts, Puerto Rico was suddenly excluded from filing Chapter 9 bankruptcy via the Bankruptcy

Amendments and Federal Judgeship Act (Pierluisi, 2015). This further exacerbated the ability to recover, as eliminating these rights meant the Puerto Rican government relinquished the ability to obtain the necessary protections at a point when the island critically needed to restructure its debts (Colon & Vilarino, 2014).

The high value ratio of debt to gross national product for Puerto Rico was one critical concern to investors, however, local resident's concerns grew as they discovered that by issuing "non-sovereign" bonds Puerto Rico's government was committing to security pledges and other covenants backed by the government's full fledge taxing power (Park & Samples, 2017). This led to bondholders requesting that payment of their bonds take precedence over things including payment to police force, teachers, and pension programs (Park & Samples, 2017). It quickly became widely apparent that Puerto Rico was in a financial situation never before seen, becoming the first US state or territory at risk of declaring bankruptcy, or a type of financial qualification similar to being unable to meet its debt obligations. In this case, the repercussions of the massive governmental liabilities would directly impact the livelihoods and wellbeing of the island's citizens. In this particular case, the repercussions of the massive governmental liabilities would directly impact the livelihoods and well-being of the island's citizens.

The crisis and the educational community. Sadly, budget cuts and the US-assigned fiscal management panel has been forced to cut back on educational funding in order to better stabilize government spending (Long, 2017). Due to poor fiduciary management and misguided capital generating motives, the ones most affected have been the newest generation of upcoming professionals.

One article regarding university programs highlighted the effects on the University of Puerto Rico's (UPR) physics departments, where leaders state that they are left with very little

capacity to make any projections for anything outside of basic necessities (Matthews, 2016). Mass emigrations of teachers and professors from Puerto Rico to the United States only continued to reflect the tragedy and sacrifice many local educators had to make in order to survive and provide for their families (Rudner, 2019). Rasmussen's (2016) article on the debt crisis sadly points out the government's high debt load and poorly performing economy driving the population reduction and resulting in the island's population soon being less than it was 100 years ago.

The crisis and the manufacturing environment. As leaders began to assess the manufacturing environment and its associated standing within the global strategy, they understood how the economic crisis in Puerto Rico was being factored into the current decision-making models in place. In 2013, "the US Bankruptcy Court for the District of Puerto Rico reported that more than eleven thousand bankruptcy petitions had been filed" (Colon & Vilarino, 2014, p. 87) ranking the island 31st in bankruptcy filings. The greatest risk to the bankruptcy and bond debt was led by the Puerto Rico Electric Power Authority (PREPA), the island's sole supplier for electricity, an absolutely essential entity for the sustainment of manufacturing operations in Puerto Rico (Caban, 2018).

Medical device and pharmaceutical manufacturing. Medical device and pharmaceutical manufacturing represent the largest sector of industry-specific manufacturing in Puerto Rico ("Industry Take a Hit," 2017). This industry is unique with respect to the requirement of skilled labor and highly regulated and stringent processes. Relocating manufacturing out of Puerto Rico for these specific industries can prove to be extremely costly and a high-risk option with respect to patient needs.

Puerto Rico benefitted greatly, in terms of economic growth, in the mid-20th century as a result of tax incentives established by the United States (Feliciano, 2018). These incentives allowed subsidiaries of US corporations to send back profits to their parent company without being required to pay federal taxes, however, these benefits expired in 1996 for new business and upheld a 10-year phase out period for existing business finalizing the availability of these exemptions in 2006 (Toledo, 2017). With the development and inclusion of the North American Free Trade Agreement (NAFTA) and the Central American Free Trade Agreement (CAFTA), companies began to seek out additional, less costly, operational set ups in other countries that now had similar logistical and economic access to the United States. According to Toledo's (2017) article, the expiration of Law 936 in 2006 for all existing business on the island resulted in a nearly 50% drop of the island's manufacturing industry.

The shifting of tax incentives in Puerto Rico and the ever-growing debt structures of the Puerto Rican government began to cause more and more industries to relocate their manufacturing operations elsewhere colliding in a massive economic crisis (Feliciano, 2018). For the island to remain a competitor for the pharmaceutical and medical device industries, which has long since held a presence on the island, the people of Puerto Rico in conjunction with governmental leaders would have to look at ways to provide additional legal incentives for investors.

Park and Sample's (2017) article highlights the threat of the debt burden in Puerto Rico and its ability to topple its economy and "destabilize its relationship with the United States" (p. 9), thereby requiring the creation of new legal frameworks which would work to design a global governance to include international financial regulation. These intended frameworks and their potential impacts on local businesses, such as manufacturing facilities on the island can impact

the strategic planning process for the impacted leaders. The observations of this research can be used to support the development of those legal frameworks. Operating under these conditions and understanding that the economic crisis puts an even greater pressure on plant managers to provide incentive for foreign direct investment into the region, further merits the need to understand the complexities and strategies plant managers are employing in the strategic decision-making process and how those strategies directly correlate to a profitable, well-run operation.

Executive decision making for expansion into foreign countries. Paradigm shifts are occurring in the 21st century across multiple Fortune 500 companies, as the leaders of the supply chain are becoming more and more sought after for their skills of understanding the end-to-end process, also known as the value stream. The value stream encompasses each step of the process from order intake to customer delivery in the manufacturing of goods and services (Oberhausen & Plapper, 2017). More and more organizations are realizing the value of these adaptive leaders, forced to think of the impact to the customer from multiple variables around the globe.

Whereas, in the late 20th century, CEOs were traditionally finance or sales-oriented professionals, the new century has defined a new leader – the value stream leader. These leaders understand all the support and functional areas and their interconnected dependencies that rely on one another in order to achieve overall success. The manufacturing site leader, otherwise known as the plant manager, is best poised for success when they understand the aspects of the value stream and the role of the manufacturing facility within that stream. As organizations delve further into a global manufacturing footprint and seek alternatives for lower cost manufacturing around the world, plant managers must maintain an awareness of the direct and indirect costs

within the parameters of factory operations. This further leads to an opportunity for increases competitiveness against global counterparts in low-cost countries.

The infant manufacturing industry and the association of tariffs. Infant industries, or newly found industries in an economic region can be made the subject of tariff protections in order to drive economic and industrial development. One article further defines the concept of the infant industry theory as the supposition that emerging industries need the domestic protections of tariffs in order to properly compete against international competition via measures of import duties, quotas, and controls in the exchange rates (Isran, Siddiki, Kumar, & Zaidi, 2019). In Harris, Keay, and Lewis's (2015) article on Canada's approach toward protecting infant industries through the development of the 1879 National Policy, they determined that in one scenario of an industrial organization model, output expansion, productivity improvement, and falling prices were all in response to the introduction of a protective tariff. In addition, the authors provided a second model titled the Learning-by-doing model, in which they highlight the resulting positive correlation between the increase in industry experience and the increased productivity associated with the protections provided by tariffs, thereby bringing an infant industry to maturity sooner (Harris et al., 2015).

The relationship between tax incentives and the medical device and/or pharmaceutical industry represents a deeply intertwined history whereby the very nature of determining the prominent countries for medical device and pharmaceutical manufacturing are heavily embedded with the associated tax incentives for that region. The very nature of intellectual property (IP) assets, characterized as intangible assets, and the ability to easily transfer them to an international entity, hence protected by a country's lower tax rates than those in the US allows for significant financial incentives of resource shifting (Brajcich, Friesner, & Schibik, 2015). This incentive,

however, normally applies strictly to internationally distributed products, thereby allowing US companies to record deferred liabilities on their books for the tax liabilities associated between the difference of the foreign tax versus the US tax rates, assuming that the revenues and/or assets will realize back in the US via a liquidity requirement or dividend repatriation (Brajcich et al., 2015).

North Carolina recently served as a textbook case. The state flourished under one of the country's most generous tax subsidies of 35% via a local investment tax credit in renewable energy, which also supplemented a 30% federal renewable energy tax credit (Glazer, 2016). These credits brought in billions of dollars of investment into North Carolina, reinvigorating economies across the entire state, however, in 2016 a political climate change took hold and state tax credits were removed from the budget (Glazer, 2016). The abrupt removal of state protection and enticements for continued investment in the region has now forced the residents to find creative solutions for private investment, requiring that they continue advocating for better state policies in order to avoid the collapse of the industry altogether. This is one example of the impacts of abrupt governmental withdrawal before the surrounding infrastructure and stakeholders are readily prepared to make the transition out of the infant industry environment.

The infant industry serves primarily to help preserve the domestic manufacturer up to the point in which they can become economically competitive. The extent to which the local government provides tariff protections are limited, therefore serving to promote a period of maturation and economic strengthening, not to protect or promote inefficient industry (Isran et al., 2019). In the end, the goal is for the local producer to develop the competencies needed to compete at the same price point as the larger foreign manufacturers. In the case of a country like Ireland, which continues to benefit from one of the lowest corporate tax rates in the world at

12.5%, their tax incentives continue to remain a stimulant in a country which not only protects its foreign direct investment through low tax rates, but also through additional tax incentives derived by the increasing value of intellectual property (Barker, 2016), which in the case of medical device and pharmaceuticals clearly translates into the value of company patents.

Territories such as Puerto Rico and countries like Ireland wisely took the available time provided through these tax haven periods, to build their core competency in pharmaceutical and medical device manufacturing. Through the available tax incentives provided over decades, these countries not only invested in the infrastructure, but in the leadership capabilities and the education of next generation leaders that were locally embedded into the culture through friends and family. These new leaders began to shape the future investment and the next generation of manufacturing infrastructure in the region.

The new role of the plant manager. Prominent organizations such as General Electric, Ingersoll Rand, and Disney are retitling their key leaders from operations managers and plant managers to global integrated supply chain leaders, setting a new expectation for organizational leaders to be familiar with all key activities across the value stream (Kull, Wiengarten, Power, & Shah, 2019). These traditional supply chain functions include activities such as global sourcing of materials, world class planning principles, and inventory management, in addition to the traditional operations management and manufacturing. Business are now seeking a well-rounded individual with demonstrated core competencies of effective cost management to manage the factories and exemplary leadership skills for people development and sustainment of top talent.

As a result of these traditional management shifts, more and more high-ranking executive leaders are becoming increasingly savvy with the financial benefits of global sourcing, to include, the outsourcing of manufacturing facilities into regions with core competencies either

logistically, from the commodities perspective or associated labor strengths via a talented human capital pool in the local area (Kull et al., 2019). Countries such as Ireland and Puerto Rico have defined themselves as key locations for pharmaceutical and medical device manufacturing because of the lower-cost, highly skilled workforces in the region. Other countries such as Costa Rica, China, and Mexico are respected for their logistical advances and low-cost labor availability. India and Brazil are prominent global leaders in the area of IT infrastructure and outsourced call centers. Familiarity of these global strengths in key locations is imperative for multi-national corporation (MNC) leaders as they seek methods to maintain a competitive advantage either through enhanced quality, improved delivery, or lower cost than their associated competitors (Kull et al., 2019).

Puerto Rico's advantage over low cost country sourcing. A competitive advantage can be built based on familiarity and the opportunity for collaboration. This is another avenue in which Puerto Rico provides an advantage to US organizations. Puerto Rico provides a setting of compatibility in both its close cultural ties to the American way of life, as well as the island's commitment to a high level of literacy in English, both in spoken and written formats (Ebsworth, Ebsworth, & Cai, 2018). Many are unaware, but Puerto Rico's official language is both English and Spanish and both are taught in schools as the very beginning of elementary education (Ebsworth et al., 2018).

Although the labor rates regarding compensation on the island cannot compare to its competitors in the low-cost country categories, Puerto Rico can fare less costly regarding labor wages compared to its US counterparts (Lugo-Sanchez, 2017). This is a relevant factor because many US medical device and pharmaceutical companies actively manage manufacturing facilities and centers of excellence in the United States. In addition, following the 2016

bankruptcy filing proceedings, Puerto Rico's minimum wage was dropped to nearly half the cost per hour when compared to the US minimum wage in specific industries (Lugo-Sanchez, 2017). This alone allows for a direct labor cost savings for manufacturing workers in Puerto Rico as compared to the US.

In addition, regarding foreign direct investment abroad, the island is reachable without requiring an international passport or work visa, hence, American families often spend many years comfortably on the island as part of corporate commitments. In many cases, employees can comfortably relocate their family members and maintain committed to developing the local manufacturing centers in accordance to the US corporate protocols. With a large population of American expatriates on the island, the demand for school age education at US standards has been high enough that it has made a way for an industry of strong privatized schools to provide a competitive education for the children of US expatriates. This has further established Puerto Rico as a desirable destination for business leaders.

Lastly, the island possesses over 60 years' experience manufacturing pharmaceuticals and medical devices. The history of the industry on the island alone has catered to the establishment and investment of products manufactured using advanced manufacturing techniques, particularly in this heavily regulated industry. The great majority of the pharmaceuticals and medical devices traditionally manufactured on the island represent products in the advanced products segment, which are widely distributed and demanded around the world for use in patients, but still have patents or other critical and protected features that maintain a higher need for skilled manufacturability than the competitive products offered in low-cost country markets (Juppa, 2013).

The vast amount of manufacturing centers across varying medical and pharmaceutical industries over the last 30 years on the island has bred a generation of experienced leaders that have prepared for and successfully executed multiple regulatory agency audits. These leaders understand the intricacies of the regulatory environment. They are manufacturing leaders that have well understood the documentation requirements, process controls, traceability, and repeatability standards deemed by good manufacturing practices. The value of labor as capital is plentiful in Puerto Rico, where the culture of plant managers and manufacturing leaders are designed primarily within the boundaries of stringent standards and unparalleled quality standards. It is a direct result of the immeasurable value of the people on the island which has ensured Puerto Rico remains a top contender in the global race for continued investment in medical device and pharmaceutical manufacturing.

Strategic manufacturing decisions in an economic downturn. The question then becomes whether companies can immediately react to a shift or downturn in the economic environment. What happens when an organization is faced with a failing economy in the foreign territory where they have invested their manufacturing centers or toppling governments threaten to compromise the sustainability of those investments?

According to one article, the behavior of firms under declining conditions or resource constraints has not been widely considered in corporate sustainability literature. However, following the US economic recession of 2008, Panwar, Nybakk, Pinkse, and Hansen (2015) conducted research to determine that the core initiatives of the business remain intact, whereas the peripheral initiatives, particularly those that operated in a relatively dynamic context, significantly declined in correlation with the downtown in financial performance. The research was focused primarily on small manufacturing firms. These firms represent the greater majority

of US firms, however, the researchers did determine that smaller firms sustainability-oriented behavior is unique, in that, it represents a source of pride and directly aligns with the foundational values of the overall organization; therefore, areas of the business such as production processes or product features or direct product subsets, such as product marketing strategies are directly intertwined with downstream supply chain processes and are least likely to be directly swayed by an economic downturn (Panwar et al., 2015).

A separate article explored the factors contributing to survival and competitiveness of manufacturing companies in Australia and Sweden (Soosay, Nunes, Bennett, Sohal, & Jabar, 2016). The authors wanted to identify the alignment of strategies in the context of an environmental downturn. Soosay et al. (2016) concluded that from an economic and social sustainability standpoint, manufacturing strategies had to deploy resources and build capabilities through the use of resource-oriented strategies or market-oriented strategies, depending upon their experience in the international markets versus the impact of macro-economic conditions, in order to best manage costs, maximize profitability, and maintain or develop a strong market position.

Lastly, the limited available literature highlighted the environmental factors that would support causes such as re-distributed manufacturing in order to address the need for lower cost, lower economies-of-scale investments in local manufacturing as a solution to economic upheavals abroad (Luthra, Mangla, & Yadav, 2019) and concluded that while the manufacturing sector is seeking methods to transition away from centralized, globally-based organizations and large-scale manufacturing models to a more locally distributed manufacturing model, 21 key challenges were identified that would require special implications for managers to mitigate and prepare for. The identification of these specific 21 individual challenges highlighted that the

concept of re-distributed manufacturing has emerged further in academia than in the practical application of global business operations, thereby, establishing a causal relationship between these challenges and providing a cluster diagram which eliminates the "mutual interactions among high priority decisive forces and core problem challenges" (Luthra et al., 2019, p. 959). This supports the realization that manufacturing operations tend to establish deep roots within the soil of their physical proximity and their subsequent local economies, making an immediate departure as a result of economic upheaval a serious and costly decision, which must be weighed against long term projections.

In conclusion, the literature highlights three unique articles that support the tendency for global operations to lean toward an alignment of longer-term benefits in maintaining the current state of their operations rather than abruptly halt the operation on site as a result of economic downturns. Whether it was through the focus of core initiatives, the alignment on resource and/or market based strategies, or the development of causal relationship diagrams, the research indicates that operations are most likely to realign their current manufacturing strategies in a way that does not entirely disconnect them from their original market segments and associated infrastructure in their current operating footprint.

Total cost of ownership. Companies and their associated leaders are adopting methodologies such as an analysis of the total cost of ownership (TCO) when determining where to source their products from available supplier around the globe, considering locations to combine manufacturing facilities, or determining whether set up a new manufacturing center all together. The total cost of ownership is often a high level and somewhat general calculation, which may include subjective methods of accounting, such as a 10% carrying cost for the total inventory value. This calculation may be widely used in the determination of "make" versus

"buy" of a company's product or its associated key components. One article tested the value and principle of the total cost of ownership in a laboratory operation in order to understand the costs associated with pre-analytics, throughput costs, and the structure of hidden costs and identified that soft costs associated with pre-analytical sorters, the sequencing of tubes, and determined that the selection of the tube and its use had an associated impact on the overall cost of the process (Stankevich, Gontard, & Gorodetsky, 2019). This is one example in which the total cost of ownership cannot be defined strictly through the exchange of cash, but is inclusive of the intangible costs of service associated with one process versus another.

In another study, an analysis was performed for the medical device producer, Siemens, in which the decision to source from a country with traditionally low wages such as India, China or Eastern Europe was measured as part of a TCO exercise and determined that the model did prove to be applicable and relative when measured from a cost perspective (Weber, Hiete, Lauer, & Rentz, 2010). However, the article did highlight that particularly within the medical device industry the supplier qualification regulations can pose additional challenges, driven mostly by language barriers and other cultural communication barriers (Weber et al., 2010).

With the medical device and pharmaceutical industries' tight management of regulated change control processes, it is imperative that items such as material certificates, documented patterns of traceability, down to the lot sizes, are all readily available upon audit requirements. As such, these organizations tend to avoid the use of making strategic sourcing and manufacturability decisions strictly based on cost management, particularly, when the intangible costs of a major finding on an FDA or other regulatory agency audit can prove much more costly.

Decision-making strategies and the human effect. There is little research available in what the experience is like for these executive leaders as they consider expansion into new territories. While there are rules and templates for considering whether a specific region may or may not be a good fit financially, there is little research on the experience for these executives and plant leaders as they process these high dollar investments into areas abroad, with consideration to government instability. The role of the executive and plant leaders is to evaluate their environments strategically, understanding both the internal (personal and human) and external (environmental, economic, financial) factors and the impact they can have on the future of the organization and its intended direction (Steptoe-Warren, Howat, & Hume, 2011).

Anderson (2009) highlighted the traditional knowledge of executives stating, "decades of wisdom about foreign market entry tells managers to assess whether their unique skills and capabilities might offer comparative competitive advantage" (p. 276). Anderson (2009) also stated that "they are encouraged to analyze these potential hurdles carefully, and decide if their company-specific skills and capabilities outweigh country-specific challenges in operating abroad" (p. 276). This is clearly understood and generally accepted. There is little to no information as to how certain volatilities in the decision-making models are captured and weighed, particularly in volatile regions such as Puerto Rico where the current economic environment is weighing heavily against whether companies should consider continued foreign direct investment on the island or further expansion as the country presses forward to reinvent themselves following the disaster of Hurricane Maria in 2017.

Studies show very little regarding whether current decision-making strategies in practice today incorporate the personal perspectives of the decision maker or whether there is a certain bias that tends to threaten the decisions for the operation in one regard or another. For cultures

like the Latino community in Puerto Rico, there is little research on the perspectives of the local leader's role in the larger economic crisis or their ability to impede its impacts locally to the employees of the facility and their families at home by providing the stability of local place of work.

Lastly, there is little analysis on the personal perspective of a leader enmeshed in the crisis and forced to make strategic decisions that may or may not fall in-line with certain risk tolerances. In the case of Puerto Rico, many of the local manufacturing leaders have a vested interest in the success of their broader organizations, but also in the growth and prosperity of the local economy on the island, which often times houses many generations of family members and life-long friends and acquaintances.

Matching talent and decision-making ability. Areas such as corporate marketing, where top chief marketing officers (CMOs) understand the shifting needs of the customer from service-level expectations to experiential expectations, also understand that the best method to achieve maximum customer satisfaction across a global platform is to tap into global talent (Holtzman, Montana, Petit, & McKenna, 2014). This is one key method for companies to ensure their customer's encounters with the product exceeds the expectation of a standard buy. In other words, in order to provide the consumer with the most desirable product or service, the organization must be willing to recruit, train, and empower a talented team of people to deliver that product or service.

Leaders are eagerly interested in delivering superior customer-oriented performance and in investing in core competency areas for product manufacturing, such as medical devices and pharmaceutical manufacturing in Puerto Rico, if it means the value of the quality is critical. There is no denying that when one considers the skill set and capabilities of manufacturing a

pacemaker, defibrillator, or stent - quality cannot be compromised. As such, leaders in this type of environment must be decisive, transparent, and unwilling to compromise the standards. Production requirements in the manufacturing and medical device sectors can even be categorized and considered as a crisis environment, requiring an entirely different style of leadership.

Leadership styles in a crisis environment. One article identified the results of several studies suggesting the authoritative and or an agentic style of leadership is genuinely preferred in a crisis or high-risk environment (Haddon, Loughlin, & McNally, 2015). The advantage to directly interviewing and studying the plant managers currently operating in this crisis environment is to determine if it is the decisive and authoritative leadership that remains in effect, now that the "economic dust has begun to settle." In addition, there is the opportunity to understand whether these leaders are surrounding themselves with decisive and autocratic leaders to help balance the scales of decision making. Lastly, there is an opportunity to analyze the leader's focus on "futuring" which is considered taking a viewpoint based on internal and external factors and forecasting how today's strategic decisions will impact the organization 10 years from the point of that decision (Patton, 2019).

Decision making in a crisis environment can have high risk implications. Walumba, Maidique, and Atamanik (2014) identified decisions as a result of two individual factors: the goals of the decision maker, and the limited capacity the individual(s) have with which to make the decision. This is particularly true in the case of high-stakes decision making in which more and more leaders are now responsible to make quick and long-reaching decisions based on the multitude of information at their fingertips, particularly in the case of significant time constraints, crisis situations, and high-stakes environments. In the case of these fast paced work

environment, the article summarizes the importance of maintaining an awareness regarding the heuristics and biases to which humans are subjected to as the impact of a leader's life experiences or personal values will affect the experience and the results of the decision making process (Walumba et al., 2014).

For plant managers in Puerto Rico, it is valuable to understand how their personal biases about the island's current economic situation or how it arrived to be in that situation affects the strategic decision-making process for the plant's key focuses in the current year and subsequent years. While effective decision-making strategies are the very backbone to arriving at financially sound business decisions, there are hundreds of different strategies available to choose from. The strategies for running a highly regulated manufacturing facility in an environment facing an economic crisis are new to the Puerto Rican people. These leaders facing these responsibilities are aware of the magnitude of the decisions before them and the array of available strategies; however, articles that continue to highlight the benefits of these strategies and the needs of these strategies, do very little at explaining the human experience for the decision maker who is responsible for executing the strategy in a tumultuous economic environment.

Affective events theory. Weiss and Cropanzano (1996) popularized the Affective Events Theory, a theory explaining the relationship between employees and work events that can create a subsequent emotional state. In Luo and Chea's (2018) article they further highlight the example of how an employee's affective state when in the workplace will determine their attitude toward jobs. This, in turn, impacts cognition-driven behaviors about jobs such as intending to terminate employment or remain with the organization (Luo & Chea, 2018).

The primary identification of an effective approach is the association of the role moods and emotions play on a person's job satisfaction with respect to the moods and emotions driven

by a positive or negative job event (Haarhaus, 2018). In the case of plant managers in Puerto Rico, economic instability of the Puerto Rican government and the economic upheaval of recovering from Hurricane Maria act as the negative events and allows for the researcher to gauge the emotional impact of the negative events and how they further impact the strategic decision-making process for the factory.

Decision making and physiology. There does appear to be a certain amount of scientific literature that addresses the neurological implications of stressful situations and executive-level decision making. For example, Barrasso-Catanzaro and Eslinger's (2016) article focused on the brain's pre-fontal cortex, the area of the brain most sensitive to social influences and emotions with respect to decision making and highlights the necessity of "unfolding the executive functions" (p. 108) of the pre-fontal cortex in order to reach psychological maturation for the most effective decision making. However, despite the scientific evidence that is available of optimal brain development and the associated impacts on decision making, there is still a significant lack of literature available with respect to the human experience in making key strategic decisions and how stressful situations factors in, especially something as prominent as a local government economic crisis, such as the government bankruptcy declaration currently underway in Puerto Rico.

Applying scenarios in the application of strategic planning. One methodology for incorporating the human factor into the strategic decision-making process is to integrate the use of scenario planning. Scenario planning is very popular when formulating a strategic focus in military decision making. Commanders often run through various scenarios in which key representatives of their team role play a specific scenario in order to identify the team's emotional reaction to varying scenarios and determine their team's strengths and weaknesses.

This helps the military's top leaders assess their own reactions as well, when they come across one of the many rehearsed and considered scenarios.

Scenario planning is not uniform and allows leaders to determine the outcome if things go well and the associated likelihood as well as a robust analysis of the potential pitfalls if things go wrong (Schwarze & Taylor, 2017). This leads to a combination of a fixed environment status. In the example of manufacturing plants currently operating in Puerto Rico, the realities of the Puerto Rican economy and the financial objectives expected of a manufacturing facility in the upcoming year serve as the uninfluenceable external factors, whereas, the action variant could be the emotional discourse of the employees as they continue to hear of the mass emigrations on the island and the continuing increases in the unemployment rate.

The current state of the Puerto Rican economy makes incorporating scenario planning into the decision-making process an ideal proposal with both tangible and intangible implications. Understanding the commonality or potential integration of this methodology through direct observation could also aid in better understanding the humanistic aspects of the plant manager's decision-making experience.

Strategic decision making and human emotions. There is no questioning the impact emotions can have in the decision-making process, especially when combined in a region known for its high levels of nationalism and pride. Leaders are repeatedly challenged to stem far beyond their "gut feel" to logical and statistical data that supports their intention to drive an organization in a particular direction. Yet, there simply is no way to eliminate the aspect of the human bias when dealing with humans. In the case of sustaining manufacturing operations, operational expansions, and sustainment analysis, these are not strategic decisions made by computers, they will automatically require human intervention and decision making.

Kisfalvi and Pitcher (2003) researched the in depth implications the executive leader of the team has on the success of the overall decision making process and states that "even in the absence of animosity, emotional factors may have a decisive influence on the process because of the interplay between behavior, cognition, and affect is permanent and pervasive, endemic to the species" (p. 44). Because the emotional aspect is present is undisputable and well documented in varying themes of published studies. Little is published regarding the translation of these observations into the development and execution of a decision making strategy that could aid the leaders currently navigating the path forward toward running a successful manufacturing operation despite the governmental impacts on economic stability in Puerto Rico.

One similar approach to this study was a qualitative analysis that analyzed the role of emotion, intuition, and emotion regulation in financial decision making in the area of trader performance (Fenton-O'Creevy, Soane, Nicholson, & Willman, 2011). This research parallels the level of experiential analysis and understanding being sought out by the research on foreign expansion. Fenton-O'Creevy et al. (2011) researched the impact the participant's emotions had on their decision making and shed light on how the participants experienced these emotions with respect to their craft as well as how that role changed with increased expertise and maturity. The research not only sought to understand the individuality and uniqueness of the experience of the strategic decision-making process for manufacturing operations in Puerto Rico's post Hurricane Maria and post government crisis environment, but in particular gauges what the experience determines is essential with regard to developing a strategy for strategic decision making. The unique possibility of being some of the early leaders to deploy these decisions during Puerto Rico's desperate need for economic stimulation provides a wealth of information and experience

for other executives that are still contemplating whether it is the right time for them to move their operations into Puerto Rico or to maintain their current operations on the island.

Strategic decision-making strategies. Strategic decision making is an essential entity of success in commercial operations, particularly when challenged with global competition and market leaders around the world vying for the competition of the primary markets. For businesses to differentiate themselves among their competitors, their leaders must deploy strategies that will generate the necessary profits to keep the shareholders happy. For manufacturing specifically, plant leaders must optimize their key leadership competencies and demonstrate the ability to successfully manage all operational requirements across the manufacturing and supply chain. Particularly in Puerto Rico, plant managers have the opportunity to demonstrate the successful execution of their operation in a manner that highlights the core competencies they demonstrate when leading successful operations under external pressures and economic hardships.

Strategic decision making and lean manufacturing. Manufacturing is no longer viewed as strictly a functional output of business need. The methodologies employed by the Japanese following the second world war, to include the Toyota Production System and the Deming principles of quality, eventually becoming the Total Quality System, began a paradigm shift from mass manufacturing and output management to a part of the company's competitive competency (Breja, Banwet, Iyer, & Douglas, 2016). This implies that organizations must recognize the value of an experienced manufacturing site, particularly sites with a strongly embedded lean culture. Integrating a total quality management (TQM) approach and the best practices of lean methodologies, as demonstrated by the Toyota Production System is a journey, many years in the making. The manufacturing facilities that have incorporated this into the

"production way of life," offer an intangible advantage that does translate directly to the bottom line in efficiencies, waste elimination, and a spirit of continuous improvement. Golec (2015) described the new strategy for manufacturing as one that is designed to use its strengths in order to help create the ideal business and ensure that its strategic performance is in line to support and build on the competitive needs of the company.

One prominent area of strategic focus regarding cost control is determining a location and a supplier for sourcing. Deker's (2011) article on the evidence of strategic decision making and its failure to get thoroughly employed in the use of making outsourcing decisions is a key example of companies getting short sighted on cost-containment strategies and limiting the usage of quantitative and qualitative tools for analysis that explore the hidden costs of such strategies as well. In some cases, leaders are solely focused on the benefits of low-cost country opportunities. This can occur to such an extent they are willing to compromise the ideal quality standard for the opportunity cost that will be gained through low-cost country sourcing.

Summary of the literature review. Puerto Rico is suffering through an economic crisis they have never known before. After 60 years of growth, investment, and development in the region they are now fighting to maintain the factories that remain operating on the island. It is essential now more than ever that plant managers poise their plants at a competitive advantage over other global offerings. Decision making models and key decision-making strategies that involve the feedback and collaboration of the plant teams are integral to the success and future investment of manufacturing on the island, a small geography in the Caribbean, with such wealth in natural resources and human capital. Understanding the real-time experiences of today's plant managers as they navigate through the challenges of strategic decision making during the

economic crisis will only add value to the future modeling of effective decision making for leaders in Puerto Rico in the future.

Transition and Summary of Section 1

The proposal of the research was a result of gaps in the literature regarding the strategic decision-making process and the associated models for leaders looking to either enter the Puerto Rican manufacturing sector or determine an effective path forward for those operations currently on the island. The interview questions and observations were centered on the insights and perspective of the operational site leader and driven by the plant manager's experience successfully operating under the island's current crisis condition. These observations directly correlated the effect the leader's strategic decisions have had on the success of the overall operation on the island. The case was compiled via interviews from the leaders about their experiences during their annual operating plan analysis and the execution of their strategy. These interviews also explored how decision-making strategies are evolving internally with respect to the current economic situation.

Section 2: The Project

This study explored how plant managers for medical device and pharmaceutical manufacturing facilities in Puerto Rico utilized unique methodologies toward strategic decision making to maintain cost competitiveness and retain corporate support for manufacturing on the island despite the multiple challenges associated with the government bankruptcy. To explore this research question, plant managers in Puerto Rico, responsible for either medical device or pharmaceutical manufacturing currently operating on the island and members of their staff were interviewed, their annual operating planning process was discussed and plant specific documents on the site's mission and strategy were reviewed. Additionally, a local representative of the Puerto Rican local government was interviewed to discuss their perspectives as a government representative amidst the challenges of rebuilding an economy following the expiration of critical tax incentives and a potential loss of trust in the local government. Lastly, an interview with the executives overseeing the manufacturing facilities in Puerto Rico, further allowed for direct insight into the long term strategic planning implications the current economic environment in Puerto Rico has had on corporate strategy and placement of manufacturing in the once renowned island, known for its mature infrastructure and skilled labor in the area of regulated manufacturing.

In order to address the research question, a qualitative study, using a case study methodology was employed. This section below highlights the details of the research by providing a more in-depth view of the overall research question and the purpose to be achieved, to include the researcher and the participants. In addition, the section below will cover the research method and design, population and sampling, and the methodology for data collection.

Lastly, the section will summarize the techniques of data analysis as well as the overall reliability of the study and its associated validity.

Purpose Statement

The purpose of this qualitative case study was to increase the empirical knowledge of strategic decision-making strategies demonstrating successful operations in the volatility of Puerto Rico's economic and governmental crisis and reduce further economic impacts on the island tied to plant closures. More specifically, the intent of this investigation was to develop the connection between the medical and/or pharmaceutical plant manager's strategic decision making and operational planning process and a successful plant operation more clearly understood. The specific population selected was determined to understand the unique needs and demands of the strategic decision-making process when faced with Puerto Rico's current economic instability.

This case study focused on select Puerto Rican plant managers and their associated leadership stakeholders having recently completed the strategic operating plans underneath the umbrella of a bankrupt government will provide insights into the elements the Puerto Rican economic crisis is having on the overall decision-making process. This in turn will provide a framework for the development of a more relevant process for strategic decision making for other leaders in comparable circumstances on the island and use scholarly research as a method to improve business practices (Creswell, 2009).

Role of the Researcher

The role of the researcher, in this case study, served to collect data (Stake, 2014). The data collection included in-depth interviews designed to capture the essence of the experience for the plant managers, their leadership teams, and members of their direct staff considering the

unique aspects of their leadership challenges underneath the umbrella of governmental economic instability in Puerto Rico. The focus of the interviews with the manufacturing leaders was designed to understand the impact the affective environment had on the strategic decisions employed at that factory. In addition, the researcher conducted on site observations of manufacturing leaders executing the goals and objectives of the strategic decision-making strategies that developed the annual operating plan, reviewed relevant company documents published specifically regarding the future direction and strategy of the facility, and researched relevant corporate-level communications to support local observations and align them with the company's higher-level strategy.

The researcher was also responsible for conducting an in-depth interview with a member of the local Puerto Rican government. This interview served to provide an introspective view for those on the governmental side of the new economy. The goal of the interview was to capture the insights of government leaders seeking to reinvigorate the local economy and understand the challenges they determined in regaining economic strength. These interviews also helped to analyze and assess the impact of the government bankruptcy on the local manufacturing environment in Puerto Rico from all angles.

In the case of all company specific documents for the manufacturers, each company's anonymity was maintained through the usage of code names for each individual organization (see Appendix A). The company was referred to by its code name at each mention of corporate-level communications or relevant financial information. Only publicly available financial information not considered confidential by the company's leadership team was used when referencing the research.

Participants

As part of capturing the essence of the human decision-making process (Creswell & Poth, 2013) two executive level leaders currently overseeing, either directly or indirectly, medical device and/or pharmaceutical factories on the island were selected for an interview. Additionally, participants leading pharmaceutical or medical device manufacturing centers and an individual representative of their staff were selected in order to fully meet the criteria of the experience intended to be captured. A governmental representative was also selected to take part in an interview. Participants in the study were selected because they were either directly or indirectly responsible for a pharmaceutical or medical device manufacturing facility on the island of Puerto Rico or they served as a representative of the Puerto Rican government following the government bankruptcy.

All participants representing manufacturing leadership held their role of executive leader, plant manager or member of the plant staff served as leaders of a medical device or pharmaceutical manufacturing facility and communicated their intent to remain in their respective roles for two quarters of the current fiscal year. The government representative requirements included a tenure of at least three months in a position that allowed for direct exposure or influence from Puerto Rico's inception of the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA). This level of exposure allowed for more relevant insights from the impacts of the government bankruptcy and the growth potential in the existing economy.

In addition, all plant manager participants were anticipating remaining in the role of plant manager, directly responsible for the facilities under their care, for a minimum of two financial quarters. This was deemed a key factor in selecting the participants because of the influence the

follow-on fiscal budget would have on the rating and performance of the participant. The potential lack of direct accountability for the financial performance of their site had to be ruled out as a factor to ensure the authenticity of the strategic decision-making process. The intent of the study was to capture the experience of the strategic decision-making process by a leader who would be present to face the results of those decisions and were willing to provide their inputs toward the research.

To ensure confidentiality of all recorded information, all the files in electronic format were captured and stored in one password protected computer. This computer was owned and managed by the researcher. While there were multiple users on the computer used to house the information, the electronic files were stored under a password-protected user ID and only the researcher had the password. All hard copies of documents and transmissions were stored in a locked cabinet and all interviews were conducted behind closed doors either in the researcher's home office or at the office of the plant manager behind closed doors. Each participant and their associated company were provided a code name to protect their privacy and anonymity (see Appendix A).

All participants were provided a consent form and an applicability form (see Appendix D, E, and F). The applicability form was used as documented evidence that each of the selected participants met the criteria of the case study. No interviews were conducted until a signed consent form and a completed applicability study was returned to the researcher and filed both electronically and via a hard copy. Upon completion of the consent form each participant was interviewed using a series of questions. For the manufacturing leaders, the nature of these questions was to provide a robust depiction of the participant's experience of the decision-making process in Puerto Rico's current economic condition. For the economic representative,

the questions were centered on the economic climate for local manufacturing and their perceptions with respect to government initiatives to re-invigorate investment in the local economy, specifically for the pharmaceutical and medical device industries.

Research Method and Design

Research can be classified as a methodology or a tool to help better understand a relationship or a particular situation. While multiple theorists and field experts in the areas of research provide different specifics to their methodology such as Creswell's (2012) six-step approach, the ideas are based on a similar concept. The type of research method and the specific strategy and design of that method helped ensure a more robust analysis and more accurate findings for the researcher.

Discussion of method. Creswell (2012) identified three types of research methods include quantitative, qualitative, and mixed methods. The quantitative method is based on the application of linear modeling of independent relationships or the ability to measure, typical using an instrument, variable that may be mathematically or statistically analyzed (Goertzen, 2017). In the case of the research for leaders in Puerto Rico, the study was to be based on real time observations and findings associated with the interpretive conclusions of the research. There were no direct numerical correlations to be ascertained by the observations, making a quantitative approach incompatible to the method of study.

The mixed methods approach, according to Yin (2016) required a study that combines the elements of both the qualitative and quantitative approaches. This study was philosophical in nature with philosophical assumptions that were addressed through the combined approaches of both qualitative methods and quantitative methods. As the purpose and proposed design element

of this research did not have a quantitative element, the mixed method approach was incompatible with the selected method.

The research method selected was a qualitative analysis. Merriam and Tisdell (2016) described qualitative researchers as individuals that are interested in "understanding how people interpret their experiences, how they construct their worlds, and what meaning they attribute to their experiences" (p. 6). The focus of the research was to explore and understand the experiences of a specific population of business leaders in Puerto Rico. The research allowed for the study to be formulated around the concepts of words and open-ended questions (Creswell, 2012). Qualitative analysis allows the researcher to understand how the specific population being studied, in this case pharmaceutical and medical device manufacturing leaders and local economic representatives in Puerto Rico, are interpreting their unique experiences during an economic event that is the first of its kind on such a grand scale.

This method was selected to gain understanding through direct observation and first-hand interviews with participants directly affected by the affectual environment within the strategic decision-making process. Because the object of the investigation can be classified within the boundaries of a very specific population and a delimitated focus area, the case study was the most well-suited research method (Stake, 2005). In addition, Yin (2016) described qualitative research as a methodology that seeks to establish cause and effect relationships through the adherence of value free measures. The very nature of this study's focus on verbal interpretation, real time observations, and a focused population meet the criteria across multiple experts as a qualitative study.

Discussion of design. In the case of understanding the cultural implications and the real-time experiences of those leading businesses and those supporting the local economy during the

economic crisis, the research was conducted by interviewing key participants, such as those in critical roles for executive decision making in manufacturing and those in leadership roles serving as an economic representative. The intent behind this experience was to capture firsthand information that led to obtaining a described essence of the human experience, in this case, the executive decision makers, as it related to the strategic decision-making process (Creswell, 2009). Merriam and Tisdell (2016) stated that qualitative studies are inductive in nature and center on the researcher's observations and findings as a method to induce a type of theory or create a new one.

In the case of this observation, a case study design allowed the researcher to select a pre-designed group of participants – in this case local economic representatives in Puerto Rico, executive leaders for plants in Puerto Rico, and plant managers plus members of their staff, fully responsible for the successful operations and management of medical device or pharmaceutical manufacturing on the island of Puerto Rico. Various levels of management representatives, in this specific industry were selected because of the stresses already placed on, what was once, Puerto Rico's number one industry as a result of a loss of generous tax incentives and government crisis. In addition, the mid to executive level leaders in the medical device and pharmaceutical industry are required to manage profitability and sustainability in an environment with new burdens placed on them by the new fiscal government crisis associated with the government's inability to repay millions of dollars in maturing bonds to bondholders around the world. The case study is further enhanced with the added insights of the economic representative, which provides a differing perspective of a population directly related to the associated impacts of a government bankruptcy.

Summary of research method and design. The case study focused on interviewing and observing manufacturing leaders as they navigated through the strategic decision-making process considering the multiple external challenges and requirements needed to maintain a competitive advantage for operations in Puerto Rico. The case study also gathered further insights and perspective from the catalysts of those economic impacts, through the interview of a local economic representative operating in Puerto Rico.

Population and Sampling

The primary differentiator of a case study as opposed to other methods of qualitative research is focused research on a specific case within a bounded system (Stake, 2005). The bounded system or representative population in this research can be identified as pharmaceutical and/or medical device manufacturing leaders working in Puerto Rico or with direct oversight responsibility for a facility in Puerto Rico, following the implementation of PROMESA in June of 2016. In this case study PROMESA's implementation is designed to represent the period of Puerto Rico's greatest government financial crisis.

To qualify as a participant for this research, the economic representative had to hold a position that allowed for direct exposure or influence from the government bankruptcy and intend to maintain their position for at least three months. The manufacturing leaders had to support a facility in the medical device or pharmaceutical industry operating in Puerto Rico and intend to maintain their roles for at least six months following the last annual operating planning period. This period was designed to ensure the relevancy of the strategic decision-making process, as the leaders would be required to manage the consequences of those decisions, favorable or unfavorable.

The selection of the medical device and pharmaceutical industry can also be considered part of the bounded system. This relevancy of this industry is the cost to maintain and operate a highly regulated environment and the details associated with the requirements of a highly skilled labor force. Lastly, this industry represents the largest sector of manufacturing in Puerto Rico, making the economic impact of these companies relocating to other regions of the world highly detrimental and worth researching.

Discussion of population. The plant manager is the highest-level leader responsible for the direct well-being of the employees operating within their facility, as well as, the individual directly responsible for the financial performance of the factory. The core competencies of the plant manager which help make them successful include items such as conceptual thinking, results orientation, the ability to think things through with high analytical proficiency, and initiative and the firm integration of character and competence (Sturm, Vera, & Crossan, 2017).

Their willingness of the manufacturing executives, the plant managers, and their staff members to take on the responsibility of a manufacturing facility differentiates their comprehension and application of a strategic decision-making process in comparison to other lower level managers within the facility. These leaders must operate in the capacity of strategic thinking and strategic decision making. This will expand their scope from attempting to solve problems on ongoing activities and processes to responding to changes in the external environment, changes that may not always be clearly visible, and convince the entire organization to support their direction (Norzailan, Othman, & Ishizaki, 2016). In Puerto Rico there are approximately 130 medical device and pharmaceutical plants operating on the island, serving as the number one manufacturing industry on the island (Meager, 2017). It is for this reason that the case is built by interviewing and observing these a representative sample of these

leaders, currently responsible over some of the largest manufacturing facilities on the island operating in this specific function of the business.

The insights and observations of the economic representative are used to provide additional evidence of the impacts the medical device and pharmaceutical industries are facing on the island. These insights are used to add additional clarity on the complexities of the government financial crisis and the strategies being considered to further enhance the economy and begin the reparation caused by the initial bankruptcy.

Discussion of sampling. The selection of specific manufacturing leaders and a local economic representative meets the criteria of a case study, in which case the focus of the research is on the challenges of strategic decision-making post-government, economic crisis in Puerto Rico, in one bounded case - medical device and pharmaceutical plant leaders in Puerto Rico (Stake, 2005). This sampling of medical device and pharmaceutical manufacturing leaders as the individual cases that represent my case study also represent a significant representative sample one of the largest populations of industry-specific managers, with a similar scope, currently working in Puerto Rico, making the subjects for this case study purposefully selected and relevant toward the addition of the overall body of knowledge on this topic (Creswell, 2012). The executive leaders, representative staff members from each facility, and an economic representative from the local government allow for saturation of this highly specific population, which will further support Yin's (2016) recommendation that a replication or similarity of the experiences and result of the observation, does occur.

Summary of population and sampling. The bounded system, or representative population in this research can be identified as manufacturing leaders responsible for a facility in Puerto Rico, specifically in the medical device and pharmaceutical manufacturing industry,

following the implementation of PROMESA in June of 2016 and an economic representative serving in the same period. This bounded system represents the broader population group of local Puerto Rican economic representatives and higher-level manufacturing leaders in Puerto Rico. This specific population was selected because the role represents the highest-level leaders responsible for the direct well-being of the employees operating within the manufacturing facility. These individuals are also directly responsible for the financial performance of the factory. Plant managers and a staff representative were selected as a representative sample of approximately 10% of the broader population on the island.

Data Collection

Merriam and Tisdale (2016) identified interviewing and observations as the two primary data collection strategies used to gather data specific to the research question. In addition, documents and artifacts retrieval can also be used as a minimally invasive method that does not impact the settings being researched in the way a direct observer might (Merriam & Tisdale, 2016). The design of this qualitative study is to include all interviews, observations, and document reviews as part of the research study.

Expanding beyond the high-level approaches, opportunities to connect via technology has created efficiencies in the methods of researching. While the onset of technology has created some inconsistencies as to a direct tie into the four general methods of data collection (observation, interviewing, document review, and audiovisual materials), Creswell and Poth (2013) still relied on the premise that items such as email messages, texts, and narrative journals can be relayed into one of the four primary categories. Included in the subsequent headings are more thorough and detailed explanation of the data collection strategies used to collect, store, and analyze the data associated with the research.

Instruments. The beauty of qualitative research is the impact the researcher or the observer's point of view has in conjunction with the focus of the case study. The role of the researcher is an integral one and is designed to serve in a direct manner with the participants of the case study. The primary source of data collection was managed directly by the researcher, who served as the principal investigator. The types of data collected included interviews, direct observations, company literature to include literature specific to operations in Puerto Rico, and document reviews of professional articles written regarding the different aspects of the economic crisis in Puerto Rico. In addition, the interviews were collected from executive leaders, independent plant managers, and representatives of their individual staff, to broaden the perspectives and support the case across this industry operating on the island. The interview of the economic representative on the island further enhanced the realities of the government bankruptcy and offered direct observation and insights of those impacts from representatives directly influencing the local economy.

Stake (2014) referred to the practice of triangulation as a method for differentiation, confirmation and validation. Triangulation allows the researcher to confirm through multiple follow-ups or verifications that the data are understood or interpreted as intended. The responses to the interview questions included a segment of triangulation in which the researcher reviewed the response with the interviewee to ensure alignment in both the observation (when applicable) and interpretation of the responses to the interview questions. All forms of triangulation were documented and included in the overall analysis of the research.

Data collection techniques. The first method of data collection used was the participant interview. According to Creswell (2009), the individuals selected for the study should be purposefully selected, which assisted the researching in understanding and capturing the

information associated with the research question. By interviewing manufacturing leaders in a specifically targeted field of manufacturing in Puerto Rico and an economic representative serving during the economic crisis, the researcher was able to use the responses to the interviews as valid and essential inputs to the experiences of this population during this specific circumstance. The questions in the interview were all centered within the boundaries of the case study to include validation of the study's parameters, a focus on the strategic decision-making process and the annual operating plan, and validation of the impact driven by the local government crisis.

The interview process consisted of two steps. First, the candidates were identified and an email was sent out with the applicability form (Appendix E and F) and an attached consent form (Appendix D). The email included the overview and nature of the study, the role they were authorizing to be a part of in the study, and the associated instruments for data collection. Upon receipt and confirmation, the candidate met the requirements in the applicability form, the candidate was emailed a copy of the interview questions for review and contacted to schedule a phone interview with the principal investigator. The interview for the manufacturing leaders consisted of open-ended questions designed to address the experience of strategic decision making and generation of the annual operating plan following Puerto Rico's implementation of PROMESA and its representation as one solution toward managing the government economic crisis (Appendix G). The interview for the economic representative was centered around the interviewees perspectives on the impact of the government bankruptcy on the island, the initiatives to reinvigorate the economy and incentive growth in the medical device and pharmaceutical industries, and their perspective of the current challenges for the Puerto Rican government and its people (Appendix H). The interviews were either recorded and the recordings

were transcribed verbatim for future review by both the principal researcher and the interviewed participants, or the responses to the questions were emailed back to the principal investigator. Each participant was provided a copy of the interview transcripts (when applicable) for their review.

The second data collection technique used for this study was direct observation of participants in their work environment while operating in Puerto Rico. Creswell (2009) identified direct observation to the have the advantage of providing the researcher with a first-hand experience with their participants and the subject of their research as well as capturing unusual aspects of items that can only be noticed during direct observation. The principal investigator travelled to all four sites for approximately one day to meet directly with the participants and observe both the daily results of the strategic decision-making process taking place and the impacts on the management team operating in the high-pressure environment of government instability.

The third data collection technique used for the study was the review of associated documentation. Merriam and Tisdale (2016) identified documents as a good source of data because they are easily accessible, often-times free, and gather data that could be difficult to gather otherwise. For the purposes of this study, the principal investigator reviewed supporting materials such as peer-reviewed journal articles referencing current topics associated with the Puerto Rican government bankruptcy, meeting minutes for real-time meetings that were being observed, as well as relevant articles in popular publications such as the Wall Street Journal and New York Times discussing Puerto Rico's economic climate. These documents were used to support and confirm the findings of the interviews and observations associated with the case study.

Data organization techniques. Creswell (2009) addressed the importance of planning an approach to data recording prior to collecting the data with approaches such as observational protocols, interview protocols, and coding. Each of these elements were used in the collection and management of the data from the interviews, document reviews, and observational sessions. The extensive amount of data collected for this study was generated through focused interviews, on site observations and the review of multiple documents. Thus, each of Creswell's recommendations on data organization was used to segregate the material, properly code meaningful themes, and record the data properly to support the concluded findings. A summary on the physical controls and protection of sensitive information, such as company specific data, is also included at the end of this section. Observational protocols were included as part of the observational session to delineate between demographical and descriptive items such as date, time, place and setting, and reflective notes such as the principal investigator's perceptions of the setting, thoughts, and ideas that came to mind, and the investigator's personal feelings about the results of the observations.

Interviewing protocols were put in place to standardize the interview sessions across each participant. Objective controls such as the template for the interview questions, the instructions provided via email, the introductory statement, and the follow up questions were adhered to using a standardized template across all interviews. Coding was also implemented across the results of three forms of research (interviews, direct observation, and document review) to align similar themes. Each central theme or idea was identified with a code word and the information was gathered and analyzed based on the associated code. Coding allowed the research to identify multiple facets or supporting information for a category as key items of the research was compiled to each specific category.

Narratives such as journaling was also a key element of data compilation. Stake (2014) emphasized the value of journaling at the onset of each research study as a method to capture thoughts, questions, or concerns that may become relevant to the research throughout the entirety of the process. For this research, the principal investigator developed journal entries for each key research activity for further review and analysis in the data analysis section of the research. These journals were an essential portion of organizing themes throughout the review of data and identifying patterns that merited further review.

Lastly, the organization of data included adherence to the appropriate security and confidentiality protocols. Company and participant codes were applied to each of the interview participants to protect the anonymity of the interviewee and their respective organization (Appendix A). Physical security measures were also put in place such as the storage all hard copy documents, to include interview transcripts, journals, and any other company-specific information included in the case study in a locked cabinet in the principle investigator's home office. The principal investigator was the only person with a key to this cabinet. All electronic files were kept strictly on the principle investigator's password-protected computer. The principle investigator was the only individual with the password.

Summary of data collection. In summary, the data collection process of interviewing all participants over an observational period allowed for the researcher to collect the data with approaches such as observational protocols, interview protocols, and coding. Each of Creswell's (2009) recommendations on data organization were used to segregate the material, properly code meaningful themes, and record the data properly to support the concluded findings. Physical security measures were applied in order to adhere to the appropriate security and confidentiality protocols.

Data Analysis

Merriam and Tisdale (2016) described qualitative as information that takes on an inductive and comparative identity, therefore they propose drawing from the constant comparative method of data analysis as the primary means for developing theory. The comparisons were drawn against key themes in the research to identify key categorical units that aligned to the overall research question and were used as a roadmap to the conclusions of the analysis on the case study. The research question involved the exploration of how the Puerto Rican government crisis was impacting the strategic decision-making process for medical device and pharmaceutical plant managers and their teams and the supporting conceptual framework was built upon the theory that the crisis would, in fact, have a significant impact. The data analysis was managed and reviewed with a focus on answering that question and testing the theory.

Coding process. As part of the construction of data analysis, the authors recommend beginning with category construction (Merriam & Tisdale, 2016). This process began with reading the interview transcripts. These were transcripts created via the emailed responses to the initial interview questions in addition to the transcription of any recorded verbal sessions. The primary investigator also reviewed all notes, journal entries, and initial company documents and related articles. The reviews of each of these items included generation of notes, observations, and queries. The reviews also included open coding, or the use of a specific word that would be relevant to the research question and aptly used in other areas of the research (Merriam & Tisdale, 2016). Those comments were then assigned a specific number in order to transfer the open coding into an axial coding, which would reduce the broad array of key words into centralized themes and concepts. An example would include the theme of product quality, in

which case any items included in the transcripts or observational notes addressing product quality would be highlighted with a number 1 and the associated company/participant code of the individual responsible listed in Appendix A (when applicable). All the data were entered, managed, and coded using NVivo software program.

Finally, the data were reviewed and analyzed based on the results of the categorization process. This process was in support of the key areas of strategic decision making where the external government crisis was having the greatest impact on local Puerto Rican leadership teams in the regulated manufacturing industry. The review of major themes led to a comprehensive narrative and summarization that captured a response to the research question and underlying conceptual framework. More specifically, there was a direct correlation between the validation of a government economic crisis via the integration of PROMESA and the local strategic decision-making process for plant managers. The external factors associated with the government's instability was playing a significant role in the review and approach to long term strategic planning, cost management and quality-focused initiatives.

Summary of data analysis. The data analysis described in this section was applied to all areas of the case study for all executive leaders, plant managers, members of the plant staff, and the economic representatives interviewed. This ensured that the finalized results of the data were reviewed across each case and summarized with the themes presented in its entirety. This aided in providing relevancy both, across the case and with respect to each case's individual findings and the results of the others.

Reliability and Validity

Reliability. Reliability in the study is the extent to which the findings of the research can be replicated or whether the research would yield similar results if completed at some point in

the future (Merriam & Tisdale, 2016). Despite the frequent criticism on qualitative research's lacking scientific rigor and openness to personal bias, one article highlights strategies that can be put in place to provide greater reliability and validity to a qualitative case study. Some of the approaches identified include meticulous record keeping demonstrating the interpretations of data are transparent as well as including verbatim descriptions of the participants' accounts (Noble & Smith, 2015).

The research in this case study ensured that an objective criterion was applied in the selection of case study participants as demonstrated via the use of the applicability form (Appendix E and F). In addition, the transcripts were transcribed verbatim and coding was applied with objective criteria to avoid personal bias from the primary investigator. The interview questions were consistent across all participants and the method to analyze the data was also used consistently across all observations and interview reviews.

Validity. Cypress's (2017) article on the validity of qualitative research addresses some of the more contemporary challenges associated with establishing validity criteria because of the creativity and subjectivity that is interjected into the scientific process of research. Per the author's internal validity is easily described as credibility, but is not an exactly transferable concept from quantitative to qualitative research due to the difference in epistemological and ontological assumptions. For the purposes of this research, internal validity was maintained through the employment of triangulation in which the primary investigator's interpretations of the interview responses were provided to the interviewee for their review and verification. The record keeping approaches were maintained using objective standards and criteria such as "commonly used terminology" to avoid the perception of personal bias.

Cypress (2017) identified external validity as transferability with regards to additional research. Merriam and Tisdale (2016) defined external validity as the extent in which the findings of the research can be applied to other situations, or the extent of how generalizable the findings are. The guide is to ensure that the factors were not so tightly controlled that the results were forced to reflect the bias of the investigator. The population of separate medical device or pharmaceutical manufacturers in Puerto Rico allowed the primary investigator to assess a very specific population, however due to the small number of leaders that fit the requirement of the study in the densely packed square footage of the island of Puerto Rico, the study could be considered highly transferable to other plant managers on the island. Medical device and pharmaceutical manufacturing are the island's number one industry and represent a large portion of manufacturing on the island. This would deem the external validity as high for this specific population. Duplication of this study involving additional plant managers and representatives of their staff would result in a higher level of external validity with each assessment.

Summary of reliability and validity. The development of reliability in a qualitative case study can pose challenges, based on the nature of the study, therefore, some of the approaches identified include meticulous record keeping demonstrating the interpretations of data are transparent as well as including verbatim descriptions of the participants' accounts (Noble & Smith, 2015). The researcher ensured an objective criterion was applied in the selection of case study participants, the recording of the information, and the specific questions they were asked.

For the purposes of this research, internal validity was maintained through the employment of triangulation in which the primary investigator's interpretations of the interview responses were provided to the interviewee for their review and verification. The record keeping

approaches were maintained using objective standards and criteria such as “commonly used terminology” to avoid the perception of personal bias.

Medical device and pharmaceutical manufacturing are the island’s number one industry and represents a large portion of manufacturing on the island. This would deem the external validity as high for this specific population. Duplication of this study involving additional plant managers would result in a higher level of external validity with each assessment

Transition and Summary of Section 2

This research explored how strategic decision-making activities were affected for medical device and pharmaceutical plant managers in Puerto Rico amidst the current government bankruptcy and economic crisis. To address this research question, interviews were conducted with executive level leaders responsible for manufacturing facilities in Puerto Rico. An interview was also held with an economic representative in Puerto Rico to further support the insights and impacts on the local economy following the government bankruptcy. Lastly, the research question was explored by direct observation and interviews of plant managers and a representative of their staff from a medical device and/or pharmaceutical manufacturing facility in Puerto Rico. These leaders were required to remain in their roles for six months following the finalization of the current fiscal period. In addition to the interviews, the primary investigator conducted direct observation of the process and organizational documents were reviewed.

The section above described the role of the researcher, the participants, and that data collection plan. The section delved into the details regarding the parameters that would be put in place to ensure the integrity and objectivity of the data and how the data would be collected, analyzed, and maintained. Lastly, this section reviewed the controls put in place to maximize

both the internal and external validity of the research. The subsequent section will review the findings from the data analysis in a narrative format.

Section 3: Application to Professional Practice and Implications for Change

The multiple-case study's applications, findings, and recommendations will be summarized in this final section. The qualitative analysis methodology was deployed in order to obtain a first-hand experience of the leaders directly responsible for mass medical device and pharmaceutical production in modern day Puerto Rico. The goal of the study included an opportunity to witness their leadership styles first-hand and observe their facilities. This allowed the researcher to gather information on the observed soft skills that support their success and gain insight into their thoughts and approaches as they navigate multiple economic challenges associated with operating a manufacturing facility in Puerto Rico.

This section begins with a brief overview of the study that addresses the reality of the economic and environmental challenges facing Puerto Rico's manufacturing environment, particularly with respect to the medical device and pharmaceutical industries and expands into strategic decision-making strategies and its impact on teams. The overview includes a discussion of the study's purpose, the process selected to complete the study, a review of the research questions and a brief summary of the findings of the study. Following the overview, this section will include an in-depth review of the study and their associated findings, to include the summary of conclusions addressing the research question and a discussion of the impact strategic decision making has on the success of an overall operation. This section also includes the role the affective event theory (AET) has on the strategic decision-making strategy. A biblical worldview is presented to ground the research and reflect on how the findings can be further enhanced through the integration of biblical principles. Next, the section highlights a detailed review of the applicability of the findings and its association with the continued operations in Puerto Rico and strategies that will help support continued sustainment and manufacturing

growth on the island, to include areas that may need closer examination. This section transitions to a reflection of the researcher's experience with the research process to include potential personal bias, effects on the participants, and changes in thinking. Lastly, this section concludes with a summary of the key findings, their associated conclusions, and a brief summation of how the research closed a gap in the literature.

Overview of the Study

This qualitative case study explored the effective strategic decision-making strategies manufacturing leaders in medical device and pharmaceutical manufacturing deployed in their facilities in Puerto Rico in order to maintain a successful operation amidst the government bankruptcy and economic instability on the island. This was an important topic because the repeal of Section 936 completed its 10-year phase out, thereby eliminating significant tax incentives to manufacturers of pharmaceuticals and medical devices in 2006 (Pantojas-Garcia, 2016), which resulted in the termination of an economic advantage that once served as a mainframe of this industry on the island for over 40 years. In addition, the inception of the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) as a direct consequence to the largest municipal bankruptcy ever in the history of the world affecting over 73 billion dollars of debt (Colon, 2015) could directly result in heightened fears for existing manufacturers, as well as potential future investors in manufacturing, which poses a significant risk to the future economy of the island. Therefore, the focus of this study was the identification of strategic decision-making strategies and leadership approaches plant managers for medical device and pharmaceutical manufacturing in Puerto Rico exhibited that continue to support the success of pharmaceutical and medical device manufacturing facilities on the island.

The purpose of researching critical decision making strategies was so that other manufacturing leaders in Puerto Rico could implement similar strategies or affirm that their existing strategies are on the right track with maintaining a successful operation on the island as, in some cases, the facilities included in the case study are experiencing growth of the island's existing operation. The ultimate purpose of the study is to help empower leaders with strategic decision-making approaches that will assist in reducing the risk of plant closures and allow a path forward for the island to regain its foothold as a center of excellence for pharmaceutical and medical device manufacturing, which further supports the continued stability of the overall economy in Puerto Rico.

An in-depth review of the associated professional and scholarly literature initiated the steps toward accomplishing the purpose of this study. This review allowed for a solid understanding of the history of Puerto Rico's economic policies pertaining to medical device and pharmaceutical manufacturing and a detailed understanding of some of the larger economic concerns impacting the island in the existing time period. The research of current events enabled the researcher to develop the conceptual framework for this study. This conceptual framework founded itself on the premise that strategic decision making is directly correlated to the overall success and sustainability of an operation (Peterlin et al., 2015; Schneider & Jones, 2017; Self et al., 2015). Strategic decision-making is a direct result of the leader's determinations of their current environment and the pathway forward. This implies that strategic decision making may be heavily influenced by a leader's individual experiences, perceptions and judgements. The affective events theory (AET) is a study based on the correlation of the role emotion has on the evaluative judgement, or further described as the relationship between an individual's behavior and their unique experiences (Ashkanasy et al., 2017). Because the purpose of this study was to

provide leaders currently leading operations in Puerto Rico or striving to lead them in the future, the available research and published findings on the inputs to the strategic decision-making process and the experiential impacts of the plant manager in modern day Puerto Rico, the affective events theory as it pertains to strategic decision-making was selected to ground the associated research.

The qualitative method and multiple-case study design were selected to include onsite observations and interactions with the plant managers for four medical device manufacturing facilities and a representative from their staffs as well as telephone interviews with two executive level leaders from the two larger multinational companies included in the study. This portion of the study included direct observations and a review of relevant documents. In addition, the study include a face-to-face interview with the mayor of one of Puerto Rico's most industrialized townships, which allowed the researcher to gather an in-depth perspective from a government representative regarding the economic situation and the strategic decision making strategies the government is deploying to incentivize medical device and pharmaceutical manufacturing growth on the island. Lastly, the case consisted of a face to face interview with a former global operations leader in Puerto Rico that faced a pharmaceutical plant closure, in order to get a firsthand account of the factors that resulted in the local plant closure.

The findings of this study addressed the associated research questions: What decision-making strategies did the plant managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico? Followed by: What impact did the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have on the strategic decision-making process? The findings were based on the data collected from open-ended interviews, document reviews, and

observations. The observations were obtained when the researcher spent time at each site included in the case study. During the observations the research had the opportunity to tour the facility and see the tangible results of the strategic decision-making process to include the plant goals posted in various areas throughout the facility. The documents reviewed contained examples of the strategic decision-making process to include the diagrams and depictions of the corporate strategic plans, localized for the existing manufacturing operation.

Anticipated Themes/Perceptions

Axial coding was used to disaggregate core themes from the information gathered during the field study and associated research (Merriam & Tisdell, 2016). The goal of this research was to identify the resulting key concepts as is relates to strategic decision-making. Triangulation of the data gathered through the examination of multiple cases and various sources of data further enhanced the reliability and validity of the study. Saturation of the population was validated as commonalities in the responses of the questions were supported through the results of the axial coding. All participants in the case did validate a formal strategic planning session within the last year, and most participants, to include the executive level participants, validated a strategic planning session had occurred within the last three months of the case study interview. In summation, the categories of successful strategic decision making strategies for medical device and pharmaceutical facilities in Puerto Rico were found to be as follows: (a) ensure strict alignment to the strategic objectives of the parent company, (b) allocate time annually, at a minimum, to the strategic planning process, (c) validate alignment across functions within the organization, (d) ensure alignment with local economic partners, (e) develop a focus area for strong and effective leadership, and (f) segment strategic planning into contextual areas of focus. The aligned contextual areas of focus for all plants studied included the following: (a) new

product development and integration, (b) operational excellence, (c) on time delivery and supply assurance, (d) cost competitiveness, (e) quality system maturity, and (f) talent development.

With respect to the impacts the external environment has on the strategic decision-making process, the results determined that none of the participants incorporated factors from the government instability directly into their strategic planning process. Although all participants did identify indirect impact such as the need to manage communication and perceptions with external executives or addressing, the concerns of operations sustainability with the employees and the media sparked rumors over the state of the economy. The participants also addressed the indirect impacts of mass migrations associated with the government bankruptcy and the impacts that it had in both employee retention and talent development.

In addition, the interviews with the company executives and the local economic representative in Puerto Rico resulted in shared themes of executive-level strategies regarding future growth and continued operations on the island. This data further served to support the purpose statement which strove to increase the empirical knowledge of strategic decision-making strategies and reduce further economic impacts on the island tied to plant closures. The axial coding method was used to distill and interpret the collected data. The resulting executive strategies to further support the continued operation of existing manufacturing and the opportunity for future growth and expansion are the following: (a) continued use of favorable income tax incentives for manufacturing operations, (b) government investment or allowed privatization in the improved infrastructure of the electrical utility system, and (c) financial incentive instruments for construction and capital investment on the island.

Through the examination and execution of the four case study companies, the associated executive leaders, and a local economic representative on the island, the findings appear to be

similar with the themes gleamed from the review of the associated body of literature. The plant managers on the island do still serve as the primary drivers of the plant's strategic plans and set the overall perception of the guidelines and adherence to the plans locally. In addition, these leaders also serve as liaisons between the executive leaders and members of the local government, which further serves as critical in the perception of the future for the facility on the island.

The findings of the case study and the literature review are strongly aligned with respect to the demographics of the workforce in Puerto Rico, the continued strong infrastructure of a predominant medical device and pharmaceutical manufacturing presence, the highly educated workforce and the existing challenges of migration resulting from the economic impacts associated with the government bankruptcy, the job losses with plant closures, and Hurricane Maria. The research and the case study both supported the critical nature effective strategic decision-making strategies have on the results of an operation and the essential role of strong leadership or a strong leader has in driving the strategic decision-making strategies. The case study also supported the affective events theory, determining that the external environment and the plant manager's experiences played a role in their approach to strategic decision-making.

One significant difference between the literature and the study findings did emerge. This difference included the continued negative impact the economic instabilities of the expiration of Section 936 of the Internal Revenue Code and the government bankruptcy was having on plant closures and hesitancy for reinvestment on the island. In the study, the findings showed that mass migration, the costs of utilities, and the island's utility infrastructure posed more of an existing threat to the regrowth of the medical device and pharmaceutical manufacturing industry on the island today.

Presentation of the Findings

The resulted findings from this qualitative analysis included interpretations that address comparisons and similarities to the associated research as well as themes and proposed conclusions of the research question. The conceptual framework for this study was built upon the premise that strategic decision making is directly correlated to the overall success and sustainability of an operation (Peterlin et al., 2015; Schneider & Jones, 2017; Self et al., 2015). This implies that strategic decision making may be heavily influenced by a leader's individual experiences, perceptions and judgements. The affective events theory (AET) is a study based on the correlation of the role emotion has on the evaluative judgement, or further described as the relationship between an individual's behavior and their unique experiences (Ashkanasy et al., 2017). Because the purpose of this study was to provide leaders currently leading operations in Puerto Rico or striving to lead them in the future, the available research and published findings on the inputs to the strategic decision-making process, resulting in a sustainable operation through the direct observation and insights of leaders on the ground. The affective events theory as it pertains to strategic decision-making was selected to ground the associated research.

The data gathered for this case study came from multiple perspectives to include plant managers and a member of their staff currently responsible for leading and executing the strategic decision-making process in the facilities. These leaders were all actively serving within a medical device or pharmaceutical manufacturing facility in Puerto Rico during the study. Additionally, two executive level leaders associated with the companies visited on the island were interviewed regarding the strategic decision-making responsibilities for existing operations in Puerto Rico to determine a corporate level viewpoint of the environment in Puerto Rico for medical device and pharmaceutical manufacturing. Lastly, a local mayor for one of Puerto

Rico's most industrialized townships was interviewed in order to gauge the insights of an economic representative on the island, operating under the inception of the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) and the Fiscal Oversight and Management Board. The mayor provided unique insights into the impact the government bankruptcy has had on fiscal reviews at the municipality level as well as the strategies in place between local government leaders and the medical device and pharmaceutical manufacturing facilities operating within their jurisdictions. The research was gathered from interviews, in person observations of the four facilities included in the case study, and a review of relevant documents for the organizations. In addition, all participants were given the opportunity to review the researcher's conclusions from the data to ensure appropriateness and alignment with their inputs and insights.

Case Study Participants. Participant 1 and Participant 2 from Company 1 (P1C1 and P2C1) serve as the Director of Operations/Plant Manager and the Engineering Manager of their respective organization. The organization operates as contract manufacturer of medical devices in the northeastern region of Puerto Rico. The company is headquartered in Minneapolis, but has resided in Puerto Rico since 2004. The plant director joined the organization in 2019, but led their strategic decision-making session in December. With more than 30 years' experience in the medical device industry in Puerto Rico and having served on the energy committee of the commerce department, his wide array of experiences helped define his vision and approach toward an effective strategy decision-making strategy that was scheduled to support a four percent growth rate for 2020 (P1C1, personal communication, March 9, 2020). The engineering manager has served in his existing role for approximately 10 months and concurred the dates of

the last strategy decision-making session and overall focus areas as depicted by the plant manager (P2C1, personal communication, March 9, 2020).

Participants 1 and Participant 2 from Company 2 (P1C2 and P2C2) serve as the Senior Director and Engineering Manager of a large facility in the southeastern portion of Puerto Rico. This facility currently employs approximately 1,100 associates and serves as one of Puerto Rico's largest medical device manufacturing facilities on the island (P1C2, personal communication, March 11, 2020). The organization, a top 10 medical device manufacturer, represents 90,000 employees and over $30 billion dollars in annual revenues. It operates in over 150 countries and serves over 75 million patients worldwide. Both leaders have over 20 years' experience in multiple multinational organizations specializing in medical device manufacturing in Puerto Rico and have experienced the challenges leading medical device manufacturing departments following the Section 936 tax code expiration, Hurricane Maria, and the government bankruptcy in 2016.

Participant 1 and Participant 2 from Company 4 (P1C4 and P2C4) have a combined 50 years' experience leading various departments in a medical device manufacturing facility in the northeastern section of Puerto Rico. They now serve as the Vice President of Operations/Plant Manager and the Director of Manufacturing Engineering respectively. Their organization represents over 10 billion dollars in annual revenue and employs over 36,000 employees at their multiple operations around the world. The organization is categorized in the top 20 medical device manufacturers in the world.

Participant 1 and Participant 2 from Company 5 (P1C5 and P2C5) serve as the Director of Operations and Senior Manufacturing Engineer, respectively, for a site with more than 900 employees in the southeastern section of Puerto Rico. This facility has manufactured medical

devices for over 15 years on the island. Both leaders have over 20 years' experience working in both engineering and operations in the medical device industry in Puerto Rico. Their company is a top 10 medical device manufacturer with over 30 billion dollars in annual revenues and facilities in over 150 countries throughout the world.

The Vice President of Company 4 (VP1C4) is the Vice President of Global Operations Strategy for the organization. He has served as an employee of Company 4 for over 13 years in various roles related to operations and manufacturing. His existing executive level position provides him direct oversight of the operations strategy for the organization in Puerto Rico.

The Vice President of Company 2 (VP1C2) is the Vice President of Contract Manufacturing for a division that operates in multiple facilities to include Puerto Rico, Costa Rica, the US and China (VP1C2, personal communication, March 6, 2020). He has over 20 years' experience in medical device and pharmaceutical manufacturing, including three years as an operations leader at a medical device manufacturing facility in Puerto Rico.

Participant 1 from Company 3 (P1C3) is the Executive Vice President and Head of Operations for a global pharmaceutical company. He is leading the reconstruction and upfit of a new pharmaceutical manufacturing facility in Puerto Rico's north-central region. He is a former Senior Vice President for Global Pharmaceutical Manufacturing for one of the world's largest pharmaceutical manufacturers. P1C3 was also directly impacted when his site closed in the early 2000s (P1C3, personal communication, March 12, 2020). P1C3 served an integral voice for leadership representatives that experienced the direct impact of plant closures on the island and provided additional insights on the executive strategies global manufacturing leaders consider when evaluating Puerto Rico as a location for pharmaceutical manufacturing.

Participant 1, the study's economic representative (P1ER1) is currently serving as a local mayor for one of Puerto Rico's most industrialized townships since first elected in 2012 and was reelected in 2016 for a second term. P1ER1 has had direct exposure to the influences and effects of the new budgets under the Puerto Rico Oversight, Management, and Economic Stability Act of 2016. She provided in depth responses to the approaches the municipality is taking to reinvigorate the economy and manage local investments under a reduced budget (P1ER1, personal communication, March 10, 2020). P1ER1's municipality is recognized as a more industrialized township and currently houses one of the island's largest pharmaceutical manufacturing facilities on the island.

The combined experience of these executive and manufacturing leaders in the pharmaceutical and medical device manufacturing environment in Puerto Rico in conjunction with the firsthand insights of a well-respected government representative actively serving as mayor for one of Puerto Rico's more industrialized townships provided the researcher with an abundance of information for the purposes of this case study. There were many similarities from the participants to include that every single one of the manufacturing leaders concluded that the expiration of the tax incentives associated with Section 936 of the Internal Revenue Code or the recent government bankruptcy in Puerto Rico did not play an active role in current day strategic decisions associated with operations in Puerto Rico. In addition, all participants highlighted the significant industry advantages associated with the local talent of those educated in Puerto Rico, either through local technical schools specializing in tool and die welding or the engineers graduating from the widely respected University of Puerto Rico – Mayaguez campus. The participants also unanimously agreed that the high cost of energy in Puerto Rico represented one

of their biggest challenges in managing existing cost constraints, attracting additional investment, or committing to a long-term strategic position on the island.

The researcher hosted interviews with each of the participants in order to gather data and insights on their perspective of existing manufacturing operations in Puerto Rico. In the case of the manufacturing site leaders and members of their staff, the researcher gathered data through onsite visits, facility tours, documents reviews, and direct communication in which the researcher was able to observe the leadership style of the plant managers directly. The site visits also included a tour of the facilities to directly observe the impact the strategic decision-making sessions had on the layout and communications posted in the production areas. Multiple strategies were identified by the participants as integral to the successful development of the strategic decision-making process for the facilities and their associated teams.

Successful strategic decision-making strategies for medical device and pharmaceutical facilities in Puerto Rico. According to the research, strategic decision making is directly correlated to the overall success and sustainability of an operation (Peterlin et al., 2015; Schneider & Jones, 2017; Self et al., 2015). Strategic decision making is a direct result of the leader's determinations of their current environment and the pathway forward. This implies that strategic decision making may be heavily influenced by a leader's individual experiences, perceptions and judgements. When the plant managers for facilities in Puerto Rico, manufacturing executives, and members of the plant staff were asked about the milestones and focus areas of their strategic planning sessions, responses generally feel into the following categories: (a) ensure strict alignment to the strategic objectives of the parent company, (b) allocate time annually, at a minimum, to the strategic planning process, (c) validate alignment across functions within the organization, (d) ensure alignment with local economic partners, (e)

develop a focus area for strong and effective leadership, and (f) segment strategic planning into contextual areas of focus. The findings associated with each of these six categories are presented below, followed by a description and deeper discussion of the contextual areas all participants highlighted with respect to the six specific key performance indicators (KPIs).

Ensure strict alignment to the strategic objectives of the parent company. The literature on strategic thinking highlights the importance of knowledge sharing and alignment from top to bottom, across leaders at all levels within the organization (Self et al., 2015). While the specific concept of cascading KPIs or metrics was not directly outlined in the literature, the concept of aligning values and strategies to the headquarters global objectives was discussed amongst all participants representing the manufacturing sector demonstrating saturation on this topic. The participants all voiced a direct connection to the strategic objectives of the parent company as a determinant baseline for the direction and strategy of the site objectives. P2C5, an engineering manager, identified the parent company's imperatives as the baseline for the plant's decision-making session, stating:

> Our first imperative is quality, our second is supply, our third imperative is R&D (research and development) or innovation, and our fourth is cost. Safety is embedded in a 'fifth' which serves as a conglomerate of how we operate to include operational excellence and EHS (Environment, Healthy, & Safety). (P2C5, personal communication, March 23, 2020)

Each of these areas highlighted by P2C5 were the strategic objective focus areas outlined by the organization for their global operations strategy and the determining factor for what the facility would ensure they were directly aligned to locally.

During the interview with the one of the more tenured executive leaders, VP1C2, when asked about the primary milestones related to the strategic decision-making session he immediately highlighted the organization's focus on metrics performance in safety, quality, service and cost before providing more granular examples of the exercises in strategy led for his specific team (VP1C2, personal communication, March 6, 2020).

In the case of P1C4, when asked about the baseline and milestones for the plant's strategic decision-making process, the participant highlighted the value of beginning with the parent company's strategic objectives and direction associated with the overall growth, technological, and operational strategy before moving into a more tactical level planning for the facility (P1C4, personal communication, March 13, 2020). This represented a similar pattern among other leader interviews that began with the corporate level objectives as the parent level guideline.

In the case of all the interviews for the manufacturing leaders, each of the leaders began by outlining a clear association to the parent level objectives before establishing a more specific focus on the application of those objectives to the specific focus areas of the facility. This demonstrated a pattern and an industry wide practice of ensuring that facilities on the island were "marching to the same drumbeat" of the corporate operational strategy. This was further supported by the executive leaders, highlighting that the facilities strategy was based on fiscal strategy first outlined by the corporate teams. For example, VP1C2 described manufacturing decisions made for the facility in China to be part of a localization strategy that currently leverages tax incentives for locally made products (VP1C2, personal communication, March 6, 2020), thereby drawing the conclusion that China's plant specific strategies would have to tie

directly into the corporate strategic objectives of delivery associated with the targeted build requirements for that site.

Allocate time annually, at a minimum, to the strategic planning process. Strategic planning must remain consistent in order to be effective. If it is not revisited and prioritized accordingly, it can easily lose its power to serve as an effective tool for progress. One article describes the best methodologies for decision making in understanding the limits of the human cognitive system and describes the importance of selecting data that drives goals that will work in combination an individual's motivation as they seek to make decisions that will support those goals (Walumba et al., 2014). This further serves to support that the human cognitive system and intrinsic motivations serve as dual forces that drive action, therefore consistency in the discussion of the strategic objectives for a facility and visual displays of those messages in an easy-to-remember manner will serve to further facilitate the successful execution of those strategic objectives.

While conducting the research, all the manufacturing representatives confirmed a minimum of one annual strategic planning session. However, in most cases the initiatives outlined in the strategic plan were visited more frequently.

P1C2 and P2C2, employees for the same site, both confirmed the most frequent review of the formal strategic objectives, with P1C2 stating, "Every week in my staff meeting, I set aside at least 2 hours of discussion to go through those strategic objectives and initiatives" (personal communication, March 11, 2020). In the case of other sites, formal strategic objectives reviews tend to be quarterly and can be more focused more on the actual results to the forecasted projections or the financial projections for that quarter as well as a review of the progress made at that point on the annual objectives (P1C4, personal communication, March 13, 2020). In the

case of C4 the visual diagram of the 2020 and 2021 Operations Strategy Timeline was published on the wall of P1C4's office highlighting the timing of the quarterly reviews and the associated inputs for each of those sessions (document C4).

In the case of the executive leaders, the sessions tended to demonstrate more variation. VP1C2 had communicated hosting a session with his direct team in September of 2019, whereas the strategy session he had participated in with both his peers and his direct manager occurred in December of 2019 and February of 2020. It drew a conclusion of the agility happening on the strategic sessions at the executive level, whereas the plants, based on the consensus in their responses held to a more formalized session once a year with quarterly or more frequent follow ups to the agreed upon annual objectives.

In all cases there was a consensus of the importance of hosting a formal strategic planning session with multiple stakeholders once per year at the very minimum. When probed about the value of these sessions as the impact on the operation throughout the year, P2C5 stated, "I cannot envision a way of moving toward the future without that strategic vision. It gives you a 'north,' of which to follow and pretty much it supports that each of those decisions are driven by the imperatives" (personal communication, March 23, 2020).

Validate alignment across functions within the organization. According to the research, the strategic planning process encompasses a portion of thinking and brainstorming in conjunction with the specific planning elements (Steptoe-Warren et al., 2011). Therefore, the execution of data gathering and input realization from critical stakeholders, both internally and externally, serve as an essential part of establishing enough data and viewpoints to proceed forward with the strategic decision-making planning session. As an example for collaborative effectiveness, Intindola, Weisinger, and Gomez (2016) conducted a study testing the

effectiveness of the strategic decision-making process within multi-sector collaborations and determined the improved results of collaboration partners exists when the scope of the collaboration is defined upfront and the levels of interdependence are defined, but in general, collaboration drove improved processes for strategic decision-making.

Peterlin et al. (2015) posited that strategic decisions are "major decisions characterized by strategic positioning, high stakes, and the involvement of several of an organization's function" (p. 274). Thereby, this is additional research that further supports the involvement of inputs from areas throughout the organization, particularly those closest to the execution of the products and services that will drive company value and market impact.

The research in Puerto Rico confirmed the consistent practice of gathering information from multiple parties within the facility in order to establish inputs from multiple stakeholders. In addition, each manufacturing facility leader focused on the importance of cross functional alignment in order to ensure maximum efficiency and output. P1C5 stated, "We usually go two levels down into the organization to invite them to these sessions" (personal communication, March 12, 2020), as a traditional manner of practice during the strategic decision-making process. In addition, the plant manager highlighted the establishment of specific project initiatives by the front-line teams and their leadership operating on the floor. In reviewing the importance of cross functional alignment, he went on to describe that "we assign the basic improvements in the areas, led by the direct labor. They get support from engineers and the supervisors – when its needed, but the majority of the improvements is managed by themselves" (P1C5, personal communication, March 12, 2020). This example demonstrates the importance of front-line engagement and alignment to the strategic objectives as they would be directly responsible for leading these initiatives throughout the course of that strategic operating period.

The engagement of middle managers and leaders within the plant's specific departments also posed as an essential and standard practice throughout the strategic planning process. In the literature it was highlighted that

> Strategies formulated with knowledge from middle management and other relevant individuals within an organization, rather than just the strategic thinker are likely to be superior as consideration is given to both information regarding what actions are required as well as whether the actions to be taken are operationally possible in terms of resources. (Steptoe-Warren et al., 2011, p. 240)

In the discussion on the recent decision-making strategy session for a new startup in Puerto Rico, P1C3 described his cross functional participation as a first-time initiative. The team had never collaborated on the strategic objectives before. When describing his perception of the initiative he stressed,

> This is the first time we do it. We knew we needed to do it, because we are a small company in a period of growth, and we needed to ensure we were aligned with one common strategy and one common set of objectives to move us to achieve that strategy. That was the thinking behind it. (P1C3, personal communication, March 12, 2020)

Having served as a global operations leader for a pharmaceutical organization in the past, P1C3 understood the criticality of involving all stakeholders, cross functionally to support the strategic planning session and provide their individual inputs to ensure overall alignment. A cross functional approach not only allows the planning session to include the variable and considerations of various functional areas, but also allows the leaders from each of these areas to hear the priorities and considerations from the other various departments and tie them together in a unified manner for an overall corporate objective.

Ensure alignment with local economic partners. The location of the facility plays a critical role toward determining and establishing the competitive advantage for the facility. According to the literature, Miltenburg (2009) highlighted the industry and geographic location of the facility as a major contributor to the overall manufacturing strategy. When interviewing VP1C4, whose title is currently Vice President of Global Operations Strategy for the organization, he communicated the annual review and focus of each facilities capability as part of the corporate strategic decision making process to include the capability of the facility, the ability to source strong local talent, and the auxiliary benefits of government tax incentives and support (VP1C4, personal communication, March 13, 2020).

Each of the manufacturing site leaders interviewed took pride when discussing their role in supporting the local economy and the advantages the relationships with local economic leaders had on the facility overall. This included local government incentives established through relationships with the local townships as well as established relationships with local areas schools that helped support partnerships as an employer of choice. P1C4 highlighted her goals for the facility on the island to be open and communicative with the local economic leaders by visiting the local economic development office monthly (P1C4, personal communication, March 13, 2020). She went on to state, "You also have to be very close and collaborative with the economic development office in Puerto Rico. Which is one of our strategic swim lanes that we pursue" (P1C4, personal communication, March 13, 2020).

The partnerships with the local schools also provide added benefits to the strategic advantage for the facilities and allows them to compete globally in specific areas of manufacturing. According to multiple site leaders, Puerto Rico provides a strategic advantage in the highly technical skillsets of tool and die operations. P1C1 has heavy requirements for skilled

tool and die application at his facility, when asked about the advantage of economic partnerships, he stated,

> Our employee base are tool and die makers. Across the street we have a school of school and die makers that provide us more than 80% of our new hires for tool and die makers. I've partnered with the school next door and it has worked very well. I have not suffered from a lack of students because of the location of the school to the operation and the set up that we offer on the manufacturing floor. (P1C1, personal communication, March 9, 2020)

P1C5 is also responsible for a large facility that is heavily based on the partnerships with schools providing a strong technical base and focus of study. Referencing Tim Cook's (CEO of Apple) interview on 60 Minutes, in which the CEO highlighted the significant shortage of tool and die makers in the Unites States, P1C5 highlighted the following:

> I have 300 of those here…So why do we keep bringing business here? It requires basic training and a lot of experience. And then we invest a lot in finding the right talent, nurturing that talent, retaining that talent and developing that talent (at the facility in Puerto Rico). (P1C5, personal communication, March 12, 2020)

When interviewing all manufacturing personnel, to include the executive leaders, they each provided examples of critical skillsets the people at the facilities in Puerto Rico played in the continued growth and investment of the facilities on the island.

The interview with a local mayor in one of Puerto Rico's townships also further supported the importance of economic partnerships to stem additional growth and development on the island. P1ER1 described her initiatives in providing financial incentives as a common measure to help support growth on the island and in her municipality (P1ER1, personal

communication, March 10, 2020). It is not unusual for her to waive local municipal taxes in support of growth initiatives for local manufacturing centers. P1ER1 states that when challenged by others that she is allowing these companies to avoid paying certain taxes, she responds by stating:

> These are the factories that are employing my people. So, this allows me an opportunity to give them a win to win option, and by reducing some payments it shows them that we are willing to work with them and shows them that we are an attractive place to be. But in doing so, I ask them to employ a certain percentage from my local township. This guarantees jobs for the people in our township and this allows the economy to go full circle. (P1ER1, personal communication, March 10, 2020)

The confirmation of the economic initiatives providing value for both the manufacturing organization as well as the citizens of the island further serves to support that in Puerto Rico there are plentiful opportunities whereas despite the government bankruptcy the local municipalities have available instruments to incentivize investment and growth in their specific regions. P1C3, currently responsible for overseeing the establishment of a new facility in a Puerto Rican township, stated:

> The other very important strategic decision is building relationships on the island, not only with the government but with key players on the island, such as the pharmaceutical industry. Whether they are pharmaceutical designers, whether they are architects, builders, a company that does qualification and validation work. Companies that provide services. Yes, they will sell to you. That's their business, but they will assist with other things outside of just the selling. And so, building that network, that relationship, those

> relationships have been very important. (P1C3, personal communication, March 12, 2020)

Develop a focus area for strong and effective leadership. Kisfalvi and Pitcher's (2003) study in the literature on the impact the emotional state of a CEO has on the results of top management teams (TMT) demonstrates a direct correlation between leaders or leadership and the strategic decision making process, providing results that traditional methods of diversification within the TMT is not enough if its decoupled by a lack of support or interest by the CEO of the organization. In addition, the research on the impact of servant and sustainable leadership further demonstrates as it relates to the strategic decision-making process, this style of leadership is determined to be the most effective, as the leader is inclined to "make strategic decisions that take into account the economic, social and ecological dimensions of such decisions, as expressed by various stakeholders" (Peterlin et al., 2015, p. 290).

VP1C4 highlighted the value of the local talent and leadership in review of a facility's strategic potential in the existing network, stating, "We then look at the ability of hiring the correct and right talent for that location" (VP1C4, personal communication, March 13, 2020). P1C3 also talked about the company's dedicated search to the right leadership when seeking to launch a new facility and operation in Puerto Rico stating:

> So, to show he was fully committed he brought in the right people. He contacted me because I've been in this industry for 32 years. I've got a lot of experience. I've done big company; I've done small companies and I was a good fit for that. And even though we are a small company, we've been very selective of the people we brought on board. So, he not only committed to Puerto Rico, he committed to bringing on the best people. He's done a good job at that. (P1C3, personal communication, March 12, 2020)

In the case of both examples it is clear that multinational organizations need to ensure they have local leaders on the island they can trust and will serve the community in parallel with the needs of the broader organization.

The leaders interviewed successfully operating a manufacturing facility also aligned on the importance of their role to clarify the actual happenings on the island versus the media coverage that may skew events on the island for a more sensationalistic approach. For example, P1C4 provided one example, explaining:

> So, we have to always be upfront with corporate, just to give them peace of mind. So, let's say PROMESA came, we communicated immediately to say, 'We acknowledge this is happening on the island, but there's no impact to the private sector.' Because the media coverage can be very misleading. (P1C4, personal communication, March 13, 2020)

P1C5 had a similar experience, highlighting:

> It worries people, when people read in the news there's a new tax…We have to come in and say, 'This may or may not affect us.' The majority of the time it does not affect us. But it worries people. (P1C5, personal communication, March 12, 2020)

In the cases of these leaders serving as plant managers, they realize that a consistent requirement for them as leaders is to serve as liaisons between the environment in Puerto Rico and the perceptions of the management team.

As a result of understanding that strong leadership is a core advantage to continued investment and growth on the island, leaders ensure that leadership development is an essential focus area in terms of the strategic planning for the site. The investment in the next generation of talent and leaders will further support the cause for strong and profitable operations on the island. P1C4 described the leadership strategies as one element of a four-segment value proposition for

the factory. In her description of the factory's competitive advantage she explains, "The first element is talent, so what we continue telling the team: What's in it for you here is that we are making sure that we are attracting, engaging, and retaining the best talent available on the island" (P1C4, personal communication, March 13, 2020). The representative of her staff, P2C4 caveated even further, highlighting:

> Leadership today is more into what we project, living our values from a company standpoint, adapting ourselves to a changing environment, which requires more agility, more flexibility of our leaders. So, this is no longer like a senior leadership strategy, this is more like a site leadership strategy. And that pertains as well to the lower levels, leadership across every single function at the site. In my opinion, that is what is helping the whole community that lives here. (P2C4. personal communication, March 13, 2020)

With the unique requirements of leaders leading internationally operating facilities, owned and managed by American and European companies, among others, the consensus among the manufacturing leaders participating in the research is the critical element of leadership and leadership development programs in the premier development of world class strategic decision-making strategies.

Segment strategic planning into contextual areas of focus. A deep review of the design of the manufacturing strategy that will best propel a manufacturing network forward in an international setting was developed and Miltenburg (2009) reported "that each focused factory in a manufacturing network provides six strategic outputs: cost, quality, delivery, performance, flexibility, and innovativeness for each product family produced in each focused factory" (p. 6186). These six strategic outputs represents three of which were identified across all of the facilities researched in Puerto Rico. The concept of segmenting the strategic planning decisions

into contextual areas of focus was recognized and highlighted across all sites and all manufacturing participants interviewed, thereby concluding that saturation was reached in determining this segmentation to be a critical strategy toward effective strategic decision making for medical device and pharmaceutical factories in Puerto Rico.

Each of the facility representatives mentioned the development and integration of key performance indicators (KPIs) as a direct output used to measure the performance or adherence to target in each of the agreed contextual areas of focus. In the case of the first company, P2C1 posited that the review of their KPIs served as the initial baseline for the strategic planning review and helped to identify their focus areas based on how they had done in the previous year (P2C1, personal communication, March 9, 2020). He concluded that the team used "scrap data…our machine utilization and…our process performance such as efficiencies – machine efficiencies, labor efficiencies in comparison to our standards to ensure we are meeting them" (P2C1, personal communication, March 9, 2020). Hence, he was able to define reviews in the areas of quality, cost and delivery in machine and labor efficiencies. P1C2 went to even greater detail as he highlighted the company "imperatives" which is a word they use to describe the strategic objective area stating, "Yes, we operate under five imperatives (pillars) quality, supply, innovation, cost, and organizational excellence. What we do is identify specific KPIs or tangible targets that we want to accomplish in each of these imperatives" (P1C2, personal communication, March 11, 2020).

What the researcher was able to determine was that the use of breaking the strategic objectives into contextual areas of focus was exercised by all facilities evaluated. This leads the researcher to further summarize that the use of determining the specific areas of focus and

establishing key performance indicators under each of those areas is a critical strategy for the execution of effective strategy decision-making for the facilities in Puerto Rico.

Contextual areas of focus within the strategic decision-making strategy. According to Self et al. (2015) "top managers must strive to create an environment of learning from top to bottom within the organization, where knowledge gained through concurrent scanning and review should be conscientiously managed to enhance overall strategic thinking, as well as organizational alignment" (p. 11). In the case of the facilities in Puerto Rico, the use of visually posted KPIs served as a tool to support the gaining of knowledge through concurrent scanning and review. These metrics, tracking specific areas in the business are segmented and reviewed by the teams and the plant leadership. They serve as a diagnostic tool to determine whether the facility is operating at its optimum performance. Direct observation during the tour of the facilities, as well as the responses during the interviews, highlighted a consensus of the seven most widely attributed areas of focus for the strategic planning objectives. These specific categories were highlighted by participants at all levels of the organization and in all cases, served to identify the contextual areas driving most of the strategic efforts and initiatives for the business. In addition, by establishing a regular cadence to observe the measurement of the actual results to the targets for each of the categories below, the businesses, and more specifically, the factories in Puerto Rico are demonstrating the culture of accountability and adherence to these targets of these identified areas.

Papke Shields and Malhotra (2008) highlighted the significant shift the role of manufacturing has taken from its initial focus, referencing a 1969 article written on manufacturing's priorities of "time and motion techniques, efficiency studies, job shop, scheduling, plant layout and material handling" (p. 861) to the more recent focus areas as

referenced by surveys where manufacturing now plays an important role in the area of new product development, supply chain, personnel decisions, and information technology ventures. The role of manufacturing from a value stream perspective has significantly changed. Below the seven primary categories for the contextual areas of focus, highlighted in the field study, are summarized as they are being integrated into the operations in Puerto Rico's medical device and pharmaceutical factories.

New product development and integration. New product development and integration is the practice of designing the company's future product offerings as well as driving continued innovation and improvements to their current product portfolio. P1C3 emphasized the absolute criticality of integrating this area of the business into the manufacturing strategy, stating:

> Typically, when people talk about manufacturing organizations, they talk about 3 things: quality, service, and cost. I have a 4th one – new project portfolio. Because the new project portfolio is what moves the company forward. Supplying product and generating revenue, that's what you do, day in and day out. The step changes are driven by projects. These projects are driven by new products, new facilities, new markets, line extensions. They are all projects and you have to take care of that also, because if you don't take care of that, you can stifle the growth of your company and the forward movement of your company. (P1C3, personal communication, March 12, 2020)

VP1C2 also highlighted the new product design review as a critical factor for growth and investment in the existing factory operating in Puerto Rico. He states:

> The decisions of what to move into Puerto Rico or what to move out of Puerto Rico are primarily driven on maturity of project lines [i.e., how difficult is it to set up a line or how difficult it is to move it]. (VP1C2, personal communication, March 6, 2020)

This is further supported by the local leaders at the facility VP1C2 was referencing as both P1C5 and P2C5 both mentioned the expertise in machining and precision measurements that they have at their facility in Puerto Rico, which continues to provide them a competitive advantage for the organization and supports a long term manufacturing strategy on the island. P2C5 highlights a program he designed directly with respect to the metrology training program and the new product pipeline, stating:

> We developed a road map for training of our resources in machining and inspection methods and that has put us in the leading edge…these latest products are so complex, that's there no other option but to bring them to Puerto Rico in order to manufacture them because we have the "know how" and the people here are trained well enough to ensure that the product will be successful. (P2C5, personal communication, March 23, 2020)

Operational excellence. Shanley (2017) discussed the importance of incorporating operational excellence into the pharmaceutical industry, claiming that a focus on operational excellence as a key performance indicator is a direct result of the US Food and Drug Administration's (FDA) direct collaboration with the pharmaceutical manufacturers. Operational excellence, or organizational excellence as it is called in C2 and C5 is a measurement of initiatives to drive continuous improvement in the operation and remove non-value-added activities that the customer is not willing to pay for. The goal of operational excellence when partnered with other areas of the business is to eliminate costs and inefficiencies associated with wastes in the value stream. P2C2 talks about the company's focus on the pillar of organizational excellence, stating, "This pillar is central to everything we do here. We have dedicated teams that are targeted to drive improvement projects that will continue to make the factory in Puerto Rico

widely admired for its commitment to excellence" (P2C2, personal communication, March 11, 2020).

Operational excellence ensures that the facilities in Puerto Rico remain focused on the future. The programs are available to ensure certifications validate these initiatives. According to P2C5, "From the OPEX [operational excellence] side of it, we have been celebrating system conversions, and people certifying in black or green belt certifications" (P2C5, personal communication, March 23, 2020). The focus on waste elimination provides cost incentives and service performance that keeps the island at the forefront of the competition among other sites in the network.

On time delivery and supply assurance. The fundamental measure of the manufacturing facility's performance is its ability to deliver quality products in conjunction with market demand. On time delivery and the ability to assure a committed supply to the organization's customer base is at the heart of measuring a facility's ability to perform. When factoring in the inputs for decision making, P1C1 commented, "If I'm making decisions, I need to ensure I have the system providing the most accurate data possible. This system will provide us on time delivery (OTD), down time, and machine utilization" (P1C1, personal communication, March 9, 2020). These inputs were essential in his ability to determine that the OTD performance metric was initially not doing well and allowed him to begin to shift his focus toward a longer-term view rather than just reviewing what had to be produced that day. The factory at the end of February was now averaging 98% OTD (P1C1, personal communication, March 9, 2020).

When reflecting on the criticality of the metrics, P2C1 stated, "We have to be very competitive in that aspect and we know that delivery times are the most critical things to our customers, sometimes even more so than price" (P2C1, personal communication, March 9,

2020). P2C5 also agreed that measuring the supply plan and delivery metrics served as the heartbeat of the facility's metrics confirming that, "The same goes with supply, we measure inventory, backorder, product attainment or plant attainment and availability" (P2C5, personal communication, March 23, 2020).

Cost competitiveness. Manufacturing facilities derive a large portion of their value to the organization based on the cost competitive position. Their goal is to minimize the total cost of ownership and maximize the available margin using good cost management practices. Weber et al.'s (2010) article highlighted the strategies and pitfalls of low cost country sourcing as a failsafe method for reducing the cost of materials (which is often the highest cost in the cost of goods sold), stating that, "In many cases the main criterion for supplier selection is purchase price. However, other direct or indirect costs are related to the purchase of goods and should also be taken into account" (p. 4). This statement is based on the ideology that challenges with language barriers, time zones, and initial quality results of the product pose significant costs to the parent organization that are not directly tied to the overall cost of the product (Weber et al., 2010).

Puerto Rico's official language is both English and Spanish, thereby ensuring that many of its citizens are fully bilingual. Its proximity to the United States also aids from a time zone perspective. Although the minimum wage following Hurricane Maria significantly dropped the rate below the US minimum wage (P1ER1, personal communication, March 10, 2020), the cost of skilled labor on the island is similar or comparable to the US, eliminating its consideration as a low-cost country option for manufacturing. As a result, the plant leaders must ensure that they are able to offset the labor costs associated with the management and skilled labor with other cost factors, such as cost of poor quality.

P1C5 proudly highlighted, “We are competitively able to improve our costs, year over year, so every time we become more attractive” (P1C5, personal communication, March 12, 2020) when discussing his cost position at the factory, given the large portion of skilled labor he houses in order to support the manufacturing of machined implantable components designed for some of the body’s most sensitive areas. P2C4 was well acquainted with the need to ensure a cost competitive position in the manufacturing network, stating, “We focus on our resources, our technical abilities, and the infrastructure to extend beyond just the building, and our return on investment” (P2C4, personal communication, March 13, 2020).

When asked in more detail how the organization manages the inputs of the strategic decision-making process are managed in Company 5, P2C5 added, “We go to “cost” where we have KPIs like scrap dollars and cost down percentage” (P2C5, personal communication, March 23, 2020). The support of KPIs for cost management, such as scrap values, inventory management, and equipment efficiencies and downtime were shared themes and focus areas across all the plants in Puerto Rico.

From an executive perspective VP1C2 described the following process in reviewing cost performance at the strategy level. He stated the following:

> We’d also look at the financial performance in the previous quarter or previous fiscal year, depending upon the time horizon for the strategic planning session and we would assess how we are doing against those goals and objectives and whether or not we need to take additional action. (VP1C2, personal communication, March 6, 2020)

The reality is that despite Puerto Rico being a Commonwealth of the United States, and considered an international operation for some intents and purposes, the labor in Puerto Rico are considered Americans and do not need a passport to live and work in the US, therefore the labor

costs must be comparable to incentivize talent to remain on the island. Understanding these cost constraints on labor, it is a general practice in the strategic decision making process for leaders on the island to maximize cost competitiveness through other areas of the business, to include 'soft costs' that tie to the research as a measurable factor in the total cost of ownership.

Quality system maturity. Geyer et al. (2019) defined good manufacturing practices as a system that ensures products are repeatedly produced in a way that lies in accordance with the quality standard. Medical devices and pharmaceuticals are heavily regulated by products under the direct authority of notified bodies such as the US Food and Drug Administration (FDA) for the United States or the European Medicines Agency (EMA) for European countries. Adherence to the auditable quality practices of a medical device or pharmaceutical manufacturing facility is non-negotiable and deeply embedded in the manufacturing culture of the four facilities included in the case study.

The quality management system is a framework of business processes that are in place at each facility to ensure adherence to regulatory guidelines. The participants interviewed in Puerto Rico all highlighted the history Puerto Rico has [over 50 years] specializing in the manufacturing of medical devices and pharmaceuticals and highlighted the advantages that has over other countries with respect to the local knowledge base on the island to regulatory adherence. P1C4 mentioned:

> When you look at all of the landscape toward operating in Puerto Rico, you have the regulatory environment set up. More than 50 years of experience and the FDA district office here in San Juan. That says a lot, right? That talks a lot about the movement. (P1C4, personal communication, March 13, 2020)

With respect to the current initiatives that each of the factories are driving, all manufacturing facility representatives highlighted the strength of the quality systems at the facilities in Puerto Rico and the approaches they are taking either through KPI management or through the simplification of the existing system to drive efficiencies without compromising the quality standards. P1C1 mentioned:

> I have been tasked to look for areas to simplify the quality system. We have an area of quality that is very robust, but there's a point where you, as a manufacturer, loses time and money because of the excess requirements for the quality requirements. (P1C1, personal communication, March 9, 2020)

P2C5 provided additional examples of some of the facility's existing metrics, stating, "those KPIs, for example in quality, are defects per million and audit observations from external and internal audits. We have yields as another input among others" (P2C5, personal communication, March 23, 2020). There was a consensus amongst the staff members of the plant managers, the site leaders themselves and the executives that the backbone of manufacturing medical devices and pharmaceutical was to ensure the continuous focus and improvement of the quality system.

Talent development. Businesses need talented leaders that understand the decision-making process and how it will affect the organizations around them. The medical device and pharmaceutical factories in Puerto Rico are no different. In order to keep these facilities at the forefront of global manufacturing competition, they must ensure they have an organic process for talent development to include the mentoring and development of the next generation of leaders as well as programs that are able to refine the strengths and capabilities of highly specialized skillsets in short supply throughout the world. Peterlin et al. (2015) described the impact strong leaders with a servant leadership style have on the organization's ability to execute the strategic

plan, stating that “servant and sustainable leadership approaches have a unique contribution to make to enlightened strategic decision making in this expanded context of responsible leadership that other leadership theories cannot make” (p. 274). P1C4 was very proud of her facility’s approach to collaborative leadership stating:

> I think from a leadership style, we tend to think about what a world class organization would look like and what are those behaviors. My team focuses on those behaviors and the systems that are applied to those systems. So, a lot of collaborative approaches. We don’t do hierarchy approach at all. It’s a lot of collaboration. (P1C4, personal communication, March 13, 2020)

This was further supported by her staff representative as he highlighted that after working at the facility over 31 years, one of the most notable differences was the change to a more collaborative and more servant leadership style, which was driving the organization to operate more efficiently and with a greater focus on the strategic direction (P2C4, personal communication, March 13, 2020).

In addition to the leadership programs, the focus on collaborative leadership styles and a servant leadership model that is becoming more widely favored by organizations around the world, Puerto Rico is also heavily focused toward capitalizing on its niche in trade skills and world class engineering programs in the local universities. The facilities are recognizing the advantage they have in this area and are investing in promoting additional training and development in this area.

P1C1, P1C5, P1C4, and P2C5 all spent time in their interviews commenting on the strength of their position as leaders within the global organization for the talented employees they had in the more technical fields of machining, measuring, and metrology. P1C4 provided

examples of the advantages her facility in Puerto Rico has built with its reputation to supply world class talent. She stated:

> I have access to really good technical talent because we've been doing med devices and pharma in Puerto Rico for 50 years. So, I got people right now in Brazil doing things that have nothing to do with what we do here…but they have a set of skills that could help the facility in Brazil. I've got engineers in Costa Rica and in California because they have the skillset that the network actually needs from us. (P1C4, personal communication, March 13, 2020)

P1C5 agreed that the advantage he would build with the talent in Puerto Rico was helping to continue to keep Puerto Rico as an integral business unit for the parent company. With respect to the specialized skill sets in his facility, he stated:

> We invest a lot in finding the right talent, nurturing that talent, retaining that talent and developing that talent. So, this guy [a senior engineering manager] … is a very unique guy and he has a level of knowledge around making a part and measuring a part, which it's sometimes a lot harder to measure a part than to make a part. It's very hard to duplicate what he has in his brain. So sometimes the company wants to do something somewhere else and they end up here. (P1C5, personal communication, March 12, 2020)

In summation, the available talent on the island on the island and their demonstrated skillsets, which are evidenced by their deployment to manufacturing projects around the world, further highlight why the factory's commitment to the most effective leadership strategies and continued focus on talent development for technical skills must remain a top priority item as an effective decision making strategy for leaders in Puerto Rico.

Impact of the external environment on the strategic decision-making process. In 1996 incentives associated with section 936 of the Internal Revenue Code expired, thereby eliminating a 100% credit for US corporations on income derived from operations in a qualified possession, including up to 25% on passive income and up to 75% on active income as well as income attributed to intangible property licensed to a Section 936 corporation (DiPiero, 1997). Congress eliminated Section 936 via a 10-year phase out through the Small Business Job Protection Act (SBJPA) as a response to increasing tax revenues which completed its phase out in 2006 (Feliciano, 2018). According to Toledo's (2017) article, the expiration of Law 936 in 2006 for all existing business on the island resulted in a nearly 50% drop of the island's manufacturing industry.

In 2015, Puerto Rico failed to initiate payments from money's borrowed through the bond markets and threatened to become the first ever US state and/or territory to declare bankruptcy as well as the largest municipal filing bankruptcy in history ("A Crippling Blow," 2017). According to the research, this type of government instability began to cause executive leaders with deep investments in Puerto Rico to question whether or not the risk was too high to continue with their investments, particularly in the areas of manufacturing, where the infrastructure and annual costs can be directly associated with government stability and tax payments ("A Crippling Blow," 2017). As of 2017, the island continued to house over 30 pharmaceutical manufacturing centers and nearly an equivalent amount of medical device manufacturing facility, although this represented a nearly 50% decline in manufacturing operating on the island in conjunction with a population decline of nearly 400,000 people from 3.8 million to 3.4 million from 2016 to 2017 (Rawlins, 2018).

According to one article, the behavior of firms under declining conditions or resource constraints has not been widely considered in corporate sustainability literature. However, following the US economic recession of 2008, Panwar et al. (2015) conducted research to determine that the core initiatives of the business remain intact, whereas the peripheral initiatives, particularly those that operated in a relatively dynamic context, significantly declined in correlation with the downtown in financial performance. The role of the executive and plant leaders is to evaluate their environments strategically, understanding both the internal (personal and human) and external (environmental, economic, financial) factors and the impact they can have on the future of the organization and its intended direction (Steptoe-Warren et al., 2011). This would imply that the state of the economic situation and the impact of the government bankruptcy in Puerto Rico would have a direct effect on the strategic decision-making process and would thereby be directly incorporated into the annual strategic decision-making process.

When leaders were asked how the local government's current financial instability factored into the strategic decisions for the follow-on fiscal year, all manufacturing representatives interviewed concluded that the governmental economic situation was not directly factored into the strategic decision-making strategy but had more indirect implications. In fact, when interviewing the Vice President for Contract Manufacturing, his response to whether or not Puerto Rico's government instability provided an input into the manufacturing strategy, he concluded that it did not have any impact and was never discussed in all his strategic level discussions regarding the operations at the facilities in Puerto Rico (VP1C2, personal communication, March 6, 2020). P1C4 supported the shared feedback that the government instability did not apply a direct impact, stating, "From a financial standpoint, we were able to secure our financial plan. Things like PROMESA, they don't impact the private system, so they

wouldn't necessarily impact that" (P1C4, personal communication, March 13, 2020). The general consensus was that evaluating the government instability as a direct input into the annual strategic planning was not a consideration for the factories, but there were ongoing collaborations with the local government with regard to plant strategic initiatives.

P1C2 was very positive with respect to the role government support and collaboration has had and the impact to his facility. He stated, "We have actually had an excellent relationship with the local government, to the point that they have become key enablers in our achieving the strategic vision and enabled some of the significant growth that we are experiencing" (P1C2, personal communication, March 11, 2020). P1C5 shared a similar sentiment, highlighting, "The government is very supportive of manufacturing still on the island. And they still have a budget to support this type of presence and investments" (P1C5, personal communication, March 12, 2020). The goal of the local governments to partner with manufacturing operations and help drive growth and stability was further reinforced in the discussions with the local mayor of one of Puerto Rico's townships, where she highlighted her efforts to provide tax incentives for new industries seeking to establish themselves in her township or local municipal tax reductions and waivers for existing operations as a means of joint support between the operation and the government (P1ER1, personal communication, March 10, 2020). P2C4 further corroborated the support of the local government stating:

> I would say the local government is maximizing basically the different programs. I would call it incentives to attract but also to sustain the development in Puerto Rico, in this case manufacturing. Medical device is a type of manufacturing and basically the ones that are driving the most, the 80% of the island's economy. (P2C4, personal communication, March 13, 2020)

The perception of local government support reached saturation as participants continued to provide similar responses about the efforts the local government was making to help support industry on the island.

The manufacturing leaders did also concur on the indirect impact the government instability has had on either managing perception of executive leaders outside the island or other indirect consideration for the site's overall strategy. P1C4 expounded on the distinction between direct and indirect impacts associated with managing the perception of executive leaders, stating:

> We must always be upfront with corporate, just to give them peace of mind. So, let's say PROMESA came, we communicated immediately to say, 'Hey, we acknowledge this is happening on the island, but there's no impact to the private sector, because the media coverage can be very misleading.' (P1C4, personal communication, March 13, 2020)

In addition, with respect to the indirect implications, the Vice President of Global Strategies stated that government instability definitely drives more questions the previously done, but it certainly has not caused the company to pause its existing strategy on the island (VP1C4, personal communication, March 13, 2020). P1C1 also discussed the indirect implications as it relates to the government's management of the cost of energy and the electrical infrastructure and the purchase of equipment, stating, "If I need to buy five machines, I won't do that. I will only buy three because of the cost of energy, knowing the cost of energy will rise. I will have the buy the remaining two next year" (P1C1, personal communication, March 9, 2020).

As a consensus, all participants concluded that there was not a direct impact the government instability has had on the overall strategic decision-making process. There were no direct focus areas targeted to navigate the challenges associated with the government instability or measures put in place in the facilities annual plans to directly address the new financial

oversight board or the provisions associated with the government bankruptcy. The wide majority of the participants were able to highlight multiple indirect implications resulting from the government instability. This included executive perceptions of the territory's future stability as an operational asset, the resulting implications on the cost of energy, employee retention strategies as a result of mass migration, and the future implications of the resulting tax liabilities for businesses operating in Puerto Rico.

Resulting strategies to further support the continued operation of existing manufacturing and the opportunity for future growth and expansion. Anderson (2009) highlighted the traditional knowledge of executives by stating: "decades of wisdom about foreign market entry tells managers to assess whether their unique skills and capabilities might offer comparative competitive advantage" (p. 276). Anderson (2009) stated that "they are encouraged to analyze these potential hurdles carefully, and decide if their company-specific skills and capabilities outweigh country-specific challenges in operating abroad" (p. 276). One provision often used in the international business setting to enhance the development of an "infant industry" in a particular region is the use of tariff protections that are in place to help support the refining of an industry and allow for an increase in industry experience and increased productivities associated with the protections provided by tariffs (Harris et al., 2015). While pharmaceutical and medical device manufacturing is no longer an infant industry from the perspective of gaining industry experience, the entire abandonment of long-term tax incentives eliminated a direct and strong incentive for pharmaceutical and medical device to continue growing and investing in other regions with favorable tax offerings. In the subsections below, three overlying themes rose to prominence in how the participants, particularly the executive level leaders and the government representatives, determined to best mitigate additional plant

closures on the island and restore the strength of the medical device and pharmaceutical manufacturing industry in Puerto Rico.

Continued use of favorable income tax incentives for manufacturing operations. Favorable tax incentives will draw industry back to the island, particularly for US based corporations as the logistical advantages for Puerto Rico's position to North American markets far outweighs Asian countries like China and India. In the case of a country like Ireland, which continues to benefit from one of the lowest corporate tax rates in the world at 12.5%, their tax incentives continue to remain a stimulant in a country which not only protects its foreign direct investment through low tax rates, but also through additional tax incentives derived by the increasing value of intellectual property (Barker, 2016). Ireland is an excellent example of a country that has leveraged their tax programs to protect their nation's economy. VP1C2 is directly responsible for sourcing strategies for a Fortune 100 medical device manufacturer and identified the decision to manufacture and source in China as the following:

> Getting moved to China, that's a different scenario because the government has a localization mandate where at some point…they're going to have a two-tiered reimbursement structure. If you make it in country, you get 100%. If you import it, you get 50% of the existing reimbursement rate. So, what that's doing is, it's driving a lot of companies to look at how they can build what is consumed inside China, inside China. It's not a 100% scenario, you don't have to build 100% of it, but there's some type of import ratio/threshold that you must cross over in order to maximize your ability to get max reimbursement rates. (VP1C2, personal communication, March 6, 2020)

This further supports that for Puerto Rico to further establish itself as a manufacturer of choice for the global medical device and pharmaceutical manufacturers, it will have to compete globally with comparable tax incentives.

Improved infrastructure of the electrical utility system. The damage to the electrical grid in Puerto Rico following Hurricane Maria, the monopolization of the electric utility industry on the island, and the overall cost of power were all three deterrents or current causes of concern highlighted by the participants when considering the government instability's impact on the strategic decision making process or the challenges for further growth of the manufacturing industry on the island. P1C1 had the opportunity to lead the energy committee for the Department of Commerce on the island for seven years and had direct access to influence legislation. When highlighting the challenges of the cost of energy on the island he stated:

> Our major cost in industry is energy. A lot of industries have started trying to decouple and separate themselves from the government, because even though it's a very big cost per kilowatt hour, they are introducing legislation to increase that cost and that will have a devastating impact, not only for industry, but for the people on the island…This is very devastating because industry is very equipment driven. This is something that if the government continues with what it's doing, it's going to have a long-term effect on the industry. (P1C1, personal communication, March 9, 2020)

P1C3 has over 30 years' experience as an operational leader in the pharmaceutical and medical device industry on the island and emphasized the impacts of the utility costs on the island. P1C3 stated that Puerto Rico's system designed with a government monopoly provisioning electricity to the island's residents only serves as a hindrance, as governments are not always motivated by a financial or service agenda but by a political agenda (P1C3, personal communication, March

12, 2020). Puerto Rico's electric power authority (PREPA) was also one of three government corporations representing the largest organizations on the island impacted by the public debt associated with the government bond issuance and no possibility of bankruptcy protection (Pierluisi, 2015).

Financial incentive instruments for construction and capital investment on the island. The aging population of the world's residents provide continued opportunities for growth and innovation in the world's leading medical device and pharmaceutical companies. As the greater population continues to age, their health will naturally decline increasing the demand for medical care and the associated instruments and pharmaceutical products that directly correlate to that care. This positions medical device and pharmaceutical companies to continue their trajectories of year over year growth. For organizations undergoing growth periods, one of the biggest incentives from a cost perspective is to focus those growth initiatives in established areas where the infrastructure, talent, and equipment is already in place to supplement the desired growth rates. This is part of the total cost of ownership analysis which allows these heavily regulated industries to avoid the challenges of entering brand new markets associated with language barriers and other cultural communication barriers (Weber et al., 2010).

P1C4 reflected on the various instruments that could help incentive the organization to promote continued growth on the island and provided an example where the government's intervention to help support the costs of expansion partnered with the company's strategy for growing the operation in Puerto Rico. She shared the following example, stating:

> I went to them [the government representatives] and said, 'Hey, we have invested a lot of capital in the last 10 years. We have expanded the site. We have retrofitted the site. We have brought in new manufacturing lines. I need help growing a little bit of that. Is there

> an incentive that you could give me, because of this investment?' (P1C4, personal communication, March 13, 2020)

She knew that by partnering with the government and gaining economic support the organization would be more inclined to invest and move forward with allocating new product lines to Puerto Rico. She concluded her example, stating, "So, we actually signed a contract with them. They gave us half of the investment, and now we are going to make sure that we expand so we can open the floor for new products" (P1C4, personal communication, March 13, 2020).

When discussing economic partnerships in Puerto Rico with VP1C4, he concurred with P1C4's assessment stating:

> I think we have had a good partnership with the DDEC [Department of Economic and Commerce Development] in terms of their understanding of what we do, and their ability to provide assistance in developing the expansion plans. And over several years and definitely up to Hurricane Maria and beyond, we certainly have significantly expanded that site. And DDEC's partnership has been instrumental in us doing that. (P1C4, personal communication, March 13, 2020)

The use of incentives for capital and construction was also highlighted during the interview with the economic representative. When highlighting the various instruments she has at her disposal to aid in the growth and advancement of the manufacturing industry in her township, she stated the government was often, "waiving construction fees when they [local businesses] are improving or expanding their existing facilities" (P1ER1, personal communication, March 10, 2020).

Relationship of themes/patterns to research questions. The findings of this study addressed the associated research question: What decision-making strategies did the plant

managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico? The findings were based on data collected from open-ended interviews, document reviews, and observations. The categories of successful strategic decision making strategies for medical device and pharmaceutical facilities in Puerto Rico were found to be as follows: (a) ensure strict alignment to the strategic objectives of the parent company, (b) allocate time annually, at a minimum, to the strategic planning process, (c) validate alignment across functions within the organization, (d) ensure alignment with local economic partners, (e) develop a focus area for strong and effective leadership, and (f) segment strategic planning into contextual areas of focus. With respect to segmenting the strategic planning into specific contextual areas of focus, the participants all defined a targeted focus in the following areas: (a) new product development and integration, (b) operational excellence, (c) on time delivery and supply assurance, (d) cost competitiveness, (e) quality system maturity, and (f) talent development.

The second research question to be addressed was: What impact did the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have on the strategic decision-making process? As a consensus, all participants concluded that there was not a direct impact the government instability or expiration of the tax incentives has had on the overall strategic decision-making process. There were no direct focus areas targeted to navigate the challenges associated with the government instability or measures put in place in the facilities annual plans to directly address the new financial oversight board or the provisions associated with the government bankruptcy. The wide majority of the participants, however were able to highlight multiple indirect implications resulting from the government instability to include executive perceptions of the territory's future stability as an operational asset, the

employee retention issues associated with mass migrations, the resulting implications on the cost of energy, and the future implications of the resulting tax liabilities for businesses operating in Puerto Rico. In terms of the affective events theory, it was determined that the governmental affects, such as the inception of PROMESA and the external environment in Puerto Rico following Hurricane Maria did have an emotional impact on the plant leaders and reflected in their approach to the strategic decision-making process.

How the findings relate to the conceptual framework. The findings of this study were interpreted through the viewpoints associated with the conceptual framework in order to draw relevant conclusions. The premise of the conceptual framework was based on the concept that strategic decision making is directly correlated to the overall success and sustainability of an operation (Peterlin et al., 2015; Schneider & Jones, 2017; Self et al., 2015). Strategic decision making is a direct result of the leader's determinations of their current environment and the pathway forward. This implies that strategic decision making may be heavily influenced by a leader's individual experiences, perceptions and judgements. The research supported the correlation between the success of an operation and the strength of the strategies used to deploy the strategic decision-making process. In addition, several specific strategies were outline by the participants of this study.

Conceptual framework. The conceptual framework for this study was built upon the affective events theory (AET), the correlation of the role emotion has on the evaluative judgement, or further described as the relationship between an individual's behavior and their unique experiences (Ashkanasy et al., 2017) and its relation to strategic decision making. The conceptual framework also draws the conclusion that strategic decision making is directly related to the overall success and sustainability of an operation (Peterlin et al., 2015; Schneider & Jones,

2017; Self et al., 2015). Because the purpose of this study was to better understand the strategies used for the strategic decision-making process executed by leaders in Puerto Rico amidst the crisis events, AET was selected to ground the associated research, specifically in how it pertains to the strategic decision making process.

The research question of this study was: What decision-making strategies did the plant managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico? Followed by: What impact did the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have on the strategic decision-making process? The initial research question assumed that the strategies the manufacturing leaders were putting in place during the strategic decision-making process would have a direct relationship with the positive results of their operations in Puerto Rico. The second research question sought to draw a parallel using the affective events theory that the experiences of operating under Puerto Rico's government economic instability would have an impact on the strategic decision-making process. In addition, the purpose of this study was to increase the empirical knowledge of strategic decision-making strategies demonstrating successful operations in the volatility of Puerto Rico's economic and governmental crisis and reduce further economic impacts on the island tied to plant closures. More specifically, the intent of this investigation was to develop the connection between the medical and/or pharmaceutical plant manager's strategic decision-making and operational planning process and a successful plant operation more clearly understood.

AET informed the expectations of this research in two foundational ways. First, the underlying assumption that affective events have a direct correlation to emotional appraisals and will impact the decision maker's strategies as it relates to strategic decision making (Page, 2016).

Secondly, the second research question regarding the impact the external environment (e.g., government bankruptcy or the expiration of the island's tax incentives) had on the strategic decision making process determines the nature of the affective event on each plant manager and members of their staff and the translating results of their interpretation into their strategic decision making strategy (Neumann, 2017; Page, 2016; Weiss & Cropanzano, 1996).

The researcher assumed that there would be specific, pre-identified strategies to the strategic decision-making process for the facilities in Puerto Rico (Neumann, 2017; Page, 2016; Weiss & Cropanzano, 1996). The external environment associated with the government bankruptcy and economic conditions in Puerto Rico would impact the leader's approach to the strategic decision-making process. These assumptions were in line with the classification of affective events in the lives of those leaders (Neumann, 2017; Page, 2016; Weiss & Cropanzano, 1996).

Findings related to the conceptual framework. Strategic decision making is a direct result of the leader's determinations of their current environment and the pathway forward. This implies that strategic decision making may be heavily influenced by a leader's individual experiences, perceptions and judgements. The affective events theory (AET) is a study based on the correlation of the role emotion has on the evaluative judgement, or further described as the relationship between an individual's behavior and their unique experiences (Ashkanasy et al., 2017).

All of the participants associated with manufacturing agreed with the idea that in order to effectively run their facilities and remain competitive in the manufacturing network, they needed to have a strong and robust strategic profile or direction in which the facility and the business operating on the island was headed. P2C5 stated:

> I cannot envision a way of moving toward the future without that strategic vision. It gives you a "north" …Having that "north" also helps you to prepare your plans, well aligned with the overall strategy of the corporation. So, I believe it's a very good process to follow and it helps you, a lot during your day to day activities and decision making. (P2C5, personal communication, March 23, 2020)

P1C3 expressed a similar sentiment, having once been responsible for global manufacturing network. He stressed the value of incorporating a strengthening of the team dynamics into the strategic decision-making session, stating:

> We ensured that we coupled the discussion, the strategic objectives discussion with the team dynamics. We wanted to ensure the team got more comfortable as there would be many of these going forward. We incorporated things such as what drives them, what motivates them, and what their leadership style is. What kind of leader are they? So, we sprinkled the session with team building activities and team dynamics. (P1C3, personal communication, March 12, 2020)

P1C2 reflected on the importance of having the discipline to think strategically and ensure that they did not get caught in the daily firefight of the manufacturing environment and protect the time, not only to establish the strategic plan, but to reflect back on it throughout the year and ensure that the team was measuring their performance to the strategic direction established during those sessions (P1C2, personal communication, March 11, 2020).

In terms of the affective event theory and how the economic environment and the government bankruptcy affected the approach to strategic decision-making, all leaders agreed that the external environment specific to the government bankruptcy was not deriving in the establishment of a specific focus area within the strategic plan. It was something that they were

all aware of and their roles as plant managers was affected by the environment as they served as liaisons to their direct teams and representatives of the stability of the island to the external executives that often drew concern over reports in the media or the announcement of government policy changes. P1C4 captured this stating:

> The media coverage can be very misleading. They can make sure that people know the bad stuff, but they cannot draw the line on how the economy is moving. So, I would say we do a lot of upfront communication to put in perspective what does it mean for C4 operating in Puerto Rico. (P1C4, personal communication, March 13, 2020)

P1C1 used a different approach to address the concerns from his staff when notices of government instability are communicated across various media platforms. His goal is to remove the conversations about the government instability from the workplace, stating:

> We don't allow anyone to speak about external politics, religion, etc. We try to remain very neutral. We try to ensure they remain focused on their day-to-day job. That's normal for the industry – remove external politics in the business in all aspects. If they ask, we have a town hall meeting, where I can offer a very generic answer. But one thing I tell the people that work with me is that they have the responsibility to educate themselves and know what's going on in the country. (P1C1, personal communication, March 9, 2020)

Although P1C1 does not engage in conversations regarding the government instability in the workplace, he did admit that the government instability, particularly in the management of utility costs has a direct implication in the strategic planning associated with equipment procurement (personal communication, March 9, 2020).

P1C5 went into detail with how the government instability and the mass migrations seen as a result of the economic hardships on the island has had a direct impact on his strategic approach to talent management. He stated:

> We are unique that we can easily get on an airplane to the US. You don't need a passport. Here you're competing with the strength of the US economy via migration. So, for us, retention is not only about keeping people in the company or in this location – it's about keeping people in Puerto Rico. We need to think about both, because there are people that move to the States within the company and you can say, I prefer that than to a competitor, but we then lose that expertise. So, we need to fight both, at every level, by the way, direct labor to executive. Fight migration out of Puerto Rico and make sure people stay here with us. (P1C5, personal communication, March 12, 2020)

The emotional impact migration of the people of Puerto Rico leaving to the United States for work had an evident impact on P1C5 and further impacted his approach on talent development and ensuring that the people in his factory knew how much he appreciated them. This was quite evident as he toured the researcher through the facility and interacted with associated on the production floor (direct observation, March 12, 2020).

In summation, through direct observation and the interview process it was evident that the literature was in line with the research. The strategic objectives for the operations, derived from the strategic decision-making sessions, were an integral input into the overall success of the operation. The governmental affects and the external environment in Puerto Rico following Hurricane Maria did have an emotional impact on the plant leaders and reflected in their approach to the strategic decision-making process.

Summary of the findings. The multiple case study approach was used as the qualitative analysis methodology, deployed in order to obtain a first-hand experience of the leaders directly responsible for mass medical device and pharmaceutical production in modern day Puerto Rico. The goal of the study included an opportunity to witness their leadership styles first-hand and observe the state of their facilities. This allowed the researcher to gather information on the observed soft skills that support their success and gain insight into their thoughts and approaches as they navigate multiple economic challenges associated with operating a manufacturing facility in Puerto Rico. It also allowed the researcher to determine the impact in the facilities the strategic decision-making process was having, either through the implementation of visual factory tools or the feedback and insight of those on the plant staff.

The data gathered for this case study came from multiple perspectives to include plant managers and a member of their staff currently responsible for leading and executing the strategic decision-making process in the facilities. These leaders were all actively serving within a medical device or pharmaceutical manufacturing facility in Puerto Rico during the study. Additionally, two executive level leaders associated with the companies visited on the island were interviewed regarding the strategic decision-making responsibilities for existing operations in Puerto Rico to determine a corporate level viewpoint of the environment in Puerto Rico for medical device and pharmaceutical manufacturing. Lastly, a local mayor for one of Puerto Rico's most industrialized townships was interviewed in order to gauge the insights of an economic representative on the island, operating under the inception of the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) and the Fiscal Oversight and Management Board.

When the plant managers for facilities in Puerto Rico, manufacturing executives, and members of the plant staff were asked about the milestones and focus areas of their strategic planning sessions, responses generally feel into the following categories: (a) ensure strict alignment to the strategic objectives of the parent company, (b) allocate time annually, at a minimum, to the strategic planning process, (c) validate alignment across functions within the organization, (d) ensure alignment with local economic partners, (e) develop a focus area for strong and effective leadership, and (f) segment strategic planning into contextual areas of focus.

The aligned contextual areas of focus for all plants studied included the following: (a) new product development and integration, (b) operational excellence, (c) on time delivery and supply assurance, (d) cost competitiveness, (e) quality system maturity, and (f) talent development. When leaders were asked how the local government's current financial instability factored into the strategic decisions for the follow-on fiscal year, all manufacturing representatives interviewed concluded that the governmental economic situation was not directly factored into the strategic decision-making strategy but had more indirect implications. The indirect implications included their communication strategies with executives residing outside the island, the employee retention issues associated with mass migrations, the communication and talent development strategies with employees within the factory, and their cost strategies associated with the high cost of electrical consumption on the island.

Summarizing the problem statement of what next steps can be derived to drive favorable operations, the responses generally fell in the following areas. The strategies to further support the continued operation of existing manufacturing and the opportunity for future growth and expansion are the following: (a) continued use of favorable income tax incentives for manufacturing operations, (b) government investment or allowed privatization in the improved

infrastructure of the electrical utility system, and (c) financial incentive instruments for construction and capital investment on the island.

With respect to the conceptual framework, the strategic objectives for the operations derived from the strategic decision-making sessions were an integral input into the overall success of the operation. The governmental affects and the external environment in Puerto Rico following Hurricane Maria did have an emotional impact on the plant leaders and reflected in their approach to the strategic decision-making process as described in the affective events theory.

Applications to Professional Practice

The findings of this study addressed the following two research questions: What decision-making strategies did the plant managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico? Followed by: What impact did the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have on the strategic decision-making process? For plant managers, or those striving to become plant managers, in medical device or pharmaceutical manufacturing in Puerto Rico, the results of this study provide practical applications to each of the themes derived from the study. This sub-section provides a detailed discussion on the applicability of the findings with respect to the professional practice of strategic leadership in business and the governmental considerations when expanding business into an international setting. More specifically, how and why the findings were relevant to improving and strengthening manufacturing operations in Puerto Rico and the factors the government and the economic environment played in the overall strategic decision-making process for the onsite leaders and the executive leaders, directly and indirectly responsible for existing operations on

the island. The biblical framework and the implication of its relation to the results of the study was also discussed, as well as the results of the study and the applicability to the academic field of international business.

How strategic decision-making strategies for medical device and pharmaceutical facilities in Puerto Rico drive favorable results. Strategic decision making in the manufacturing environment is the act of determining the middle to long range goals and objectives for an operation. Organizations embarking on a sustainability journey will have to adopt frameworks for the resulting strategic decisions that are derived from strategic planning sessions and will be highly dependent on the success of its organization leaders to make critical strategic decision as part of this journey (Peterlin et al., 2015). The literature thoroughly supports the direct impact strategic planning and strategic decision-making has on the operation. The research further correlated this direct tie as each participating facility demonstrated acknowledgment and adherence to a higher-level strategic plan for the facility.

In the sub-sections below, the following themes were derived from consistency in the responses stemming from the interactions with the site's representatives, the meetings with the executive level leaders of the manufacturers included in the case study, the direct observations of the facilities, and the associated document reviews for each company. Triangulating the information stemming from multiple sources presented shared strategies that will successfully lead medical device and pharmaceutical facilities in Puerto Rico to drive favorable results. In addition to the implementation and refinement of these strategies, the facilities risk for closure would improve as demonstrated by the facilities continuing to successfully operate on the island.

Leader's behaviors and approaches to strategic decision making will drive results. Strategic decision-making cannot occur without human intervention. It is initiated by leaders,

derived by leaders' experiences, and executed by the vision, commitment, and persistence of leaders and their associated teams. Simply put, without the "people" factor, there is no strategy. Self et al. (2015) described concurrent scanning of the organization's internal and external business environment as a crucial factor that will influence the future strategic decisions for an operation or business. The interpretation of this continuous evaluation and the knowledge gained must support or enhance strategic thinking in order to maximize its benefits (Self et al., 2015). P1C3 addressed the importance of the leader's impact as it pertains to strategic decision making, more specifically to the strategic decision-making process in Puerto Rico, stating, "In Puerto Rico people, typically, don't follow concepts, they follow their leader. So, if they associate a leader with a concept, then they are more likely to follow the concept" (P1C3, personal communication, March 12, 2020). This description clearly details the impact leader behavior and approach can have on the overall strategy. With respect to adherence to a higher-level strategic concept it was described as follows:

> For most people here on the island, it's important that their leader exemplifies what they believe in. What they believe is important. They will always be "on the lookout" for that type of behavior. They want to ensure that their leader walks the talk. They can get very cynical very quickly. On the flip side, if they see that you do walk the talk - that you exemplify the strategy then they will be more passionate. (P1C3, personal communication, March 12, 2020)

Leaders in medical device and pharmaceutical facilities must demonstrate passion and commitment to the strategic direction of their facility and understand that their direct behaviors as it relates to the operational strategy will serve as a direct input to the results of the facility and its ability to perform successfully.

Strategic objectives for the site must align to the objectives of the parent company.

Large medical device and pharmaceutical manufacturing facilities in Puerto Rico belong to a larger parent organization. In some cases, the sites are part of a larger global network with manufacturing facilities distributed through multiple continents. In order to improve the likelihood of a successful operation on the island, the facility's strategic objectives to align directly or serve as a direct product of the parent company's strategic portfolio. For example, P1C1 described the parent company's objectives branching into technical progression and leadership development, where the headquarters team would take the lead on determining the path for technological strategic direction, but the plant could define its directional focus for leadership development (P1C1, personal communication, March 9, 2020). P1C4 highlighted the inputs session as a method to gain alignment to the parent company included in the annual strategy, stating:

> We will have an initial input session with key stakeholders such as division and corporate and then our business units. And then we will fine tune those and turn them into either prolongation of current strategies or new strategies that we have to focus on, which will then be completed before the year ends. (P1C4, personal communication, March 13, 2020)

In multiple instances, the facility leaders identified a milestone in the strategic decision-making process or the annual strategic planning session that included alignment to the parent company or headquarters strategic objectives. In summation, this would cause the researcher to conclude that direct alignment to the higher headquarters is a significant theme toward ensuring the greatest success in the plant's strategic decision-making strategies.

Ensure there is no less than one annual strategic session. The direct correlation with respect to strategic planning across all the manufacturing facilities was the adherence to an annual strategic planning cycle. P1C2 clearly outlined the formality of the session, indicating, "Every year, we meet once a year and we refresh on those objectives and make sure we get alignment on what we want to accomplish for that fiscal year" (P1C2, personal communication, March 11, 2020). In some cases, the annual planning sessions included long range planning that stretched three to five years in scope, in others the teams used the annual process to break out the objectives into quarterly buckets for the current year. In every case, saturation was reached as it was determined that the theme of hosting at least one annual strategic planning session was essential to the overall success of the facility's operation.

For facilities in Puerto Rico to remain competitive, they must plan for their success. The annual planning session allows departmental leaders from the facility to gather in a unified forum and align their efforts and resources in support of the site's critical objectives. The annual strategic planning session provides structure for the team. The annual planning session also gives the leader's participants hope for the future and a stake in that future with a clearly defined focus area. Ensuring the factory scheduled at least one annual planning session per year was essential to the success of the strategic decision-making process.

Validate from site stakeholders the alignment of objectives across functions. Manufacturing facilities are comprised of multiple departments outside of the core function of production operations. Departments involved in a standard manufacturing operation include areas such as engineering, maintenance, quality control, and material control. As a result of the unique support functions operating in tandem, the opportunity for conflicting priorities and misalignment across those priorities is high. Soosay et al. (2016) described the approach of

combining elements of market-based strategies with resource-based strategies to derive the most economically beneficial solution for the manufacturing operation. The research also identified the importance of using the strategic decision-making sessions for the sites as an opportunity to deconflict department specific initiatives and priorities and align the activities and resources to the higher-level objectives. This is especially important when tactical challenges throughout the year can easily distract manufacturing leadership. P1C2 raised this point, stating, "The day-to-day and the tactical work priorities and daily firefighting can easily keep you entertained for the entire year" (P1C2, personal communication, March 11, 2020).

Leaders in the research emphasized the importance of deconflicting priorities and aligning on shared objectives as a theme for effective strategic decision-making strategies. P2C5 emphasized the value alignment and transparency had on determining his own priorities and decision-making, stating:

> It supports that each of those decisions [made throughout the year] are driven by the imperatives I just shared with you. So, if I need to make a decision, I weigh quality first, then supply, then cost, then innovation and that really helps us strive to make savvy decisions. (P2C5, personal communication, March 23, 2020)

In summary, when developing the strategic objectives and plans for the manufacturing facility, best practice determines that the leaders incorporate a look at the cross-functional alignment and resources required. This will help to ensure that the group is headed toward the same strategic direction and will avoid department specific priorities to overshadow or remove resources from the greater objective.

Incorporate objectives that drives alignment with local economic partners. The environment the facility operates in has a direct input into the success of the facility as it is the

primary provider of factory labor, the provider of potential governmental incentives for areas such as utility consumption or training and development, and the driver for one of the businesses higher fixed expenses – taxes. The driver for global business operations has been the opportunity for cost savings associated with taxes, procurement, or labor in low cost countries (Weber et al., 2010). Puerto Rico does not have the advantage of ultra-low labor wage rates, as the citizens of Puerto Rico could easily migrate to the United States without any travel or work restrictions, thereby driving Puerto Rico's pay ratios to remain similar and competitive with the US. P1C5 emphasized this stating, "The one negative, there's a lot of migration – permanently to the United States. Interestingly enough, even in a depressed economy, salaries continue going up because the talent, the good talent that is left, people are fighting for" (P1C5, personal communication, March 12, 2020).

With comparable wages in comparison to the United States and high energy costs associated with manufacturing on an island, Puerto Rico has to define its competitive advantage through economic incentives, such as tax incentives, donations on infrastructure development and other economic support items such as specialized training in highly sought after skills trades. P1C4 highlighted the value of her local economic partnerships as a core strategy in her site's value proposition. She detailed her efforts to partner with the local government as they agreed to supply half of the funding on her facility's expansion project (P1C4, personal communication, March 13, 2020) which drove the parent company's support of the investment in the facility. Economic partnerships and determining strategic objectives that can be supported by those partnerships is a strategy that has uniquely provided the facilities in Puerto Rico an advantage to continued growth and development on the island. For facilities to remain successful in current

day operations, they must seek opportunities to provide mutually beneficial solutions to the operation through economic partnerships.

Define a strategic objective that drives strong and effective leadership initiatives. Smith et al. (2010) evaluated eleven facilities in nine unique industries and determined the shared theme of the plant leader's greatest impact stemming from their role as "sensegivers." Smith et al. defined sensegiving as "a process one uses to influence how others construct meaning, that is, sensegivers attempt to shape the thinking and attitudes of others" (p. 221). Plant managers in their study focused on four core values: people, openness being positive, and being part of a community (Smith et al., 2010) and the positive impacts that derived from their leadership approach. The study further supported the literature in determining that the plant leadership and their focus on people, openness, being positive and being part of a community was demonstrating successful results within the plants that participated in the case study. To summarize, effective leadership will serve as a driver, positive or negative, on the results of the factory.

Understanding the impact of leaders on the facility, it was concluded that the most effective strategic decision-making strategies will factor objectives to prioritize and resource leadership initiatives. VP1C4 described the corporate strategy for his organization as based in terms of growth and advancing science for life and looking at the capabilities of their manufacturing network and footprint with respect to that strategy (VP1C4, personal communication, March 13, 2020). One of the first capabilities he identified was the ability to hire the correct talent and considered this factor as superior in comparison to other incentives such as economic and government incentives (VP1C4, personal communication, March 13, 2020). This further supports the criticality of effective leadership and the value of incorporating leadership

development strategies into the strategic decision-making strategy. For facilities in Puerto Rico to maintain a competitive advantage as manufacturing source, the research demonstrated that maintaining strong and effective leaders that are widely respected by the organization will serve to provide that advantage.

Outline the contextual areas of focus and develop measurement systems for each. The manufacturing facilities that participated in the case study all housed key performance indicators or area-specific metrics within the facility as a tool to measure and drive performance. These metrics were used as a visual medium to identify the area's trending performance versus the anticipated target. In the case where the area was not consistently achieving its target, the plants included sections for actions to be defined with target completion dates that would aid in driving the performance back in the right direction. The unification of the strategy demonstrated by the implementation at every site participating in the case study deemed it as a best practice and a pattern of success toward effective strategic decision-making. P1C2 provided a detailed explanation of the direct correlation between the strategic decision-making process and the use of KPIs stating:

> Yes, we operate under 5 imperatives [strategic pillars]: quality, supply, innovation, cost, and organizational excellence. What we do is identify specific KPIs or tangible targets that we want to accomplish in each of these imperatives. We often define and refine where we want to be in three years with regards to those tangible KPIs. So, then what we do is that, we define tactics [projects or initiatives] that in the short term or longer term, will take us to that three-year aspiration. Most of those tactics remain the same year after year, and in some cases those tactics change in a way that is based on the maturity of the

> initiative, where in some cases we reset the clock and take it to the next level. (P1C2, personal communication, March 11, 2020)

This is an example of how one of Puerto Rico's largest medical device manufacturing facilities implements the use and management of their metrics culture. The general theme of using metrics or KPIs at every facility was its direct association with the strategic decision-making process and its use as an effective strategy to successful compete in the manufacturing network.

How to define contextual areas of focus in the strategic decision-making strategy. Firm characteristics are identified as a factor that influence the integration of the "global factory" in Enderwick and Buckley's (2019) article detailing the characteristics and demographics of collaboration and innovation among manufacturers around the world. In order to best understand the firm's characteristics as it pertains to the performance areas for the participating facilities in the case study, the researcher sought for the manufacturing leaders to identify the core measurable areas or contextual areas of focus that were included in the strategic decision-making process. In the subsection below, each of the defined segments of the facility were shared amongst the participants of the study and identified as the achievement of saturation for the researcher, as the areas defined below were similar in scope for all participating factories. Each of the subsections below provide applicable guidelines for integration in the areas of professional practice.

Developing a pipeline for new product development and integration. VP1C2 described the pipeline of products as a key input in the executive level strategic decision-making session, highlighting that the team is tasked to "make sure we have an adequate pipeline of future projects to continue the momentum into future fiscal years" (VP1C2, personal communication, March 6, 2020). P2C2 went into more detail on these initiatives at the factory level, stating, "We also look

at any major product initiatives, line transfers, network initiatives and determine the prioritization and resources needed" (P2C2, personal communication, March 11, 2020). P1C3 also emphasized the importance of the new product portfolio and detailed his deliberate effort to ensure this area of focus was factored into the strategic decision- making strategy of his new pharmaceutical startup in Puerto Rico. P1C3 also emphasized the importance of the new product portfolio and detailed his deliberate effort to ensure this area of focus was factored into the strategic decision-making strategy of his new pharmaceutical startup in Puerto Rico. He stated:

> The step changes are driven by projects. These projects are driven by new products, new facilities, new markets, line extensions. They are all projects and you have to take care of that also, because if you don't take care of that, you can stifle the growth of your company and the forward movement of your company. (P1C3, personal communication, March 12, 2020)

In each of the above examples, the participants in the case-study are aligned that new product development and new product integration strategies are central to the strategic decision-making strategy of the facility, both in terms of resource management as well as ensuring a future for the state of the operations on the island. VP1C2 specifically identified his company's decision of what to move into or out of Puerto Rico as primarily driven by the maturity of the product lines and difficult, or prepared is the facility, to receive the line (VP1C2, personal communication, March 6, 2020). In conclusion, the need for a predefined pipeline of new product integration or new product development strategies has served as a core theme for effective strategic decision-making strategies for the operations on the island.

Defining operational excellence. One of the facilities identified their program for continuous improvement as organizational excellence, others remained with the more well-

known heading of operational excellence. In all of the facilities, whether measured by organizational excellence or operational excellence, the initiatives to drive the elimination of waste in the process or seek methods for continuous improvement was a factor driving the sustaining of multiple facilities participating in the case study. Breja et al. (2016) defined the pursuit of excellence as a strategy that results in world class performance and is realized through strong organizational management and the achievement of targeted results.

Facilities in Puerto Rico all supported various strategies to drive operational excellence within their operation as a method to stand out amongst their sister sites around the globe. P1C1 talked about using operational excellence tools as strategy toward profitability (P1C1, personal communication, March 9, 2020). P2C2 defined organizational excellence as the fundamental "pillar" of the business, stating, "this pillar is central to everything we do here. We have dedicated teams that are targeted to drive improvement projects that will continue to make the factory in Puerto Rico widely admired for its commitment to excellence" (P2C2, personal communication, March 11, 2020). Manufacturing facilities around the globe compete for prize recognition through programs such as the Shingo prize, which recognizes their operation for best in practice in lean methodologies. In an environment where lean manufacturing principle are a basic industry requirement, factories in Puerto Rico must emphasize the focus on operational excellence strategies in the strategic decision-making sessions.

Defining on time delivery and supply assurance. On time delivery and supply assurance are performance indicators that measure the factory's ability to provide the goods as demanded by the downstream customer when "pulled" or the demand signal indicates a desire to purchase the product. This performance indicator tends to be one of the most critical for defining the factory's success rate. P2C1 discussed their facility's focus on delivering products on time,

stating, “We have to be very competitive in that aspect and we know that delivery times are the most critical things to our customers, sometimes even more so than price” (P2C1, personal communication, March 9, 2020). Each plant leader or a member of their staff unanimously highlighted the importance of driving product delivery in accordance with their commitment. In some cases, the factory used multiple leading indicators to determine how they would measure their performance to delivery. P2C5 detailed performance metrics such as inventory, backorder, production attainment, and availability as various examples of the metrics in place driving to support product supply to the market (P2C5, personal communication, March 23, 2020). In summary, defining the inputs and outputs of measuring product delivery to the market is an integral performance measure for strategic decision-making strategies which further support a case for successful facilities in Puerto Rico.

Measuring cost competitiveness. Cost competitiveness is a fundamental necessity to remain competitive in the global network. Adaptations to international markets can deem high financial costs and significant management attention when the activities in the foreign market are not closely monitored (Anderson, 2009). There are segments of operating a manufacturing facility in Puerto Rio that fall within the framework of foreign business dealings and mandate close financial management and business strategies that lead the operation to manage within an optimal cost position.

P1C5 emphasized the competitive position of their large facility in Puerto Rico, stating that the plant is “cost competitive,” and detailing, “We are competitively able to improve our costs, year over year, so every time we become more attractive” (P1C5, personal communication, March 12, 2020). P2C2 also highlighted the direct focus on costs and continued efforts toward productivity improvement, stating, “We also look at our cost structures and

productivity targets to determine what we have to do to drive our year-over-year cost favorability incentives" (P2C2, personal communication, March 11, 2020).

Puerto Rico is no longer a manufacturing advantage driven by low cost wages (Vega-Rosado, 2011). The engineering and operations management professionals must be incentivized on the island to not relocate for comparable, higher paying opportunities in the United States, thereby making salaries and wages in Puerto Rico similar to the US market. As a result, factories in Puerto Rico that want to remain poised for growth and development must remain focused on the cost levers that can be pulled in order to drive the focus to continue to manufacture on the island. As part of the strategic decision-making strategies for the facility, operational leaders must provide an opportunity to understand the facility's existing cost position and ways to drive continued improvement.

Assessing quality system maturity. Puerto Rico's tenured history as one of the world's most concentrated centers for pharmaceutical and medical device manufacturing, with 45% of its gross domestic product (GDP) coming from the manufacturing sector (MacEwan, 2017), has defined itself as an industry leader with progressive knowledge in the area of quality system and good manufacturing practices (GMPs). Regulated authorities such as the Food and Drug Administration use GMPs as a method to ensure products are consistently produced and controlled according to the respective quality standards associated with the product manufactured (Geyer et al., 2019). The advantage of the operations on the island derive specifically from their experience to these procedures and the parameters associated with manufacturing under tightly controlled conditions.

In order to deploy a successful operation on the island, plant leaders must assess the current state of the factory's quality system and ensure robust practices are in place. This

includes ensuring the facility manages to an environment that will drive little to zero audit findings during cyclical inspections by notified bodies. It also ensures the existing manufacturing processes are driving quality at the source. Some examples in the facilities that participated in the case study of quality systems focus included defects per million as part of a six-sigma analysis, yields and scrap rates (P2C5, personal communication, March 23, 2020). The level of understanding associated with adherence to GMP standards, familiarity with the design for quality at the source, and the consistency to remain focused on quality performance through the use of metrics and periodic verifications of the quality system will ensure the facility remains competitive and develops mature quality system.

Drive talent development. The case for Puerto Rico is its talent pool. The leaders interviewed in the manufacturing facilities highlighted this core strength in multiple instances. The executive leader for C4 emphasized it as well, emphasizing the ability to hire the correct and "right" talent for the location was an integral input into the core strategy of location selection for the manufacturing facilities in the organization (VP1C4, personal communication, March 13, 2020).

In some cases, the decision to move product lines into the factories in Puerto Rico is a direct result of the talent-based climate the leaders on the island have perpetuated, focusing on developing and honing the talent and skillset of their employees. P1C4 discussed in detail the strength her talent base provided in the value proposition for her facility as she recalled her presentation to the executive leadership, stating, "What's in it for you here is that we are making sure that we are attracting, engaging, and retaining the best talent available on the island" (P1C4, personal communication, March 13, 2020). P2C4 drove this point as well, indicating, "We can also export our talent and support the company to continue building upon…the global operations

strategy, which is a feeder to our local strategy as well" (P2C4, personal communication, March 13, 2020). In each site there were multiple examples where the unique skillset of the employees in the Puerto Rican facilities were either deployed abroad to other areas around the globe to support the larger manufacturing strategy or serving as a driver for an increase to the production area in the existing facilities.

The investment in sought after skillsets and strong leadership continues to make Puerto Rico an attractive market for continued investment in an industry they are well positioned to support. Therefore, it is essential to empower employees to fine tune their trades and career growth with continued learning. The strategic plan should also incorporate increased recruitment of employees in specialized trades to support the impact of attrition resulting from retirement or migration or pilot internal apprenticeship programs that will serve to pass on the knowledge gained by existing industry leaders. This direct focus on a specialized core competency can only help serve the case of Puerto Rico's industry strength as a medical device and pharmaceutical manufacturer.

How the external environment impacts the strategic decision-making process. Puerto Rico's manufacturing sector has significantly constrained in size and scope following the decision to eliminate the income tax incentives provisioned by Section 936 of the Internal Revenue Code in 1996 and throughout the decision's 10-year phase out, which was finalized in 2006 (MacEwan, 2017). In 2015 the Puerto Rican government made headlines for identifying its inability to repay bond debt resulting in one of history's greatest financial bankruptcies (Pierluisis, 2015). In 2016, the oversight board controlling the island's budget via the enactment of the Puerto Rico Oversight, Management, and Economic Stability Act was incorporated into local legislation ("A Crippling Blow," 2017). With such significant economic upheavals, the

research sought to determine the impact these external impacts were having on the strategic decision-making process for plant managers in Puerto Rico and how it affected them as leaders through the process.

The research identified that all participants in the case study were clearly aware of the economic conditions and the negative connotations associated with them, but none of the facility leaders factored these impacts directly into the strategic decision-making process, thereby determining that there was no direct effect between the expiration of the tax incentives and/or the government bankruptcy and the strategic decision-making strategy in the modern day environment. The consensus among all manufacturing representatives when posed with the question about the impacts these external factors had in the design or execution of the strategic decision-making process was almost unanimously, “no impact.” If this is indeed the case, then there is no implication for manufacturing leaders in Puerto Rico to directly consider a strategy to address the government’s instability into the strategic planning session or decision-making strategies.

With respect to the indirect effects, the plant leaders provided a consensus for indirect impacts associated with the government instability. They highlighted the focused communication plans that needed to be prepared to quell the concerns of executive level management outside the facility. P1C4 addressed this stating, that the government’s instability “creates a lot of uncertainty that you have to continue managing, especially outside of Puerto Rico” (P1C4, personal communication, March 13, 2020). In addition, the plant managers addressed the need for additional communication on this topic with their associates to address the concerns the employees have on the implications to the business. P1C5 provided examples of the communications that must take place with all of the associates when new taxes are being

considered in the government to assure them that they may, or may not be affected, and that there is no tangible, immediate impact to the factory (P1C5, personal communication, March 12, 2020).

The leaders did highlight the impact of the large migrations that resulted following the announcement of the government bankruptcy. This has been the most significant indirect impact the leaders have experienced which has driven increased focus on talent development and talent retention strategies. The migrations have also made the environment for strong operations and engineering professionals highly competitive and is driving facilities to continue to strive to improve their work environment and serve as a top considered employer on the island. P1C4 detailed these initiatives stating:

> So, we are making sure that once you're here, you have a career path and we're going to help you develop. At the same time, we are attracting. We are doing a lot of branding. So, we want the university students to know that we are the employer of choice. We want Puerto Rico to know that we are one of the top employers. We want females to know that we are the leaders out there. (P1C4, personal communication, March 13, 2020)

In summary, while the external environment did not have a direct impact on the strategic decision-making process, leaders in the facilities in Puerto Rico are striving to remain competitive despite the indirect effects by (a) managing the narrative around the situation to the external executive team, (b) driving timely and transparent communications with the workforce to ensure they understand the minimal immediate risk to the private sector and their facility, and (c) driving initiatives to promote their operations as a competitive employer and ideal place to work to help strengthen their employee base despite the increase in migration off the island to the United States.

How the resulting strategies can further support the continued operation of existing manufacturing and drive future growth and expansion. The conversations with the participants in the survey, particularly with the executive leaders and the economic representative, served to provide additional long-term economic strategies to address the general problem statement of the research, which is the large volume of medical device and pharmaceutical manufacturing plants closing their operations in Puerto Rico. The study revealed the following three opportunities that can be considered as ways to drive additional growth and investment in the pharmaceutical and medical device manufacturing industry in Puerto Rico.

Identify and advocate favorable income tax incentives for manufacturing operations. Harris et al. (2015) defined the use of tariff protections as a method to help support the refining of an industry. Tax incentives are strong financial drivers for global manufacturing investment as demonstrated by the economic benefits Ireland has derived providing one of the lowest corporate tax rates in the world (Kull et al., 2019). VP1C2 described his organization's current focus on advancing their investment in the China facility as a direct result of the reimbursement strategy for items manufactured in China and imported into China (VP1C2, personal communication, March 6, 2020). For the Puerto Rican government to better compete on the global manufacturing scale with the low-cost labor countries they must revisit more aggressive tax incentives or financial reimbursements for manufacturing on the island. Roy's (2020) article advocates to a partial restoration of the Section 936 tax incentive to help stimulate additional manufacturing investment on the island.

Advocate for the improved infrastructure of the electrical utility system. The cost of energy and the ability to sustain electrical power on the island was unanimously the participants' biggest concern with respect to the external environment. P1C1 detailed his concerns stating:

> Our major cost in whatever industry is energy. A lot of industries have started trying to decouple and separate themselves from the government, because even though it's a very big cost per KWT/HR, they are introducing legislation to increase that cost. And that will have a devastating impact, not only for industry, but for the people on the island. So, the cost of the energy is very high. This is very devastating because industry is very equipment driven. This is something that if the government continues with what it's doing, it's going to have a long-term effect on the industry. (P1C1, personal communication, March 9, 2020)

Each of the plant leaders discussed plant-led discussions on the topic of energy or desired methods to self-sustain their operations through the independent production of energy via solar farms, wind farms and other mechanisms.

The availability of electricity at a reasonable price is a core fundamental requirement for production operations. For Puerto Rico to avoid closures or derail new investors factoring in the cost of energy, the plant leaders must advocate for an improved system and a government investment in the infrastructure that will provide manufacturers the peace of mind needed for long term investment on the island.

Request financial incentive instruments for construction and capital investment. P1ER1, the local municipality mayor, highlighted the use of financial incentives as a strategy she deploys to manufacturers to promote investment in her township. When discussing the impacts, the expiration of Section 936 on her township, she stated:

> The Law 936 expiration had a big impact on us, so one of the ways we reinvented ourselves was to create new tax incentives and this has resulted in keeping many

> manufacturing plans in our township and we can continue growing the economy, which is most important. (P1ER1, personal communication, March 10, 2020)

VP1C4 also highlighted the attractiveness of sustaining existing financial incentives indicating the following when asked about the incentives the broader organization is considering when evaluating investment in Puerto Rico:

> We are not looking for new incentives, but we're certainly concerned that existing incentives or existing structures would deteriorate over time, so that's one commitment we would be seeking from DDEC [Department of Economic and Commerce Development] in the future, is that things will not get into a point where it would become unfavorable for us to remain on the island. (VP1C4, participant communication, March 13, 2020)

VP1C4 did specify that this is incremental to support an already existing broad satisfaction for their existing operation on the island (VP1C4, personal communication, March 13, 2020).

While considering the overarching general problem statement of the research, the discussions that stemmed from the plant representatives, the economic representative, and the executive leadership generalized on three important areas that could support continued growth and development of the pharmaceutical and manufacturing industries on the island. With each strategy, the island stands a greater chance of regaining its foothold as a premier global manufacturer and distributer of medical device and pharmaceutical worldwide.

Biblical framework implications. The biblical framework for this study mainly consisted of the biblical story of Jonah and his obedience to adhere to the Lord's command and save the land from the destruction that many deemed it had deserved. The findings of this study dealt closely with the impact of a leader on the organization, which would, in turn, provide a

blessing and a favorable course to Puerto Rico, determining a similar parallel to Jonah's impact on the city of Nineveh and its future. The implication of the findings in relation to the biblical framework further support the Lord's calling on us as individuals or as a collective group to intervene, at times, in order to "save the land." They implications are discussed in more detail in the sections below.

Salvation began with the messenger's rebellion. The book of Jonah begins with a command from God. "Go the great city of Nineveh and preach against it, because its wickedness has come up before me" (Jonah 1:2, NIV). The story of a city's salvation is first instigated through the Lord's recognition of its potential and his anger against how they were using his earthly resources and provisions for wickedness rather than good. Through the journey of eventually saving a city, the Lord uses Jonah to reveal his majesty to others as well, even using Jonah's rebelliousness as a vessel to demonstrate to the others aboard the boat that he was God above all the other gods the sailors prayed to.

In the first chapter of the Book of Jonah, the Lord reveals how when the violent storm and harrowing winds faced off against the ship carrying Jonah at sea, the other sailors grew afraid and began calling out to their own gods (Jonah 1:5, NIV). Upon Jonah's admitted revelation that he was the true source of the storm and the Lord's wrath, they all agreed that Jonah was to be thrown overboard as it had been revealed to Jonah that in doing so, the seas would immediately calm (Jonah 1:11-12, NIV). When the crew threw him overboard and saw that the storm immediately subsided, "the men greatly feared the Lord, and they offered a sacrifice to the Lord and made vows to him" (Jonah 1:16, NIV). Despite the Lord's anger at Jonah's rebelliousness that led him to instigate a violent storm at sea against the ship, the Lord used the experience as an act of mercy and love to reveal himself to those on the ship.

From the very onset of the mission to save Nineveh, the Lord used Jonah to save people that would sail to other parts of the world and share the message of the miracles they had experienced from the one true God while at sea. Similarly, the crisis of a global pandemic where the western world is in dire need of pharmaceuticals and life-saving medical devices, the message of rising a nation to its former glory in the medical device and pharmaceutical manufacturing industry is lifted up and the need for the Lord's presence and protection is stronger than ever for those suffering the crisis.

The Lord has mercy on Nineveh. In the Book of Jonah, the Lord's initial command was for Jonah to preach against Nineveh because of their wickedness (Jonah 1:1, NIV). Jonah's repentance in the belly of the fish and acknowledgement that "salvation comes from the Lord" (Jonah 2:9) led him to obediently deliver the original message, warning the people of Nineveh that the city would be overthrown in 40 days (Jonah 3:4, NIV), but then something changed and the scriptures are very clear to highlight the repentance from the city's highest authority – its King (Jonah 3:7-9, NIV). The impact of the city's highest earthly authority, the head of its leadership, coupled with the remorse of the city's patrons reversed their judgment and the Bible reads that the Lord, "relented and did not bring on them the destruction he had threatened" (Jonah 3:10, NIV).

Puerto Rico has experienced financial and economic turmoil as a result of greed and a focus on short term gains regardless of the long-term impacts. P1ER1, a current member of Puerto Rico's government, addressed this reality and the resulting fallout, stating the current governmental leaders are:

> Looking for ways that our residents are not affected as they are not at fault of the bankruptcy that has been caused by various administrations of all parties. Maybe because

> they wanted to initiate new projects, but they didn't think about the long-term effects. The projects were not planned very well. They always thought about the current time and did not properly plan for the future. (P1ER1, personal communication, March 10, 2020)

Similarly, to Nineveh, the island's governmental leaders exercised poor financial decisions that later paralyzed the foundation of a future economy in Puerto Rico. In addition, the US leaders significantly crippled an industry in Puerto Rico with the expiration of Section 936, without an alternate incentive plan to offset these impacts, strictly as an initiative to increase tax revenues that were needed to supplement the domestic US economic policy for small businesses (Feliciano, 2018). The moral of the story of Jonah is that God is greater than the actions of man and can provide repentance to nations that acknowledge their sins and choose to adjust and act in accordance with His will for their land.

The Lord's compassion. Throughout the Book of Jonah, the Lord demonstrates compassion to those that may not have deserved it. He begins with compassion of the sailors on the boat that immediately began praying to other gods when they feared for their lives (Jonah 1:14-16, NIV). He demonstrated compassion to Jonah, allowing him to survive the depths of the ocean in the belly of a great fish after three days, and continue his mission despite his initial resistance to do so (Jonah 2:10, NIV). Lastly, he showed compassion on the city of Nineveh following their repentance, despite his initial communicated intent to destroy the land (Jonah 3:10, NIV).

Strangely enough, even after having experienced the Lord's compassion and mercy directly, Jonah was angered by the Lord's decision to show that same level of compassion to the city of Nineveh, challenging, that having known the Lord would extend mercy, he should never have been called to deliver the message (Jonah 4:1-3, NIV). The Lord, with infinite wisdom

chooses a real life parable of a plant that dies, to teach Jonah how the 120,000 residents of Nineveh and their animals, were far more important and had earned the Lord's mercy and grace in comparison to the plant Jonah grieved over (Jonah 4: 10, NIV). The underlying message is the Lord's compassion is offered to those who repent and seek him.

The people of Puerto Rico far exceed 120,000. The opportunity to model after Nineveh is present. With genuine repentance, from the island's governmental leaders and a commitment to do things in accordance to biblical principle, the island can seek the Lord's repentance and regain its standing in His favor, spiritually and economically.

Field of study implications. The researcher's field of study was international business. This study was directly related to the field of international business because while Puerto Rico is a US territory its unique position as an independent commonwealth opens the topic of international trade, tax incentives, and businesses operating abroad. The challenges for Puerto Rico are the desire to leverage the opportunities of an international territory but adhere to the United States regulations without the full protections, financial incentives, and government legislature of a US state.

Strategic decision-making strategies in an international business setting. Researching manufacturing growth and sustainment opportunities and their operation in other countries or territories is the core, foundational, research question for those involved in international business (Smith et al., 2010). Manufacturers are plagued with the cost/benefit analysis of sustaining an operation abroad or manufacturing domestically. The effective strategic decision-making strategies for plant managers are a fundamental topic of understanding cognitive and emotional implications toward decision making in manufacturing operations which often serve as a company's core operation (Jarmolowicz et al., 2016). This study provides tangible strategies that

leaders in manufacturing in countries around the world can implement or validate are in existence to ensure adherence to best practice as demonstrated by the facilities in Puerto Rico.

Impact of the external environment on strategic decision-making strategies. United States companies continue to serve as the largest medical device and pharmaceutical manufacturer in Puerto Rico, yet, as demonstrated by the tax implications of the expiration of Section 936, domestic fiscal decisions can impact US investments in Puerto Rico like an investment in another country. The Puerto Rican government bankruptcy also served as a direct impact to US investments and required the integration of a US Fiscal Oversight Board to get it back on track. This study serves to provide investors and business leaders in an international setting a direct insight into how these external economic upheavals are impacting the strategic decision-making process for some of the largest facilities on the island.

Strategies for medical device and pharmaceutical manufacturing. The study of an industry which provides such critically needed products such as pharmaceuticals and medical devices served as an advantage for other countries as well, such as Ireland, a similar country demographically positioning itself to flourish under the same industry. This study allowed business professionals in an international setting to understand the implications and opportunities of government and economic impacts to the privatized sector. It also served as real-life case study of the recovery efforts and recommended governmental interventions that should take place to reinvigorate and support an industry's growth using the principles of the "infant industry" concept (Harris et al., 2015).

Recommendations for Action

The findings of this study may impact business leaders directly operating manufacturing facilities in Puerto Rico or external leaders seeking growth and development opportunities in

Puerto Rico. Lastly, it may impact executive level leaders with existing oversight of facilities in Puerto Rico and considering the strengths, weaknesses, opportunities, and threats of their facilities operating in Puerto Rico's current economic environment. The researcher conducted a thorough review of professional and academic literature related to the demographics in Puerto Rico, both economically and amongst its residents, as well as the history and events leading to the inception of the Puerto Rico Oversight, Management and Economic Stability Act (PROMESA). The findings from the literature review in conjunction with the research in the field led the researcher to propose the recommendation listed in the following sub-sections. These recommendations provide guidance on implementing effective strategic decision-making strategies in the manufacturing environment and the focus areas for government support.

Commit to the development of a strategic planning session. The research has demonstrated a direct correlation between the strategic decision-making process and the favorable results of the factories in Puerto Rico which participated in the case study. In each facility, the leaders could directly identify the fundamental aspects of the strategic plan with the strategies implemented to drive favorable results on the production floor and close alignment with the company headquarters. The common strategies implemented across the facilities are outlined below as a roadmap of specific recommendations that will assist manufacturing leaders to develop an effective strategic decision-making process.

Recommendation 1: Communicate commitment to strategic planning. Commitment to the process must start at the top. Leaders of the manufacturing facility must encourage their direct staff, at a minimum, to participate in the strategic planning session. The plan should have recommended inputs so the leaders participating have the necessary information going into the meeting. These inputs may include performance data from the prior year, half year, or quarter as

applicable. The team needs to understand that this session is a priority for the facility's leaders and will serve as a direct guideline to the year's upcoming priorities.

Recommendation 2: Seek review and alignment with parent company representative. Plant leaders want to ensure that the goals and objectives they seek to prioritize during the strategic planning session tie directly to the goals and objectives for the parent organization. This will ensure funding and prioritization support from the regional and corporate leaders as well as position the facility as a strategic driver within the manufacturing network. Close alignment to parent company objectives will also ensure a streamlining of communications between the plant leaders and indirect support from the headquarters team as priorities are fully aligned and well understood.

Recommendation 3: Set a formal date with quarterly follow ups. Ideally the official date for the strategic planning session should be placed on the calendar with enough time to ensure maximum participation. It also allows the participants the enough time to prepare the necessary data for the meeting. Quarterly follow ups will keep these priorities front and center of the organization's objectives and will allow for a request of additional support if performance is not in line with the expectations set during the planning strategy. Quarterly follow ups can also be used as an opportunity to reassess the original targets and assumptions that went into the goal setting. If something organizationally significantly changes during the year, the opportunity to adjust should be considered during these intermittent sessions. It is also value added to ensure maximum participation during these sessions for all that were involved the development of the annual strategic plan. This maintains organizational priority and supports team unity.

Recommendation 4: Incorporate review of cross functional alignment. During the strategic planning session, all departments within the facility should be represented. Subject

matter experts or leaders within each of these areas will ensure that the goals and objectives of their specific departments align or support the priorities of the overall strategic plan. In order to maximize effectiveness across the entire facility, it is important for the priorities and expectations of the cross functional departments to support one another or de-conflict as much as possible. This keeps the organization moving in the right direction unilaterally.

Recommendation 5: Identify leaders to advocate local economic partnerships. Partnerships with the local government, such as the local office of economic development or the mayor's office will likely provide additional support for the operation. The facilities in Puerto Rico support various charities within their local municipalities and served the community during the crisis following Hurricane Maria. As a result of these partnerships, the facilities in some cases, have been able to leverage free advertising at the local technical schools within their townships and seek out the top graduates from each semester's graduating class. Local economic partnerships can serve as an advantage of the municipality's overall perception of the facility as an employer of choice. The goal is for each facility to identify a leader or a small team to serve as representatives for the facilities to the local governmental leaders.

Recommendation 6: Incorporate a focus area for leadership development programs. A fundamental input of the strategic planning process for the facilities in Puerto Rico, is the establishment of a leadership development program. Each facility highlighted strategic initiatives to improve the growth and development of their employees. In some cases, programs were designed for the direct labor population through in house "academies" that helped further their technical skillset. In other cases, the established development programs were driving talent and leadership development as part of the succession planning for the facility. In all cases, leadership

development programs demonstrate a fiscal and emotional commitment to the future operations of the facility and the leaders that would drive the facility forward.

Recommendation 7: Select focus areas and design measurement systems for each area. Each facility and business represented in the case study used metrics or key performance indicators (KPIs) as a method to establish targets for specific areas in the business and a way to measure the performance against that target for a predetermined period. In some cases, the metrics were reviewed weekly, in others they were monthly or quarterly. The commonality between the participants of the study was the generation of focus areas, such as quality, safety, or cost, and the metrics that were designed to measure the performance against those focus areas for the employees within the facility. Metrics were used a non-bias tool to measure the performance of a department, team, or individual in accordance with the predetermined goals.

Recommendation 8: Ensure self-awareness. Determine how the affective events influence decisions. The affective events theory correlates a direct tie between emotions and their role on evaluative judgment, hence determining that the leader's direct experiences and influences will factor into the decision-making process. Understanding that previous experiences and the emotions associated with the workplace environment will factor into the leader's approach to the strategic decision-making process, the leader must deliberately focus on self-awareness and provide an environment of collaboration and open discussion amongst all of the participants in the strategic decision making process. By engaging the insights and viewpoint of others, there is a greater opportunity of capturing best practice for each area through consensus, rather than leading strictly from the viewpoints and perspectives of the plant manager.

Establish focus areas for government support of the operation. Manufacturing operations serve as a major employer in the areas where they operate. They provide positive

economic stimulation to their surrounding areas as the employees of the factory generate income and spend portions of their earnings locally. They serve as a large source of revenue to the government through tax expenses and often infrastructure investments in the region that can drive cost-of-living increases, which can further increase government revenues. As a result, the local governmental body has a stake in the success of the manufacturing facility within its jurisdiction. Manufacturing leaders should negotiate to ensure they gain support either through fee waivers associated with infrastructure growth or investment, tax incentives, or credits for expenses associated with government owned agencies. In the case of Puerto Rico, the local government has offered utility credits for government managed utility agencies to help offset the cost of the utilities. Ensuring a true economic partnership between the local government and the manufacturer further supports the advantages to a sustained operation within their jurisdiction.

Approach to disseminate study findings. The researcher intends to disseminate the study findings, applications, and recommendations through the publication of this dissertation in Liberty University's repository and ProQuest Dissertations collection. In addition, the researcher intends to submit the publication to one or more academic journal articles, describing the study process and outcomes. Based on this study, the researcher intends to engage in presentations at related conferences, speaking to professional groups about the industry potential in Puerto Rico.

Recommendations for Further Study

The purpose of researching effective decision-making strategies was so that other manufacturing leaders in Puerto Rico could implement similar strategies or affirm that their existing strategies are on the right track with maintaining a successful operation on the island. The ultimate purpose of the study is to help empower leaders with strategic decision-making approaches that will allow for the island to regain its foothold as a center of excellence for

pharmaceutical and medical device manufacturing, which further supports the continued stability of the overall economy in Puerto Rico. Several strategic level decision-making strategies for medical device and pharmaceutical operations and a detailed view of the contextual areas of focus were provided through the data gathered. The research also determined that while the existing government instability was not directly factored into the existing strategic decision-making process, there were multiple areas in which government intervention or government incentives could significantly support increased commerce and additional investment on the island.

The research process also highlighted a couple of areas that would benefit from further examination. One significant area is the opportunity for independence and self-sufficiency in the generation of power on the island. The high cost of power on the island was identified by all participants at all levels as one of Puerto Rico's greatest economic challenges for growth and investment on the island. Facility leaders are seeking opportunities to become more self-sufficient in the generation of power. Governmental leaders are seeking ways to identify strategies for necessary revenue generation but still incentive businesses to invest on the island and not allow the cost of energy to serve as a hindrance. Facility leaders are seeking opportunities to become more self-sufficient in the generation of power, governmental leaders are seeking ways to identify strategies for necessary revenue generation but still incentive businesses to invest on the island and not allow the cost of energy to serve as a hindrance. Therefore, an opportunity to continue to study methods to provide government incentives for the current cost of electricity, privatization options of this industry, or infrastructural opportunities for self-sufficiency would provide great value against the high cost challenge businesses on the island face today.

In addition, as the study was underway, the pandemic associated with the coronavirus/COVID-19 plagued the world, leading to complete disruptions of the supply chains associated with pharmaceuticals and medical devices as they shipped from low-cost country manufacturers. This led industry leaders to challenge if the United States had become too heavily dependent on pharmaceutical manufacturing in China and India and whether or not government incentives similar to the former Section 936 of the Internal Revenue Code should be reenacted in Puerto Rico in order to strengthen the availability of the pharmaceutical supply chain to Americans (Roy, 2020). These current events further supported the validity of the study in the modern-day economic environment. Therefore, the following are recommendations for additional study that could add to the literature and better equip future business leaders that are seeking ways to further enhance the profitability of their existing operations in Puerto Rico or considering expanding their operations onto the island.

Recommendation 1: Investigate methodologies and a pathway forward for producing electrical power in Puerto Rico. The financial challenges for the high cost of energy and the state of the existing electrical infrastructure was a generally shared concern with the manufacturing leaders. Some defined it as a sunk cost that needed to be managed through financial improvement in other areas (P1C5, personal communication, March 12, 2020), while others defined it as a prevalent concern that could impact the investments businesses are making on the island with respect to the procurement of equipment, which would drive the cost of energy even higher (P1C1, personal communication, March 9, 2020).

The larger manufacturing facilities considered in the study highlighted various initiatives to produce their own energy, while the executive responsible for global strategy described the importance of the opportunity for the government to provide a greater financial benefit for those

that do produce their own power (VP1C4, personal communication, March 13,2020). Thus, further study focused on methodologies for large scale energy production and the opportunities available in conjunction with Puerto Rico's ecosystem is recommended. It may provide additional investment opportunities for those most concerned about the sustainability and cost of the electrical energy on the island.

Recommendation 2: Investigate tax incentives for growth of pharmaceutical and medical device manufacturing in Puerto Rico. The expiration of one of Puerto Rico's most prominent tax incentives did drive a reduction of manufacturing operations on the island. The literature proves that the number of facilities and employees associated with manufacturing in Puerto Rico today is significantly less that it was prior to 1996 when the 10-year phase out of Section 936 was first declared. While the participants did not substantiate this economic impact as a direct input into the annual strategic planning process, both the economic representative and the facility leaders identified that financial instruments such as tax credits or waivers still serve as an effective tool to stimulate growth for continued investment on the island or new investment for potential investors. Ireland is a great example benefitting from one of the lowest corporate tax rates in the world and continues to see growth and investment in the medical device and pharmaceutical industry (Barker, 2016). As a result, it is recommended that further study on potential tax incentives be conducted to help identify a pathway forward for additional growth and investment in Puerto Rico.

Reflections

Reflecting upon the effective strategic decision-making strategies for manufacturing leaders in Puerto Rico and the impacts of the economic environment on the island, the researcher reflected on the experience, the process of gathering the data for the study and any potential bias

or preconceived ideas that could have influenced the study's process and outcomes. In the sub-section below, the key points addressed above, as well as a reflection on the biblical principles associated with the study were identified and addressed in further detail.

Research effects on participants and the situation in Puerto Rico. The study impacted participants by raising awareness on the inherent value the strategic decision-making process had on their overall operation. While this was widely recognized as a standard framework for a manufacturing facility, this study helped to point out the impact their personal leadership style has on the development and execution of the objectives. In addition, the executive level participants were pleased to see Puerto Rico's inherent advantages following a 50-year history in the medical device and pharmaceutical industry was being studied further, allowing additional supportive literature to the existing operations on the island. The study also served the medical device and pharmaceutical manufacturing industry, collectively, with information on the advantages of manufacturing regulated products in Puerto Rico particularly in the current environment where US legislatures are questioning the significant shifts to manufacturing in low-cost countries such as China and India.

Researcher bias. The researcher began her career in medical device manufacturing in Puerto Rico in 2008, working on the island for three years before relocating to the United States, thereby leading to a potential bias of the effectiveness of the operations in Puerto Rico. As a former manufacturing professional in Puerto Rico, there was the possibility to skew the responses strictly in favor of the facilities in Puerto Rico. To combat this possibility, the research used pre-defined interview questions that remained neutral to allow the responses to be open ended and designed for a free flow of information either in favor or opposed to the strategies being used in the facilities in modern day Puerto Rico. In addition, the researcher included

participants in the research serving as higher level executives, that did not reside on the island and whose jobs rely on making the best quantifiable decisions for their organizations, including evaluations of operations outside of Puerto Rico.

Changes in thinking. The researcher's biggest change in thinking was the relevance the Section 936 tax expiration would have on the factories currently operating in the facility. The researcher was very surprised to discover that while manufacturing leaders were aware of the impact as a financial loss, from an incentive standpoint it had been 14 years since this final year phase out of this catalytic moment had taken place and the government had since researched other alternative incentives to drive investment.

The second biggest change in thinking for the researcher was how strongly leaders locally on the island felt about their local talent as the primary source of the facility's competitive advantage. The researcher was not aware of the wide disparity between the number of students graduating in technical trades in Puerto Rico and those in the United States, with Puerto Rico providing a much higher population as a percentage of the population. Understanding that Puerto Rico's continued investment in its engineering programs and technical school's curriculum as an economic strategy to help support continued manufacturing investment on the island was a novel and savvy concept.

Biblical principles. When reflecting on the biblical principles of grace, mercy and redemption, it was interesting to note the humility the leaders in Puerto Rico, to include the economic representative, demonstrated when reflecting on the actions of the government. It was apparent to the researcher that none of the leaders interviewed felt justified by the actions of the government nor did they defend those actions. On the contrary, there was a consensus of remorse and repentance, as a society, for what had occurred and a focus to drive change and improvement

in the economic policy going forward. The researcher felt great compassion for the leaders on the island seeking an opportunity to rebuild the economy and could not help but reflect on the Lord's compassion for the 120,000 people in Nineveh, in hopes that He would continue to offer favor and mercy to the people of Puerto Rico.

Summary and Study Conclusions

In summary, this section presented the findings, applications, and recommendations associated with the qualitative analysis of the data gathered from a multiple-case study of the effective strategic decision-making strategies for pharmaceutical and medical device manufacturing in modern day Puerto Rico. The study findings addressed two research questions. The first research question was: What decision-making strategies did the plant managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico? Followed by: What impact did the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have on the strategic decision-making process? Research data were gathered by interviewing four plant managers for medical device facilities in Puerto Rico and a representative of their direct staff. In addition, a former global operations leader in Puerto Rico was interviewed in order to gain a direct perspective on the insights of someone that suffered through a plant closure. Research was also conducted by interviewing two executive level leaders with indirect responsibilities for the manufacturing of medical devices in Puerto Rico. Lastly, a local mayor was interviewed in order to gain the direct insights and observations of an economic representative with firsthand experience of the governmental impacts and economic environment in Puerto Rico. The research included interviews with all participants named above, direct

observation of the four manufacturing facilities considered in the case study, and a review of any relevant documents.

The responses reached saturation as the researcher was gathering very similar responses to the interview questions by all participants. The triangulation resulting from the examination of multiple cases and multiple sources and varying levels of the case enhanced the reliability and validity of the study, resulting in series of conclusions and recommendations for action.

One major conclusion resulting from the study was that the plant manager's approach to driving effective strategic decision-making strategy will have a direct effect on the successful results of a manufacturing operation. The study also concluded that the plant manager's approach was directly impacted by their previous experiences, emotions, and evaluative judgment of the external environment. This supports the Affective Events Theory, which grounded the study. The study also concluded that strategic operating plan, (the output of the strategic decision-making process) has a direct impact on the favorable results of the manufacturing facility.

Through the culmination of interviews, direct observations, and a review of associated documents, the researcher was able to derive the categories for an effective strategic decision-making session as follows: (a) ensure strict alignment to the strategic objectives of the parent company; (b) allocate time annually, at a minimum, to the strategic planning process; (c) validate alignment across functions within the organization; (d) ensure alignment with local economic partners; (e) develop a focus area for strong and effective leadership; and (f) segment strategic planning into contextual areas of focus. In addition, the interviews relayed the most commonly considered contextual areas of focus to be the following: (a) new product development and integration, (b) operational excellence, (c) on time delivery and supply assurance, (d) cost competitiveness, (e) quality system maturity, and (f) talent development.

The interviews with the company executives and the local economic representative in Puerto Rico resulted in shared themes regarding future growth and continued operations on the island. The axial coding method was used to distill and interpret the collected data. The resulting strategies to further support the continued operation of existing manufacturing and the opportunity for future growth and expansion were identified as follows: (a) continue the use of favorable income tax incentives for manufacturing operations, (b) support government investment or allowed privatization in the improved infrastructure of the electrical utility system, and (c) provide financial incentive instruments for construction and capital investment on the island.

With respect to the second research question regarding the impacts the external environment had on the strategic decision-making process, the results determined that none of the participants incorporated factors from the government instability directly into their strategic planning process. All participants did identify indirect impacts such as the need to manage communication and perceptions with external executives or the need to address the concerns of the future of the operations with the employees following media-sparked rumors over the state of the economy. The participants also addressed the indirect impacts of mass migrations associated with the government bankruptcy and the impacts that it had in both employee retention and talent development. The governmental affects and the external environment in Puerto Rico following Hurricane Maria did have an emotional impact on the plant leaders and reflected in their approach to the strategic decision-making process.

Based on these conclusions, the following recommendations to manufacturing leaders in Puerto Rico were the following: (a) communicate commitment to strategic planning, (b) seek review and alignment with parent company representative, (c) set a formal date with quarterly

follow ups, (d) incorporate review of cross functional alignment, (e) identify leaders to advocate local economic partnerships, (f) incorporate a focus area for leadership development programs, (g) select focus areas and design measurement systems for each are, and (h) ensure self-awareness and determine how the affective events influence decisions.

In conclusion, by identifying the effective strategic decision-making strategies for leaders successfully operating a medical device or pharmaceutical facility in Puerto Rico and the impacts the government bankruptcy and external environment was having on their operation, the research provided an opportunity to reduce the risk of plant closures in Puerto Rico associated with poor design or execution of the strategic decision-making process and resulting annual strategic plan. It also sought to drive awareness of the challenges plant leaders in Puerto Rico are faced with given the instability of the local government on the island and the associated impact this instability may have on the existing operation. The communication of these strategies and how the manufacturing leaders can successfully manage their operations and drive growth and investment in their facilities will further serve the industry, the potential investors seeking opportunities in Puerto Rico, and the leaders of manufacturing facilities managing existing operations on the island, today.

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Appendix A: Company and Participant Codes

Description	Code Name
Participant 1, Company 1	P1C1
Participant 2, Company 1	P2C1
Participant 1, Company 2	P1C2
Participant 2, Company 2	P2C2
Participant 1, Company 3	P1C3
Participant 1, Company 4	P1C4
Participant 2, Company 4	P2C4
Participant 1, Company 5	P1C5
Participant 2, Company 5	P2C5
Vice President, Participant 1, Company 2	VP1C2
Vice President Participant 1, Company 4	VP1C4
Participant 1, Economic Representative	P1ER1

Appendix B: Economic Representative Recruitment Template

1 October 2019

[Recipient]
[Title]
[Company]
[Address 1]
[Address 2]
[Address 3]

Dear [Recipient]:

As a graduate student in the College of Business at Liberty University, I am conducting research as part of the requirements for a doctoral degree. The purpose of my research is to understand the decision-making strategies plant managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico and to also understand the impacts the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have had on the strategic decision making process. I am writing to invite you to participate in my study.

If you are a representative of the Puerto Rican government or an economic representative in Puerto Rico with direct association to the inception of the Puerto Rican Oversight, Management, and Economic Stability Act of 2016 (PROMESA) and are willing to participate, you will be asked to conduct an interview with me to discuss your observations and experiences as it relates to the enactment of this law. It should take approximately one hour to complete the interview.

Your participation will be completely anonymous, and no personal, identifying information will be collected.

To participate complete and return the attached Consent Form and the Attached Applicability form to the researcher's email at **cijerez@liberty.edu**.

A consent document is attached to this letter. The consent document contains additional information about my research, please sign the consent document and return it to me at the time of the interview.

Sincerely,

Cherisa I. Jerez
Doctoral Student, Liberty University College of Business

Appendix C: Manufacturing Leader Recruitment Template

12 January 2020

[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 doctoral degree. The purpose of my research is to understand the decision-making strategies plant managers integrate into the decision-making process to support a successful outcome and avoid closure of a manufacturing operation in Puerto Rico and also understand the impacts the external environment, such as the government bankruptcy or the expiration of the island's tax incentives have had on the strategic decision making process, and I am writing to invite you to participate in my study.

If you are a medical device or pharmaceutical manufacturing or distribution leader (executive, plant manager, or member of the plant manager's direct staff with responsibility for the financial performance or execution of the performance of a manufacturing or distribution facility and expect to remain in the position for two financial quarters of the current fiscal year, and are willing to participate, you will be asked to participate in an interview with me and allow for an on-site direct observation of the teams supporting the plant's strategic plan. In addition, you will be asked to complete a review of your interview transcript for accuracy. It should take approximately one hour to complete the interview and two to three hours for the direct observation of the factory operation, and approximately 45 minutes to complete the review of your interview transcript for accuracy.

Your name and/or other identifying information will be collected as part of your participation, but this information will remain confidential.

To participate, complete and return the attached Applicability form to the researcher's email at **cijerez@liberty.edu**. If you are eligible to participate, I will contact you to schedule the interview. A Consent Form is also attached to this email and contains additional information about my research. Prior to the participating in the interview, I will need you to complete and return the attached Consent Form to the researcher's email provided above.

Sincerely,

Cherisa I. Jerez
Doctoral Student, Liberty University College of Business

Appendix D: Participant Consent Form

Cherisa Jerez, a doctoral candidate in the School of Business at Liberty University, is conducting this study.

Background Information: The purpose of this research is to explore the type of strategic decision-making strategies leaders used in the development of the manufacturing facility's operational strategies. The goal is to understand the unique needs and demands of the strategic decision-making process when faced with Puerto Rico's current economic instability.

Procedures: If you agree to be in this study, we would like to conduct the following activities:

1. An interview with you. The interview will take about 60 minutes to complete. With your permission, we would also like to tape-record the interview to ensure the integrity of the information. The information you provide will be kept confidential to include the name and identities of the participants.
2. Provide all relevant documents (PowerPoint presentations, memorandums, emails) that you believe would assist in capturing the description of your experience during the decision-making process or your experience with the economic situation in Puerto Rico related to the government bankruptcy.
3. For participants in the manufacturing environment, allow for approximately two to three hours of direct observation of the teams supporting the site's strategic objectives through the daily operation.

Risks and benefits of being in the Study: There are no incremental any risks to participating in this study other than those encountered in day-to-day life.

There are no benefits to you directly, however, the addition to the information available about the current state of Puerto Rico's economic situation and its offerings in manufacturing may help to add useful exposure and renewed interest toward investment on the island.

Compensation: There is no compensation for anyone participating in this study

Confidentiality: The records of this study will be kept private. In any sort of report, we make public we will not include any information that will make it possible to identify you. Research records will be kept in a locked file; only the researchers will have access to the records. If we tape-record the interview, we will destroy the tape after it has been transcribed, which we anticipate will be within two months of its taping. I will dispose of all electronic documents following 3 years of the study's completion.

Voluntary Nature of the Study: Participation in this study is completely voluntary. You may skip any questions that you do not want to answer. If you decide not to take part or to skip some of the questions, it will not affect your current or future relationship with Liberty University or me. If you decide to take part, you are free to withdraw at any time.

How 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 following paragraph below. Should you choose to withdraw, data collected from you will be destroyed immediately and will not be included in the study.

Contacts and Questions: The researcher conducting this study Cherisa Jerez. Please ask any questions you have now. If you have questions later, you may contact Cherisa Jerez at cherisajerez@gmail.com or at (915)-504-9285. You can reach the researcher's faculty advisor, Dr. Reshorwn Moore at rthomas155@liberty.edu.

If you have any questions or concerns regarding your rights as a subject in this study, you are encouraged to contact the Institutional Review Board (IRB) at 1971 University Blvd, Carter 134, Lynchburg, VA 24515 or email at irb@liberty.

Please notify the researcher if you would like a copy of this information to keep for your records.

Statement of Consent:

I have read the above information and have received answers to any questions I asked. I consent to take part in the study.

(NOTE: DO NOT AGREE TO PARTICIPATE UNLESS IRB APPROVAL INFORMATION WITH CURRENT DATES HAS BEEN ADDED TO THIS DOCUMENT.)

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

_____

Signature Date

_____

Signature of Investigator Date

Appendix E: Manufacturing Leader Applicability Form

1. Are you currently holding a position of executive level leader, plant manager, or equivalent mid-level manager with responsibility for the financial performance or execution of the performance of a manufacturing facility? (circle one)

   YES (1 point) NO (0 points)

2. Is the organization you work for responsible for manufacturing or distributing a medical device or pharmaceutical product? (circle one)

   YES (1 point) NO (0 points)

3. Do you expect to remain in the position outlined in question 1 for two financial quarters of the current fiscal year?

   YES (1 point) NO (0 points)

   TOTAL YOUR POINTS _____

   If points total less than three, you do not qualify as a candidate for this case study

By signing below, I agree the answers to the questions above are correct to the best of my knowledge:

_____

Your Signature Date

_____

Your Name (printed)

Appendix F: Economic Representative Applicability Form

1. Are you currently holding a governmental or economically related position that allows for direct exposure or influence from Puerto Rico's recent inception of the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA)? (circle one)

   YES (1 point) NO (0 points)

2. Have you been in your current role or a similarly related position for at least three months?

   YES (1 point) NO (0 points)

   TOTAL YOUR POINTS _____

   If points total less than two, you do not qualify as a candidate for this case study

By signing below, I agree the answers to the questions above are correct to the best of my knowledge:

_____

Your Signature Date

_____

Your Name (printed)

Appendix G: Manufacturing Leader Interview Questions

1. Please provide some key facts regarding your organization and its relationship to Puerto Rico:
    a. What kind of product is manufactured at the facility in Puerto Rico?
    b. Is this a medical device or pharmaceutical product?
    c. How many people, both permanent and temporary, currently work at the facility in Puerto Rico?
    d. How long has the facility manufactured products in Puerto Rico?
    e. Does the company currently have more than one facility operating in Puerto Rico?
    f. Is your company currently operating a manufacturing facility in the continental United States?
    g. Is your company currently operating a manufacturing facility in other countries outside the United States & Puerto Rico?
        i. Can you provide a few examples of those countries?
2. What were the date(s) of the last strategic decision-making session?

3. Briefly describe the primary milestones of the plant's strategic decision-making session and plant development strategy.

4. What were some of the key factors used in the strategic decision-making process?

5. How do you think the leadership approach to strategic decision making has favorably impacted the results and performance of the site?

6. How did the local government's current financial instability factor into the strategic decisions for the follow-on fiscal year?

7. Can you describe the impact the government's financial instability has had on the facility's culture?

8. How would you describe the local community's perception of the facility? Is it your experience that the local community has supported the operation's path forward toward economic stability?

Appendix H: Economic Representative Interview Questions

1. Please provide some key facts regarding your organization and its relationship to the integration of the Puerto Rico Oversight, Management, and Economic Stability Act (PROMESA) of 2016:

2. How do you think the declaration of Puerto Rico's Government Bankruptcy has impacted the local economy?

3. What has been your experience the government instability, in general, has had on the people of Puerto Rico? Does this translate to the local business economy on the island as well?

4. What is your perception of the government's strategy to reinvigorate the local economy?

5. Are you aware of investment incentives the government is considering for medical device or pharmaceutical manufacturing?
    a. Do you believe there is a need for these types of incentives?

6. Are there other governmental or economic events, in addition to the government bankruptcy, that you believe has created challenges for local manufacturing centers on the island?
    a. What events on the island support your theory?

7. How would you describe the local community's perception of manufacturing in Puerto Rico? Is it your experience that the local community has supported the factory's path forward toward economic stability?

8. Do you feel the government is taking sufficient actions to stabilize the economy? Why or Why not?

9. In your opinion, what does the future of the Puerto Rican medical device and pharmaceutical manufacturing community look like?