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Strategies to Mitigate Foreign Trade Costs and Regulations that Reduce Revenues

Allan Dithan Mugisa
Walden University

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Walden University

College of Management and Human Potential

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Allan Mugisa

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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Walden University
2023

Abstract

Strategies to Mitigate Foreign Trade Costs and Regulations that Reduce Revenues

by

Allan Mugisa

MS, Salem State University, 2010

BS, Salem State University, 2007

Doctoral Study Submitted in Partial Fulfillment
of the Requirements for the Degree of
Doctor of Business Administration

Walden University

August 2023

Abstract

Foreign trade costs and regulations can lead to unfavorable business outcomes. Business leaders in firms engaged in global trade express concerns about the potential negative impact of foreign trade costs and regulations on revenues. Grounded in the resource-based theory of firms, the purpose of this qualitative multiple case study was to explore strategies some small medical devices and supplies business leaders use to mitigate foreign trade costs and regulations that reduce revenues. Participants were four business leaders of medical device and supply firms who reversed declining revenues. Data were collected using in-person semi-structured interviews. Through thematic analysis, four themes were identified: supply chain management, regulatory compliance, exploration of foreign market opportunities, and allocation of critical resources. A key recommendation is for business leaders to implement strategies for regulatory compliance to produce safe and quality products and to avoid unnecessary costs arising from non-compliance, such as regulatory fines and product recalls. Implications for positive social change include the potential to enhance the health and well-being of citizens in other nations and support the local community workforce.

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Dedication

I want to begin by expressing my gratitude to God for providing me with grace and faithfulness during my time of need. I would also like to dedicate this dissertation to three individuals who have been instrumental in my success: my father, Mr. Jeremiah Kiiza, and my mentor, Philip Yiga. Both believed in my abilities and provided unwavering support and encouragement throughout my academic journey. I appreciate their continuous influence on my life, which motivates me to strive for excellence.

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Section 1: Foundation of the Study

Background of the Problem

Foreign trade regulations and costs can impact small and medium enterprises (SMEs) economically. Such restrictions and costs can be challenging, mainly when exporting to a new market. Apart from the apparent customs barriers and tariffs on imported goods, several non-tariff barriers can hamper exports (Whang, 2019). While foreign trade regulations and costs may create new opportunities, abolishing foreign trade regulations and costs should be the goal (Hoekman & Nicita, 2018). Foreign trade regulations have the potential to impede the growth of small businesses and hinder national development within the business sector (Witt, 2019). Small business leaders can employ innovation and prudent management practices to deal with foreign trade costs and regulations to improve profits and global competitiveness (Feldmann et al., 2019). Through well-crafted strategies, small businesses can mitigate the impact of foreign trade regulations and costs that reduce revenues.

Problem and Purpose

The specific business problem was that small device and supplies firm leaders lacked strategies to mitigate the myriad of foreign trade costs and regulations that reduce revenues. Small businesses engaged in foreign trade face numerous challenges while operating in foreign business environments, leading to increasing costs (Hånell & Nordman, 2019). In 2018, U.S. small businesses that exported goods from the United States (U.S.) were 97.5% of the exporting companies, contributing 32.0% of total export

revenues (U.S. Small Business Administration, 2020). The general business problem was that as foreign trade regulations have continued to grow in volume and complexity, small medical device and supplies firm leaders in the U.S. face cost increases to trade with foreign countries that directly reduce revenues.

The purpose of this qualitative multiple case study was to explore strategies that some small medical devices and supplies business leaders use to mitigate foreign trade costs and regulations that reduce revenues. Foreign trade costs and regulations limit revenues for such businesses; thus, the ability to increase medical devices and supply firms' profits by mitigating foreign trade costs and regulations can have positive implications for the U.S. economy. Implications for positive social change include improving the livelihood of citizens in other nations by providing them with essential products that are manufactured abroad to enhance their health and wellbeing.

Population and Sampling

The target population consisted of 12 senior-level managers from 12 medical devices and supplies firms in the Northeast U.S. These medical devices and supplies firms had to have at least \$2 million in revenue and be engaged in foreign trade operations for at least 3 years. I used the purposive sampling method to obtain a sample of eight participants from a target population of 12. Data sources for the study included interview data from participants and document reviews of U.S. trade statistics and business reports from organizations involved in the study.

Nature of the Study

The three types of research methodologies are qualitative, quantitative, and mixed methods. Mixed methods research involves the use of quantitative and qualitative research methodologies. This approach is time-consuming because it requires two different forms; thus, it is inappropriate for the proposed research study for which the qualitative method is appropriate. The quantitative method involves using statistics (Polona et al., 2018). The quantitative research method does not align with the study because data collected on business leaders' strategies to increase revenues is not in a correct format for quantitative research; therefore, the approach is inappropriate. According to Yin (2018), the qualitative method enables in-depth explorations of a topic. Qualitative research studies involve words instead of numbers and are also more subjective than quantitative research (Walker & Boyer, 2018). The qualitative methodology was selected to explore statements from small business leaders that explain strategies they used to mitigate foreign trade regulations and associated costs that reduce revenues.

Three designs are available for qualitative research: case study, phenomenological study, and ethnographic study. The phenomenological design involves lived experiences of participants and focusing on individual experiences (Langdridge et al., 2018). The ethnographic design involves understanding a research problem through observations of ways of life and interactions with participants in a group setting (Eisenhart, 2017). One

benefit of case study research is the flexibility of using numerous data sources and data collection methods (Siedlecki, 2020).

The multiple case study design involves exploring several phenomena on related topics to provide substantial evidence about the topic under study (Yin, 2018). Also, interviewers can obtain explanatory answers from open-ended questions (Saunders et al., 2015). A single case study design provides is limited to one case and does not permit analyzing data across different situations (Yin, 2018). The multiple case study design was the most suitable approach because it allowed gathering ample and pertinent information of business strategies from multiple small business leaders regarding various foreign trade regulations and their impact on revenue reduction.

Research Question

What strategies do some small medical devices and supplies business leaders use to mitigate foreign trade regulations and costs that reduce revenues?

Interview Questions

Interviews consisted of the following questions:

1. What strategies do you use to mitigate foreign trade regulations and costs to enhance the revenues in your organization?
2. What strategies have you found to work best to mitigate foreign trade regulations and costs to enhance the revenues in your organization?
3. What strategies have failed to mitigate foreign trade regulations and costs to enhance the revenues in your organization?

4. How do you evaluate the success of the strategies that mitigate foreign trade regulations and costs to enhance the revenues in your organization?
5. How do you implement strategies that mitigate foreign trade regulations and costs to enhance the revenues in your organization? Who in the organization is involved?
6. What challenges have you had to implement strategies that mitigate foreign trade regulations and costs to enhance the revenues in your organization?
7. What have you done to meet the objectives of mitigating foreign trade regulations and costs to enhance the revenues in your organization?
8. What additional information would you like to share about the strategies used to mitigate foreign trade regulations and costs to enhance the revenues in your organization?

Conceptual Framework

The resource-based view (RBV) of firms was the conceptual framework for this study. Wernerfelt developed the RBV in 1984. It stresses internal aspects of firms through analysis of various resources possessed by the firm. An organization is an entity comprising various resources that are accumulated to form a competitive advantage (Shan et al., 2019). The RBV is an alternative to understanding firms and their competitive strategies. According to the RBV, valuable resources that are difficult to imitate can position the firm for sustainable growth and success (Das & Teng, 2000).

Technological and global strategy can be understood by applying the RBV. Developing innovation strategies to respond to uncertainties in foreign markets can create strategic assets that enhance overall performance (Azar & Drogendijk, 2016). The accumulation of a firm's resources determines its competitive strategy (Das & Teng, 2000). Firms can also gain access to strategic resources through alliances. Collaborations are increasingly important in the competitive landscape because firms can use collaborations to access other firms' valuable resources (Das & Teng, 2000). Strategic alliances can lead to required resources to mitigate the impact of export regulations and costs that reduce profits.

Valuable resources help firms exploit available opportunities or avoid environmental threats and develop or implement strategies to improve their efficiency and effectiveness (Ferreira et al., 2016). Some SMEs have difficulty succeeding in foreign markets because of lack of resources (Anwar et al., 2018). The RBV can assist in analyzing organizational capabilities and planning to acquire missing resources, which can be aligned to improve organizational performance and competitive advantage.

Operational Definitions

Foreign Trade Regulations: Acts from executive agencies that allow, forbid, limit, or restrict exchange of goods, services, and financial transactions with any foreign country for some time (Morin & Paquin, 2018).

Medical Devices: Health workers use to provide therapeutic or diagnostic services during patient care within or outside health facilities (Peter et al., 2020). Medical device

can also refer to the means through which a patient's health is monitored and improved by acting on the body in a nonmetabolic setting.

Medical Supplies: Non disposable and disposable medical items used in treating and diagnosing patients for specific illnesses, injuries, or conditions (Winger, 2018).

Assumptions, Limitations, and Delimitations

Assumptions

Two assumptions existed for this study. One was that participants answered all questions truthfully to create reliability and validity. Also, I assumed participants had an adequate understanding of strategies involving foreign trade regulations, costs, and revenues for small businesses.

Limitations

Limitations are actions outside the researcher's control that may significantly impact obtained data (Walker et al., 2017). Easy access to participants and proprietary information made conducting the study a challenge. Lack of access to sufficient data affects reliability and validity of study results (Chang et al., 2020). This study also had limitations because of reduced availability of business leaders to participate in interviews resulting from strict safety protocols that were instituted to combat the COVID-19 pandemic. As a result, information provided by selected participants might not be adequate to represent perspectives of other firms elsewhere in the U.S.

Delimitations

Delimitations are the study's boundaries, such as sample size and geographical location where the study takes place. Delimitations define boundaries or descriptions researchers set with studies (Giorgi, 2020). The study was limited to 4 small medical device and supplies businesses in the Northeast United States that had generated at least \$2 million in revenue and engaged in foreign trade operations for at least 3 years. Selected participants were business leaders in small medical device and supplies' firms responsible for implementing strategies to mitigate foreign trade regulations and costs that reduce revenues.

Significance of the Study

Local and global trade thrives in less regulated and low-cost business environments. Strategies to mitigate foreign trade regulations and costs will help businesses engaged in global trade improve their revenues and profitability. Enhanced profitability enables firms to expand their operations to foreign markets and increases the likelihood of leveraging foreign potentials and resources by engaging in business transactions and deals (Goyal & Kumar, 2018). Small business leaders must implement the best strategies to enhance profitability through foreign trade (Hoedoafia, 2019). The growth of exports is increasingly gaining acceptance as a strategy for improving performance in SMEs. There is a positive relationship between the growth of exports and performance of SMEs (Paul, 2020). Growth opportunities, access to new knowledge and

resources, and long-term profitability growth are benefits of internationalization (Anwar et al., 2018).

Some business establishments engage in for-profit activities and activities for positive social change (Luke & Chu, 2013). Small-scale farmers in Asia who participate in fair trade programs realize economic and social benefits (Qiao et al., 2016). An increase in firm profitability allows realizing several economic and social benefits to businesses, employees, customers, and other stakeholders (Lin & Wang, 2018). Contribution of foreign trade to positive social change can be witnessed in terms of improved livelihood of citizens in other nations when provided with essential products that are not available locally. Availability of essential products to communities can enhance their health and wellbeing. Increased foreign trade flows permit improved customer wellbeing by using quality products from supplying firms (Cohen et al., 2019).

Also, increased exports increase jobs in communities in exporting countries to provide more people with incomes to support a decent livelihood. The profitability of SMEs enables higher tax revenues for governments, research and development, better remuneration to employees, and savings for business expansion (Gao et al., 2021). Small business leaders who effectively apply strategies to mitigate foreign trade regulations and costs can increase business revenue and achieve social benefits.

A Review of the Professional and Academic Literature

The objective of this study was to explore strategies to mitigate foreign trade regulations and costs that reduce revenues among small medical device and supplies

firms. The study was grounded in the RBV theory. Firm resources can be used to mitigate effects of foreign trade regulations and costs that reduce revenues. Collection and organization of resources in firms helps to create strategic advantages and enable companies to earn more profit than their competition (Carr, 2003).

The literature review included information on foreign trade regulations for small businesses and their effects. I explicitly covered foreign trade costs and how they affect SMEs. I further discussed contributions of profitability to foreign trade among businesses. I also addressed strategies to enhance business profitability in terms of foreign trade.

The literature review was focused on foreign trade regulations for products sold outside the U.S., general trade rules in the U.S., and costs for small firms involving foreign trade. The following keywords were used when researching the study topic: *foreign trade restrictions, foreign trade regulations, global trade, foreign trade costs, medical devices, supply chain management, and medical supplies for U.S. small businesses*. I used Google Scholar and the Walden University Library to obtain sources for this study. The databases I used were the Directory of Open Access Journals, MEDLINE, Emerald Insight, Academic Search Complete, Business Source Complete, Complementary Index, Political Science Complete, and Science Citation Index. Of 127 sources, 86% were published between 2018 and 2022, and 75% were peer-reviewed documents. I used a research strategy that enabled exploration of several academic sources for this study.

I addressed terms, foreign trade regulations, costs, and profitability. SME foreign trade terms and policies were discussed in the context of the U.S. The literature also provided information regarding effects of foreign trade regulations, rationale for restricting trade, strategies to mitigate foreign trade regulations, and trade costs among small businesses. Strategies to mitigate foreign trade regulations and costs include continuous innovation, supply chain management, information, and communication technology (ICT) use, advocating for fair trade policies, and strategic partnerships. Issues of actual interest to the U.S. for SME exporters include solutions for e-commerce and digital economy issues, customs, and trade promotion measures, removal of regulatory barriers, access to public procurement, evaluation of professional services, and protecting intellectual property rights (Acheampong & Hinson, 2018).

RBV

The conceptual framework for the study was the RBV. Resources and skills are valuable if they enable companies to seize opportunities and face threats. These resources allow organizations to achieve their goals in the business environment. Resources that create a competitive advantage must be valuable, rare, and inimitable (Acheampong & Hinson, 2018). Valuable resources that are unique to current and potential competitors can be a source of competitive advantage. Firms must be organized to exploit their resources and capabilities (McNeill et al., 2020). Lonial and Carter (2015) suggested a comprehensive RBV highlighting entrepreneurial, market, and learning capabilities helps companies understand how to gain and maintain a competitive advantage. Companies can

combine resources across corporate boundaries to gain an edge over competitors (Foroughi & Stern, 2019). Businesses can develop valuable resources by carefully managing their relationships with suppliers, customers, government agencies, and universities.

Firm business leaders can access or accumulate strategic resources through financial institutions, strategic alliances, government programs, and innovation activities (Marjanovic et al., 2020). The ability of SMEs to develop, grow, sustain, and strengthen themselves is heavily determined by their capacity to access and manage finance (Abe et al., 2015). Tariq et al. (2019) found market resource intensity is a success factor in terms of firm sustainability and financial performance. Firms willing to invest in relationship-specific ways and pool resources uniquely will increase productivity along the value chain. These strategic resources can enable firms to develop competencies that can lead to superior quality performance. Resources in the form of funding, talented workforces, and technological applications can facilitate firms to mitigate the impact of foreign trade regulations and costs that reduce revenues.

SMEs

SMEs are independent companies with a small market share that are operated by owners or co-owners. Globally, SMEs are diverse, and each country defines them uniquely. An SME can be defined as a company with less than 500 employees in the U.S. (U. S Small Business Administration, 2020). Small businesses are the pillar of the U.S. economy because they account for 99.9% of all U.S. businesses, employ 48% of private

sector U.S. employees, and 97.5% of U.S. exporting firms (U. S Small Business Administration, 2020). Small businesses employ 47% of America's private-sector workforce.

SMEs are the backbone of the private sector because they account for 55% of employment and are 92 % of organizations globally (Al-Hattami et al., 2021). U.S. small businesses contribute to export growth, provide more jobs, and pay advanced wages through direct and indirect exports to their trading partners, namely Canada, Mexico, China, Japan, and the U.K. (Su et al., 2021). In transition economies, SMEs have spearheaded changes in terms of ownership structures, business culture, and entrepreneurial behavior since 2011 (Zhang et al., 2021).

Despite significant contribution to the U.S. economy, small businesses still face numerous challenges that require special attention to guarantee their survival beyond five years of operation. 50% of new small-business startups fail within the first 5 years of operation, and only one-third survive beyond 10 years (Small Business and Entrepreneurial Council, 2020). Related statistics show that 2.9 million new businesses emerged in the U.S. between 1989 and 1995, and 2.6 million went out of business during the same period, for a net gain of only 300,000 firms (Evenett, 2020). SMEs may not succeed because of failure to implement strategies to ensure their long-term survival.

Foreign Trade for Small Businesses in the U.S.

Foreign trade, also known as international or global trade, is the import and distribution of goods and services across borders (Ortiz-Ospina et al., 2018). A product

sold to the global market is an export, while one bought from the global market is an import (Huang et al., 2019). International trade increases access to a wide selection of commodities at varying prices that consumers can procure. Cross-border trade lowers the cost of commodities through intensifying competition and enables domestic industries to manufacture better-quality commodities (Akerman, 2018). Foreign trade can also assist in wealth distribution when nations maximize revenue by focusing on what they do best and save money on imports that would be more costly to produce domestically. For example, governments may import wheat because they lack adequate arable land and the ability to export any abundant commodity. Export revenues can be used to import goods and services that are produced worldwide rather than involving a country with less comparative advantage to produce the same goods and services (Mirza et al., 2020).

According to the Office of the U.S. Trade Representative (2019), the U.S. is the world's second largest exporter, and exports totaled \$1.6 trillion in 2019. Canada purchased most U.S. goods exports in 2019, and other significant purchasers of U.S. exports were Mexico, China, Japan, the UK, and European Union (Office of the U.S. Trade Representative, 2019). SMEs constitute most U.S. exporting firms, but their contribution to total exports is significantly less because of challenges they face in terms of foreign trade operations. Exporting activity in the U.S. is highly skewed, with SMEs accounting for 98% of exporting firms and only 32% of the \$1.5 trillion in total U.S. exports (U.S. Small Business Administration, 2020). Large companies are 2.7% of exporters but account for 68 % of U.S. exports (U. S Small Business Administration,

2020). Lopsided firm size circulation is not exclusive to the U.S. and happens all economies worldwide (Hallak, 2020). Supremacy of large firms in terms of trade abilities and aptitudes could unreasonably aid them in performing better than smaller firms. Since small businesses include most exporting firms, they can contribute more to the total volume of U.S. exports if supported appropriately.

International involvement often increases trade flows through imports, exports, and foreign direct investment (FDI). Export growth has traditionally been viewed as an economic activity that primarily benefits large corporations, and exports can also bring significant benefits to SMEs (Zhang et al., 2021). Small businesses that enter international markets can grow their revenues, diversify their customer bases, and increase profits. Companies that export expand faster and create American jobs with higher wages (Liu et al., 2021). Increased participation of SMEs in the global market accelerates innovation, facilitates the transfer of technology and management knowhow, expands, and deepens skills, and creates opportunities for productivity and improvement (Al-Roubaie & Mubarak, 2021). Exports allow businesses to enter larger markets and learn new skills to increase profitability and consumption for business owners, workers, and families.

Profitability in Small Businesses

The goal of most companies is to make a profit. Profit is calculated as the company's revenues minus costs. Profitability refers to the degree to which firms acquire revenues that are more than their expenses during a specific period (Seissian et al., 2018).

Any business needs to achieve profits from its sales and business activities for business expansion and sustainability. Firm productivity is one of the determinants of profitability (Yazdanfar, 2013). However, profit is not the best indicator of success compared to ratio of profit to company size (Seissian et al., 2018). Margaretha and Supartika (2016) asserted profitability heavily relies on firm size and productivity. A small firm with high profits is considered more successful than a more prominent firm with the same level of profits.

SMEs must generate profits because profitability affects their survival (Margaretha & Supartika, 2016). Organizations must have business models that make their ongoing operations profitable. Otherwise, they will eventually fail. Signs of inefficiency in small business revenue streams occur when it takes more time to produce fewer goods or accomplish tasks (Ahsan, 2020). Failure to streamline production processes and enhance efficiency can lead to further losses.

Foreign Trade Regulations

Regulatory discrepancies between legal systems and unsuitable international trade restrictions potentially increase trade costs and affect trade flows in the global value chain. Raising tariffs can burden employees and businesses with additional costs (Pilinkiene, 2016). The impact of the regulatory environment on trade, determined by regulations, standards, and laws that are applicable to a particular sector, is a common concern among traders (Hoekman & Nicita, 2018).

The U.S. supports trade liberalization and works with global trade organizations such as the General Agreement on Tariffs and Trade (GATT) and World Trade Organization (WTO). Trade promotes individual nations' economic growth, social stability, democracy, wellbeing, rule of law, and international transportation (Nevitte, 2017). Congress sets goals for U.S. trade negotiations, enacts trade laws, programs, and agreements, and elevates activities and synchronization functions performed by many federal agencies. By law, the United States Trade Representative (USTR) is the United States' leading trade negotiator and coordinates trade policy through inter-ministerial processes with formal public and private advice (Office of the United States Trade Representative, 2019). U.S. strategy activities incorporate SME issues and priorities into U.S. trade policy activities, raise trade and business outreach with small businesses, and improve synchronization of worldwide policy and elevation activities linking to SMEs (Gereffi, 2020). Electronic commerce is new, presenting an entirely new set of foreign trade concerns. The U.S. intends to make the Internet a tariff-free zone and guarantee completely live telecommunications markets secured with global protections for intellectual property in digital products (Cohen et al., 2019).

Impact of Foreign Trade Regulations

Despite this well-known debate, unilateral trade policies are considered inefficient as they restrict trade flows. Instead, trade agreements are favored as they can help limit unilateral actions. (Veroneau & Gibson, 2017). Trade regulations increase foreign trade costs by adding tariffs and other trade barriers. A rise in import prices because of trade

restrictions means higher commodity prices for consumers and producers (Seissian et al., 2018). Trade restrictions should be limited or eliminated to enhance trading activities. Economists have shown that international trade promotes economic growth as trade liberalization and integration have shaped the last 50 years (Pilinkiene, 2016).

Promotion of Local Industries

Several reasons exist for trade restrictions, and the most common is the promotion of local industries. This environment allowed government officials and business people to ponder the American economy without international connections (Mirza et al., 2020). While in office, President Trump was vocal about the China-US trade imbalances and took action to resolve the problem. The China-US trade imbalance was \$347 billion in 2016 (Lin & Wang, 2018).

Trade regulations are not the best way to recover from trade-related losses through tariffs and other trade barriers. If manufacturers depend on imported mechanisms or other involvements in their production process subject to trade restrictions, they will also pass on the increased cost to consumers (Natera et al., 2019). The use of tariffs will reduce the benefits from international trade flowing to consumers across the country. For example, the United States-Mexico-Canada Agreement (USMCA) was expected to increase drug costs in Mexico and Canada (Labonté et al., 2019). As a result, economists are pessimistic about tariffs to increase employment in developed countries.

Trade barriers are not the best way to help workers suffering from trade-related losses. Instead, promoting trade can improve the well-being of a nation's population.

Tariffs may be met with other retaliatory tariffs. A good example, in response to Trump's trade tariffs, the E.U. imposed tariffs on Harley Davidson motorbikes manufactured in Wisconsin, home to House Speaker Paul Ryan (Fetzer & Schwarz, 2021).

Defending National Security

The defense industry exists for national interests and is highly protected in most cases. Trade restrictions have been implemented to protect specific industries considered significant to protect national security (Dolz et al., 2018). Western Europe and the United States are reasonably open to trade, but both have reasonable protection for their defense-oriented industries. Free trade in military technology is rare, and soon, trading in high-tech equipment could evolve into a national security matter (Dolz et al., 2018). Export controls have expanded from national security focusing on military-oriented goods and technology to commercial technology. Some export controls serve national security and economic interests (Whang, 2019). Business leaders dealing with technologically advanced products must comply with government regulations to avoid the risk of closure. Such controls cannot be eliminated; therefore, business leaders should not waste effort opposing them.

Foreign Trade Costs

Organizations engaged in foreign trade encounter challenges such as increasing costs while operating in the global business environment (Hånell & Nordman, 2019). Foreign trade is the cost of exchanging goods and services across national borders (Evenett, 2020). The definition of trade costs can include barriers and obstacles that can

increase the cost of international trade (Hassan, 2020). Other factors to contemplate are transportation costs, taxes and duties, sales commissions, insurance, and funding (Rai et al., 2020). Suvankulov (2016) stated that foreign trade transaction costs significantly affect trade flows. All forces acting on the market can be variable, and trade costs require urgent attention (Ahsan, 2020). Costs of international trade include loss of occupations and income inequality because of competition between trading partners (Langenwalter, 2020).

If business leaders can effectively reduce costs without sacrificing quality, selling price, or sales, the leaders will pave the way for increased profitability. Reducing costs increases profitability, but only if sales prices and the number of sales remain constant (Zeuthen, 2018). If cost savings reduce product quality, lower prices are favored to maintain the same level of sales (Metcalf et al., 2020). To obtain cost savings to improve profitability, some U.S. companies shifted their manufacturing operations to China (Lin & Wang, 2018). Cost reduction is a task carried out among a relatively contained number of players, who are often internal or keep in touch with the company. Cost reduction concentrates mainly on employing in-house resources effectively (Rai et al., 2020). Maximum efficiency in reducing costs is achieved through negotiating the best possible prices for materials, personnel, and facilities.

Marketing Campaigns

The global economy has evolved rapidly over the past two decades (Krausmann et al., 2018). The global marketplace consists of consumers with different cultures and

backgrounds; therefore, marketing campaigns must respect cultural diversity to achieve the intended objectives. Multi-ethnic cues in advertising campaigns signal high quality, brand inclusiveness, and popularity among some Asian consumers (Licsandru & Cui, 2019). Using marketing mix strategies to build and expand their products or services can assist firms in increasing their foreign market share (Kalogiannidis et al., 2020). Firms must have the most recent information on market demands to manage the changes in the global market environment.

Small business owners must have access to timely and relevant information to assist them to reduce identifying and exploiting market opportunities and improve their performance in export markets (Racela & Thoumrungroje, 2020). Gielens (2021) SMEs involved in foreign trade must accurately assess the global market to allocate their limited resources more appropriately and achieve sustainable growth. In the long run, competitive advantage depends on more speedily building core competencies at lower costs. Company-specific advantages such as the R&D and marketing orientations positively impact its performance (Hsiao & Hsu, 2018).

Some organizations can use interconnected social media platforms to achieve significant innovative results. Social media has impacted almost all aspects of life, and corporations that embrace the medium create a stronger connection with their customers. Proactive companies monitor independent sites for honest feedback on their products (Cho et al., 2017). Also, after-sales services provide a foundation for reengineering and improving the existing product line (Durugbo, 2020). With their flexibility and ability to

adapt and differentiate their products, SMEs have a competitive advantage over large companies in the global market because they can respond quickly to changing market conditions, and shortened product life cycles can be obtained (Falahat et al., 2020).

Continuous Innovation

Innovation efforts facilitate the growth and development of firms and the entire economy (Bobillo et al., 2018). Innovation as a strategy can mitigate the impact of export regulations and costs that reduce profits. Innovation enables firms to improve their existing product offering and offer new products cost-efficiently to meet the evolving market needs. Consequently, innovation can enable firms to improve their productivity. According to Caballero-Morales (2021), organizations can use innovation as a survival strategy to develop products for new markets and use digital resources to facilitate communication and networking efforts.

Firms affected by the Covid 19 pandemic that started in 2020 will likely use continuous innovation to secure growth and recovery (George & Tarr, 2021). Innovation can improve a firm's competitive advantage (Shahri & Sarvestani, 2020). For innovation to add value to an organization, significant investment in research and development is required. Well-crafted R&D and product development strategies can contribute to a firm's growth and success (Bobillo et al., 2018). A high level of research and development (R&D) expenditure positively impacted exports (Raghupathi & Raghupathi, 2019). Innovation and technology open the firms' gates to exploring and exploiting local and international opportunities (Yun et al., 2020). The advancement of innovations improves

production at high levels of quality and quantity. Products can be transformed based on regulations and available resources; value addition can also be promoted during development and production (Torsekar, 2018).

Agile methods entail rigorous process improvements, improving the quality and quantity of the products produced and sold out on the market (Lobato et al., 2019). Agile methods previously limited to software can be applied in various industries, and hybrid innovation models are also recognized in the information economy (Mills et al., 2020). Using agile techniques efficiently can enable firms to offer high-quality products at reasonable costs and deliver improved customer experiences. Also, the agile approach is preferred for sectors that incur significant capital investments (Zamith & Gonçalves, 2018).

For an innovation strategy to succeed, most employees in the organization must play a role or contribute to its success: employees at both lower and managerial levels. Managerial actions determine the type of culture an organization supports and can also facilitate the implementation of the innovation strategy. Implementing an innovation strategy is an important managerial role. (Currie & Spyridonidis, 2019). If an organization's innovation strategy aligns with its culture, the innovation speed will become more significant. Innovation behavior supported by organizational culture facilitates business development (Stacho et al., 2016).

ICT

Business leaders' technological abilities help to determine innovative endeavors, and firms can obtain market acceptability and establish long-term comparative advantage through innovative products and services (Hasan & Uthamaputhran, 2020). Implementing digital technologies permits the creation of product offerings that suit customers' needs (Coreynen et al., 2017). The adoption of eCommerce enables access to new customer segments and helps improve profitability (Mäki & Toivola, 2021).

Businesses employ enterprise-wide systems to pursue hyper-efficient operations. I.T., through enterprise-wide solutions, can empower firms with such capabilities as environmental scanning and customer services and enable them to perform and compete better in the uncertain market and environment (Chae et al., 2018). Enterprise-wide solutions that enable sharing of information across the entire organization include enterprise resource planning systems (ERPs), decision support systems (DSS), customer relationship management systems (CRMs), and knowledge management systems (KMS). Firms that successfully manage knowledge, which is regarded as a critical resource, gain the ability to improve their performance and competitive advantage. (Gürlek & Çemberci, 2020). Enhanced return on investment, reduced inventories, optimized supply chain management, and time to production are some benefits of using enterprise-wide systems (Rashid et al., 2018).

ICT can enhance the various aspects of the business and create new opportunities to improve its competitive advantage. Appropriate implementation of ICT substantially

impacts intellectual property management, innovation, and profitability (Valdez-Juárez et al., 2018). After using ICT to improve the various aspects of the business, it is important to coordinate them effectively to create value. Combining ICT with other related resources can empower a business to build value (Bayer et al., 2020). The operational use of decision support systems such as business intelligence offers a competitive advantage when firms can develop better relationships with employees and increase their process institutionalization (Yiu et al., 2021). Enterprise-wide solutions enable management to make more accurate business decisions and improve process management (Osuszek & Ledzianowski, 2020). Adopting technology-enabled systems across the organization offers opportunities to streamline numerous processes to achieve cost savings and improve profitability. Enterprise-wide systems are a significant determinant of competitive advantage (Dezdar, 2017). Also, the power of different ICT platforms relies on improved internet services and capabilities. Internet-enabled businesses can reduce transaction costs in export markets and increase export revenues (Jean & Kim, 2020). Improved internet services can boost open innovation efforts and reduce transaction costs, thus promoting organizational growth.

Adopting emerging technologies can also enable firms to deal with foreign trade regulations and costs. Blockchain technology, machine learning, and artificial intelligence offer opportunities for improving business processes and cost savings. Some potential benefits of blockchain technology to eCommerce include secure storage of money, improvements in supply chain management, and reduction in transaction costs

(Xuan et al., 2020). Also, blockchain technology offers organizational-related benefits in various sectors, namely, health information exchange, pharmaceutical supply chain, clinical trials, and medical insurance management (Abu-Elezz et al., 2020). Firms can use blockchain technology to improve supply chain adaptability, alignment, and agility, leading to competitive advantage and better firm performance (Sheel & Nath, 2019). Regarding foreign trade, efficient enterprise systems help to eliminate delays that can increase the cost of goods.

Supply Chain Management

Digital technologies are applied to several goods, services, and processes. Similarly, supply chain management can be improved by facilitating digital technologies. Integrating digital technologies into supply chain management helps firms stay competitive and realize better performance (Ardito et al., 2019). Developments in supply chain management and other factors can improve a firm's competitive position (Bhandal et al., 2022). With free trade, national boundaries should not define the potential market for any product. Changes in the global retail industry, such as the rise of the global value chain and digital transformation, offer SMEs new opportunities to integrate into the global economy (Lwesya, 2021).

Lean supply chain management, employed with other technologies such as big data, cloud computing, and the cyber-physical system acting on lean practices, can produce superior results (Núñez-Merino et al., 2020). This approach can enable an organization to create substantial value by integrating the multiple systems it uses to

operate. One feature of technological advances is that they have significantly reduced the economic costs of international transactions. Some online prices are substantially lower than regular retail store prices, even if shipping charges are added because online suppliers can avoid most distribution costs and save on inventory costs. One example is the internet's effect on shopping for personal items (Matulova et al., 2018). The advent of the internet creates easy access to various markets through millions of websites worldwide, selling almost to any consumer (Hine, 2020). A firm must use digital technologies and other measures to improve its supply chain management. Firms seeking to achieve supply chain sustainability must integrate financial and non-financial sustainability initiatives (Rezaee, 2018).

Proper supply chain management requires adapting to changing market needs or market disruptions. In a dynamic and unpredictable marketplace, the supply chain is a significant determinant of value creation for firms (Bhandal et al., 2022). Supplier selection is critical, especially for firms operating in a highly competitive environment such as foreign markets. Appropriate supplier selection for firms facing competitive market conditions supports operational and strategic benefits (Cho et al., 2021). Strategic flexibility and improved performance in SMEs can be realized through proactively developing strategic relationships with suppliers (Sen et al., 2022). Gunasekaran et al. (2017) stated that I.T. increases efficiency and responsiveness within an organization's logistics and supply chain, leading to a competitive advantage. Strong logistics capabilities help firms achieve long-term sustainable competitive advantage; hence,

organizations must develop dynamic strategies that respond to the changing global market needs.

Fair Foreign Trade Policies

Fair foreign trade policies reduce costs by facilitating links between buyers and sellers; thus, business leaders who need to improve productivity in their firms must engage in negotiations to promote fair foreign trade policies. Economists have shown that international trade promotes economic growth through the characteristics of trade liberalization and integration (Pilinkiene, 2016). Regarding the positive effects of trade, Mukherjee et al. (2016) reported in a study of the Indian textile industry that tariff reductions positively affect profitability. According to their research, trade liberalization increased imported raw materials and improved profitability at the enterprise level between 2000 and 2009. They found a more substantial effect on lowering import tariffs. In addition, large companies tend to benefit more from trade liberalization than SMEs (Mukherjee et al., 2016). Surprisingly, large companies that benefit from tariff cuts by increasing imports of high-quality commodities can profit more than SMEs that cannot take advantage of such cuts because of their size. Zhang and Nguyen (2019) posit that U.S. firms have higher chances of negotiating free trade agreements with trading partners.

Also, improving access to information on regulations, restrictions, and export opportunities can facilitate the seamless exchange of goods and services. Foreign trade agreements can cover other areas to cover non-tariff barriers, such as quotas, product

standards, labor, and intellectual property (Hoekman & Nicita, 2018). Small business firms that understand the various restrictions and opportunities can mitigate the impact of trade restrictions in foreign markets can achieve organizational growth and improve financial performance.

Lobbying Governments

Lobbying for favorable government policies and regulations can reduce the impact of foreign trade regulations and costs. Evidence of the stark differences exists between developing and advanced countries regarding the time needed to move an export container from a factory to the nearest port fulfilling all customs, administrative, and port requirements (Vermeulen & Rachynska, 2020). Foreign trade regulations can exist in patent protections for businesses that invest heavily in intellectual property. Businesses must invest heavily in lobbying efforts to encourage a nation's legislating organs to pass domestic and foreign trade regulations that favor their industries and enterprises. Significant involvement of large global firms in the domestic innovation systems of developing countries leads to more stringent adoption and convergence to advanced country I.P. protection standards (Brandl et al., 2019). Successful lobbying efforts will provide the industry-required protections to improve business activity. Adequate patent protection for U.S. pharmaceutical exports can increase business activity and market share in developing countries (Boring, 2015).

Businesses can also lobby the government to provide trade facilitation programs to reduce trade costs and create conditions for increasing trade. These programs can be

narrow or wide. Programs may target reforming specific policies, such as customs procedures, or be part of an integrated regulatory policy and strategy (Marples et al., 2020). Depending on the nature of the programs and their implementation, outcomes may vary in substance and degree. Reducing delays at entry and exit points enables a reduction in import and export costs, thereby improving competitiveness (Liu et al., 2021).

Strategic Partnerships

Small business entrepreneurs can collaborate with larger firms to assist them with their business needs. According to Hogenhuis et al. (2016), young ventures can access financial resources, commercial experience, and networks through collaboration with larger established firms. According to Shin and Lee (2019), strategic alliances between SMEs and multinational corporations involve sharing information, technology resources, and proprietary information. Rigtering and Behrens (2021) posited that collaboration between startups and large established firms helps create a transformational environment and opportunities for renewal within the startup. Large firms provide financial resources, commercial experience, access to knowledge, and networks that support new business opportunities and boost profitability. Interconnectivity among local firms promotes sharing of knowledge, intellectual property, and funds for timely product development. (Molloy, 2021).

As organizations grow, a need exists to extend beyond national borders into foreign countries to increase market share, which presents new challenges. Collaboration

between firms in different geographical can alleviate the challenges of internationalizing firms and yield some economic benefits. Inter-firm relationships assist internationalizing firms in dealing with uncertainty in foreign markets (Bai et al., 2022). Global strategic partnerships can help lower the risk of accessing new business frontiers (Kaur et al., 2019). SMEs can access foreign markets through partnerships with other firms in the global market. Collaboration with other firms aids in reducing the risk of joining new markets with limited information and financial resources. Strategic partnerships expand the firm's resources and capabilities to facilitate achieving the partnership goals (Valbuena-Hernandez & Ortiz-de-Mandojana, 2022).

Strategic alliances between smaller and established firms offer opportunities for smaller firms to navigate foreign trade regulations. Ballor and Yildirim (2020) stressed that multinational corporations with special access to international policymakers and national governments have the power to push for trade-liberalizing policies. In the pharmaceutical industry, inter-firm partnerships between big pharmaceutical companies and smaller firms can assist smaller firms in overcoming regulatory and financing challenges. (Yoon et al., 2018). The ability of small businesses to overcome regulatory challenges restricting foreign trade can create opportunities to increase trade flows. With fewer restrictions, more products will be exchanged across national borders.

Medical Device and Supplies Sector in the U.S.

Across the globe, the medical devices and supplies industry plays a cardinal role in improving the health sector. Medical devices and supplies include test kits and related

apparatus, disinfectants and sterilization products, medical consumables, medical therapies, medical diagnosis devices, protective garments, thermometers, and soap. The COVID-19 pandemic has exposed the sector's vulnerabilities in fulfilling critical customers' demands. The 2019 Coronavirus Pandemic (COVID-19) disrupted U.S. economic activity in early 2020, and, despite growth in total domestic production (GDP), the economic activity reached pre-pandemic levels in the third quarter of 2020 but remained relatively low (Zheng et al., 2020). The pandemic has changed economic, political, and social factors, affecting industry operations. Such an environment requires strategic thinking by the owners and administrators to ensure proper service delivery among countries in the same sector. Bown (2021) argued that incentivizing the domestic industry to increase production, stockpiling PPE for emergencies, and importing PPE would help alleviate the medical supply shortages.

Global trade and globalization have affected the medical devices and supplies business because it determines the levels of profitability and sales that the company can achieve in a specific period. For that matter, the best strategies and paradigm shifts in medical devices and supplies firms need to be considered for the positive undertaking of business activities and operations (Eze et al., 2019). Also, most countries, especially in the developing world, cannot afford the required state-of-the-art medical devices and equipment. Residents in emerging countries take advantage of any price reductions and enjoy the benefits of the remanufactured devices to deal with the persistent healthcare challenges in countries from the lack of advanced medical equipment for healthcare

services delivery (Eze et al., 2019). Medical devices and supplies are critical in improving the health system, but all the products and services must conform to the prevailing regulations. Stakeholders in the health sector must adhere to the provided rules and regulations to improve the health services and care of the country where they are implemented (Schnell-Inderst et al., 2018). Improving standards for the medical devices and supplies industry might reduce legislative burdens, costs, and any medical services delays that might slow down health services and treatment delivery (Carmelo, 2018).

Regulations of the Medical Devices and Supplies Sector in the U.S.

Medical devices and supplies must obtain approval before being sold for public use. Medical devices and supplies firms in the U.S. are regulated by the U.S. Food and Drugs Administration (FDA), which oversees their activities and business operations (Jones et al., 2019). The FDA regulatory process is tailored to guarantee adequate premarket assessment and timely post-market safety concerns. The FDA ensures that any developers and manufacturers of medical products meet the required regulatory provisions and standards for better users' benefit and safety (Shuren et al., 2018). The body has various regulatory frameworks that seek to permit medical devices and supplies firms to market their goods and services in the country and abroad. The regulatory pathways involve demonstrating the safety and effectiveness of the newly proposed device on its own merits and demonstrating that the new device is equivalent to a legally existing device (Selzman et al., 2019). Selzman added that the legislation of the 21st Century Cures Act of 2016 provided the FDA with resources to expedite the development

and delivery of innovative devices through less burdensome regulatory reviews while maintaining the requirement for safety and effectiveness.

The 21st Century Cures Act primarily applies to the development and marketing of new medical devices that do not have alternatives or are superior to existing devices. The medical device industry must follow all international trade regulations on their services and products as they deal with customers across countries (Curran, 2020). Concerning regulations of the medical devices sector, efforts to comply with all the commercialization laws are seen as an avenue for accelerated growth and development and the provision of improved medical care services for U.S. consumers and beyond (Carmelo, 2018). Also, promoting good health in the communities starts with the quality of medical equipment and software adopted and used. However, such software needs to evolve according to the standard regulations set by a regulatory body in the country (Lima, 2020).

Governments fearing running out of medical supplies will impose export restrictions, while those needing supplies will relax import duties. Also, increasing prices and shortages of medical supplies are typical during pandemics. Evenett (2020) reported that by March 2020, 54 governments had placed export curbs on medical supplies and medicines associated with the COVID-19 pandemic. The trade restrictions did not bear the expected results; thus, the strategies had to be revised. Limiting shipments abroad discouraged local firms from ramping up production and investing in new capacity; therefore, the World Health Organization (WHO) called on governments to increase

production of protective equipment by 40% and to rollback trade restrictions on medical supplies to allow them to get where they are needed most (Evenett, 2020). The U.S. government invoked the Defense Production Act that instructed the 3M organization to import 166.5 million respirators and issued \$1 billion in subsidies to build a domestic PPE supply chain (Bown, 2021).

Transition and Summary

Section 1 included an introduction to the study. The purpose of this qualitative multiple case study was to explore strategies that some small medical device and supplies business leaders can use to mitigate foreign trade regulations and costs that reduce revenues. The section included the research question, theoretical framework, interview questions, purpose statement, nature of the study, significance of the study, and review of professional and academic literature. Exporting firms engaging in foreign trade encounter various challenges and costs as they venture into new territories. To overcome these obstacles, such firms need to formulate effective strategies.

Study findings offer insights regarding how leaders of small businesses can enhance their revenues and attain profitability in the face of trade limitations during foreign trade operations. The literature review includes information about marketing campaigns, continuous innovation, fair trade policies, ICT use, strategic partnerships, supply chain management, and the medical device and supplies sector in the U.S. and related regulations. Small business leaders must efficiently allocate firm resources for

global competitiveness based on strategies to improve opportunities to increase revenues, market share, and profitability.

In Section 2, I describe the research approach, including population and sampling, data collection, data analysis, data organization, and reliability and validity. This section also includes the research process which involved recruitment of potential participants and facilitation of data collection.

In Section 3, I present study findings, applications to professional practice, implications for social change, recommendations for action and further research, and a conclusion.

Section 2: The Project

Purpose Statement

The purpose of this qualitative multiple case study was to explore strategies that some small medical devices and supplies business leaders use to mitigate foreign trade regulations and costs that reduce revenues. The target population was 12 senior-level managers from four medical devices and supplies firms in the Northeast U.S. These medical devices and supplies firms generated at least \$2 million in revenue and engaged in foreign trade operations for at least 3 years. Foreign trade regulations and costs limit revenues for such businesses; thus, the ability to increase these revenues by mitigating foreign trade regulations and costs can have positive implications for the U.S. economy. Implications for positive social change include improving the livelihood of citizens in

other nations by providing them with essential products that are manufactured abroad to enhance their health and wellbeing.

Role of the Researcher

The role of the qualitative researcher is to define and interpret an unknown phenomenon for others to understand (Fusch et al., 2018). Qualitative research is an iterative process that is used to study a phenomenon to improve understanding (Aspers & Corte, 2019). Cypress (2017) reported qualitative researchers are responsible for collecting and interpreting data through their lens. One benefit of the case study method is rich descriptions of interrelated factors (Tomaszewski et al., 2020). The research process involved recruiting potential participants and data collection and analysis. Selection of the research methodology and design is an additional role of the researcher. The population for the study was business leaders in the medical device and supplies industry in the Northeast, U.S.

Shaw and Satalkar (2018) asserted researchers must remain objective despite possible biases during data collection and presentation of findings. Bias can negatively influence data collection and analysis processes (Shaw & Satalkar, 2018). The subjective nature of qualitative research makes it sensitive to participant and researcher bias (Tomaszewski et al., 2020). Noble and Smith (2015) expressed validity and reliability considerations can improve the quality of a qualitative study. Validity and reliability issues were addressed in this study. I adopted bracketing during interviews to eliminate bias. In the research context, bracketing is defined as the deliberate effort to eliminate

researcher beliefs and personal experiences before and during the research period (Baksh, 2018). I allowed participants to present ideas and opinions about questions freely without interruptions. Interview questions were designed to avoid leading participants, so they produced uncorrupted information.

For this study, member-checking was applied for each completed interview. Member-checking refers to using and sharing interview interpretations with study participants to examine validity (Madill & Sullivan, 2018). Member-checking is a process that helps to assess study data (De Marchi et al., 2020). Typically, researchers apply and adopt member-checking to validate responses from participants (Busetto et al., 2020). I shared interview interpretations with participants to obtain their feedback. The intention was to ascertain if interpretations adequately captured all participants' views the same ways they were expressed. The study participants had the opportunity to identify information that might not have been captured or elaborated upon. Also, participants were given another opportunity to add their views, and necessary adjustments were made accordingly. I maintained transparency and respected leadership positions of participants during the interview process.

Observation and adherence to research ethics are necessary for any study (Shaw & Satakar, 2018). I adopted, applied, and used an interview protocol during interviews. In research, interview protocols serve to ease qualitative data collection by including clear and timely data collection procedures (Yeong et al., 2018). Interview protocols allow researchers to collect adequate data using guidelines that control the entire process.

Safety, conformability, and general wellbeing of participants are vital for researchers to collect data and disseminate findings (Patten & Newhart, 2017).

I ensured principles of privacy and confidentiality were observed by using codes in place of participants' names or job titles. The names of medical device and supplies firms were confidential. Thus, these names do not appear anywhere in the study. I obtained participant consent before the interview process. I used an informed consent form to obtain informed consent from all participants before they were recorded or engaged in any interview sessions.

Participants

Researchers must find appropriate and experienced study participants concerning a study topic. Researchers set eligibility criteria to define participants for the study (Mullet, 2018). I considered participants who were leaders at small medical device and supplies firms that earned at least \$2 million in annual revenue and engaged in foreign trade operations for at least 3 years. Creswell (2014) asserted purposive sampling is a nonprobability method which is instrumental in obtaining qualitative information from participants for a qualitative study. Purposive sampling was applied for eight study participants.

Access to research participants presents numerous ethical challenges; thus, participants must be handled with care to protect them from getting hurt (Castleberry & Nolen, 2018). The sources of participants for the intended study were the LinkedIn website and contacts in my professional network. The professional network helped me

connect to the participants working in US small medical devices and supplies firms and willing to share the information for this study. I sent invitation letters to the study participants through email and consent forms, after which they confirmed their willingness to participate. The invitation letters consisted of objectives, research details criteria, participation, assurances of confidentiality, and the researcher's contact information. The designed consent form stated the study's objectives and the beneficiaries. The participants actively engaged in the interviews with the interviewer for approximately thirty minutes for each interview. A statement of voluntary participation and withdrawal from the interview was also presented. I set the time and day for interviews based on the advice of the study participants. All participants returned the filled consent forms by email to confirm consent.

Drabble et al. (2015) explained that the effort by the interviewer to form a good relationship with the interviewee creates a good connection enabling responsiveness and confidence to be part of the study data collection process. An atmosphere of openness during interactions establishes a good relationship and can win the study participants' confidence (Clark & Vealé, 2018). I launched the interviews among the participants with informal conversations on any issues worthy of discussion and informed them of the purpose of this study. I practiced active listening skills and ensured that the information given to me was valuable and relevant to the study. I offered regard and appreciation for the contributions made by the participants by engaging in the study interviews. I respected all the study participants and upheld their dignity by giving them a chance to

give their information without a show of judgment through verbal and non-verbal communication signals.

Research Method and Design

Researchers should select the best design and method for a meaningful study experience and findings. The research methods include quantitative, qualitative, and mixed methods. Yin (2018) suggested that these methods offer the best research only if they are well-chosen and applied to a given study. The quantitative design is for data in numbers, while the qualitative design is based on words (Busetto et al., 2020). Conversely, the mixed-method involves combining the qualitative and quantitative methods in a single study to develop more meaningful findings (Lo et al., 2020). For this study, the qualitative method aligns with the purpose of the study.

Research Method

Yin (2018) asserted that qualitative research optimally seeks to study people's views, opinions, and beliefs. One difference between quantitative and qualitative research is how the latter builds on intuition and the former on empirical evidence (Bansal et al., 2018). Quantitative methods offer new ideas and information dependent on logic, unlike qualitative studies, where new insights emerge (Leppink, 2017). Hypotheses testing mainly occurs in quantitative research; thus, no hypotheses were formulated or tested for this study.

Qualitative research allows a deeper understanding of a phenomenon under investigation (Busetto et al., 2020). Unlike the qualitative method, the quantitative

method is highly structured and lacks in-depth analysis of the information provided (House, 2018). Therefore, qualitative research was suitable for collecting and receiving detailed information from the study participants about the research questions. The qualitative method was appropriate to explore underlying information regarding strategies to mitigate foreign trade regulations and costs that reduce revenues.

Research Design

The qualitative research designs encompass ethnography, phenomenology, narrative inquiry, and case study methodologies. (Tomaszewski et al., 2020). A case study offers in-depth and expounded information for the study under investigation (House, 2018). The case study approach is appropriate for research that involves numerous research topics and questions (Tomaszewski et al., 2020). Pattern and Newhart (2017) asserted that a case study method is most suitable for complex research topics or areas of investigation. In research studies, a descriptive case study is adopted to describe the phenomenon under investigation (Yin, 2018). An exploratory case study involves developing investigations on a specific issue (Ary et al., 2018). This study used an exploratory case study to explore strategies to mitigate foreign trade regulations and costs that affect the revenues of small medical devices and supplies firms in the United States. Interviews offer in-depth information if they are conducted individually compared to other methods, such as focus groups (Saunders et al., 2015). Interviews were used for this case study, offering adequate and more detailed data from the study participants.

Data saturation is a situation where no additional themes or information emerge during data analysis (Braun & Clarke, 2021). In addition, saturation exists at the time when the study has accumulated adequate information to accomplish its objectives or research questions (Batrancea, 2021). Four interviews were held for this study, and this was considered adequate for saturation. Becker (2012) confirmed that a single participant in terms of number is appropriate for qualitative studies as they look out for in-depth factual analysis. Fusch and Ness (2015) reported that saturation happens when interview questions are applied among several participants. The researcher should adopt and apply a saturation grid to demonstrate that a set of topics measure the personal bias aspects and data triangulation. Data triangulation refers to the exhaustion of data saturation for the study since different data sources are included in a study with in-depth analysis (Fusch & Ness, 2015). For this study, semistructured interviews were used for data collection among the business leaders of the small medical devices and supplies firms in Northeast United States. Document reviews were added to the data collection methods as a means of applying triangulation with interview information.

Population and Sampling

The study's target population was 12 business leaders of small medical devices and supplies firms working in the Northeast United States. The leaders were above 18 years of age and employed with a tenure of at least three years in their positions of responsibility. The leaders had experience implementing foreign trade regulations and costs to enhance revenues and firm profitability. Participants were interviewed, and I

used the purposive method to obtain the final number of participants from a target population of 12 participants. I conducted interviews with a sample of 8 participants, and data saturation was realized. Upon achieving data saturation, I recorded the true number of participants in Section 3. The qualitative sample size of ten may be considered adequate for sampling among a homogenous population (Boddy, 2016). Saturation is when a qualitative researcher does not discover new information from the additional data gathered (Hennink & Kaiser, 2021). According to Saunders et al. (2017), purposive sampling is a non-probability sampling method that enables the researcher to use their own judgment to select cases that will best enable them to answer their research question to achieve their study objective and is often used when working with small samples such as case study research. Similarly, Sharma (2017) reported that non-probability sampling methods help acquire participants who can best answer the research questions due to the way of selection.

Eight research participants constituted the study, and the researcher selected them based on the purpose of the study. Sharma (2017) argued that purposive sampling allows researchers to have the right study participants for the research investigations. Purposive sampling enables obtaining knowledgeable participants (Ary et al., 2018). Purposive sampling is also appropriate for cases that effectively use limited resources (Campbell et al., 2020). An accurate sample size is vital in case study research, but saturation in qualitative research is also critical. Saturation is vital in assessing the adequacy of purposive samples in qualitative research (Hennink & Kaiser, 2021).

I arranged the interview time to accommodate the participants' availability and conducted the study at their convenience. While in-person interviews were preferred, I provided the option of videoconferencing interviews to accommodate a participant's schedule or individual preferences. Due to the ongoing COVID-19 pandemic, at the time of conducting the interviews and the need to ensure public safety, the interviews were conducted through video-teleconferencing. Participants were given sufficient time to reflect and analyze their experiences to allow them to generate meaningful responses to the interview questions. The participants were allowed to choose private and calm places for the interviews. Mneimneh et al. (2018) asserted that study participants require privacy to provide adequate information in a study. To triangulate data sources, I used participants' interview data, the organization's documentation, and member checking. To achieve triangulation of data sources, I utilized multiple methods to cross-validate the findings. First, I collected data through interviews with the participants to gather their perspectives and experiences. In addition, I consulted the organization's documentation, such as reports, policies, and procedures, to gain a comprehensive understanding of the context in which the study was conducted. Finally, I employed member checking, where I shared the preliminary findings with the participants, allowing them to review and verify the accuracy of the data.

Ethical Research

Ethical research is mandatory for any researcher; therefore, each researcher must consider issues such as conflicts of interest, bias, confidentiality, and informed consent

that can negatively affect the scientific process (Hong & Yu, 2021). Prior to the involvement of human participants, the ethical codes and standards required for the study were considered. Before data collection, I received completed informed consent forms from interested and qualified participants after the approval of the Institutional Review Board (IRB) and research certification. The IRB established ethical standards for all researchers of Walden University. The IRB approval was received, and the details are stated in the consent form.

I utilized email messaging to deliver an informed consent form to each participant. Ethical research guidelines of obtaining consent from all the study participants before engaging them in the interviews were followed to ensure that they have the information required for this study to make appropriate contributions. Upon receiving the consent form, participants were given one week to decide if they were willing to participate in the study. Before conducting each participant's interview, I confirmed that they had returned the completed informed consent form and reminded them of the study's objectives, potential advantages, and risks. Furthermore, I presented the purpose of the study to the participants. I informed them that they would be offered the interview transcript and the summary of the findings for review and additions. I also informed them that all study-related documents and electronic data would be stored on a computer protected by a password. No tangible incentives were offered or provided. However, upon request, each participant was entitled to receive a summary of the findings and a published copy of the study. Lee (2018) asserted that it is improper to

bribe the study participants since it influences their judgments and decisions to contribute to the study. I did not offer any incentives to the study participants to avoid bias while participating in the study.

I ensured that every participant had the freedom to withdraw from the study at any point. Lynch (2020) reported that some participants might withdraw from the study during the research process. Researchers must protect participants from ongoing harm and distress (Pascoe, 2021). The participants were informed that they could communicate their decision to withdraw from the study through written correspondence, phone calls, or email. The confidentiality of the study participants was adhered to, and I used codes to describe them and the firms they represented. I assigned different codes to the participants, such as Participant 1, Participant 2, and Participant 3, to describe them during data collection and reporting of the study findings. The published study will not reveal the participants' names, titles, and the organization's name. The principles provided by *Belmont Report* focus on respecting the study participants, beneficence, and justice. These principles provided under the *Belmont Report* were adhered to for the study.

Data Collection Instruments

Data collection instruments are useful tools in gathering data for research studies. Qualitative data collection instruments include interviews, observations, and document reviews (Tomaszewski et al., 2020). A qualitative researcher can use various methods to collect data. I played a crucial role as the primary data collection instrument. The data was collected through two main sources - semistructured interviews and documentation

from the organization. Interviews were the first choice for the data collection process, and documents from the organizations supplemented the interviews. Yin (2018) asserted that the interview method is qualitative research's primary data collection method. Interviews used in qualitative research generate adequate information based on participants' beliefs, opinions, experiences, and motives (Lee, 2018).

The interview protocol (see Appendix A) included the eight open-ended questions that guided the semistructured interviews. The eight questions were about business leaders' strategies to mitigate foreign trade regulations and costs to enhance revenues. Structured, semistructured, and unstructured interviews are the key types of interviews adopted in research (Creswell, 2014). Unlike semistructured, structured interviews are not appropriate for in-depth study exploration because they are time-consuming and hard to manage (Yin, 2018). I used semistructured interviews with open-ended questions for this qualitative study. Open-ended questions allow research participants to offer significant insights on the subject matter and comprehensively narrate their experiences. (Weis & Willems, 2017). The study interviews were carried out virtually through the Zoom video-conferencing application.

The participants received a list of the interview questions by electronic mail a week before the interviews. Conducting research may be simplified through communication technologies that require the Internet and mobile phones (Clark et al., 2019). I performed document reviews by evaluating the various U.S. trade program information, public financial reports, and other administrative documents from the

participants' companies. U.S. trade program information is available online through government websites, and financial reports and other administrative documents were obtained from the participant's company websites. The documents helped ascertain any strategies business leaders used for their firms to thrive under the foreign trade restrictions to reverse declining revenues and achieve profitability. I eliminated any potential biases that may arise from the researcher to ensure high-quality research. Also, I maintained the principles of validity and reliability to enhance the research's quality and improve its overall outcomes. Validity of the research instruments refers to the suitability of the data collection instruments. Reliability is the extent to which the research instruments measure what they are intended to measure (Leung, 2015). Research based on accurate and reliable information can be used to make informed decisions and draw valid conclusions.

I used an interview protocol (see Appendix A) to confirm that I was prepared to engage the study participants in interviews and obtain detailed information for the study. The researcher can use an interview protocol for comprehensive and systematic data collection (Yeong et al., 2018). The interview protocol functioned as a tool to ensure that the participants had comprehensively responded to the questions posed to them during the interviews. It served as a guide to verify that all the required information had been provided and that nothing important had been omitted. Also, the interview protocol contained closing remarks for the interview with the study participants, during which I extended my appreciation for their contribution to the study. I adopted and used member-

checking by checking with the study participants to ensure the accuracy of the discussions. Member-checking is described as sharing the interview interpretations with the study participants to validate the data collected (Cande, 2019).

Data Collection Techniques

For this multiple case study, data collection techniques for the qualitative study were selected. Busetto et al. (2020) reported that focus groups, document studies, observations, and interviews are some techniques used to collect data in qualitative research. I used semistructured interviews with open-ended questions to collect information from eight study participants. Semistructured interviews with open-ended questions gather data in case study research (Yin, 2018). Bashir and Marudhar (2018) reported that interview participants provide verbal knowledge, understanding, perceptions, and additional in-depth information about the research topic.

The study interviews were conducted using digital communication technology via the Zoom video-conferencing application. I used the Zoom application to capture information from the study participants during the interviews. The recorded interview data was stored on my password-protected computer to allow me to refer to it for clarity whenever I needed to. Also, I used the interview protocol to guide the study's discussions during the interviews. Yeung et al. (2018) asserted that an interview protocol is a tool that guides the researcher to check the existing alignment between the interview questions and the research study while taking note of the study delimitations. Observing the principle of confidentiality is paramount in research undertakings because it permits participants to

share information freely. Researchers share sensitive information with the participants under the privacy arrangement; therefore, a lack of privacy might hinder the research process (Lee, 2018). I selected a private, quiet, and peaceful environment for the interviews to ensure the comfort and safety of the study participants.

Documents review uses electronic or printed documents to achieve more information and insights into the topic under investigation (Saunders et al., 2015). Lee (2018) noted that document reviews help gather information for the study at a minimum cost. Also, document reviews can be used alongside other data collection methods to achieve data triangulation. Document reviews of U.S trade programs and financial reports such as monthly, quarterly, and annual reports were used to support the research study to collect more data.

Data Organization Techniques

Data organization is one of the means for achieving research quality. The main benefit of data organization and data analysis is that it enables the researcher to present the study findings in the best way possible (Ary et al., 2018). To efficiently manage and organize information, I utilized word processing software known as Microsoft Word and NVivo 12 computer-aided qualitative data analysis software. I transcribed the interview data by converting audio recordings into word processing files and was able to create a structured and well-organized dataset. Furthermore, I seamlessly transferred data between different programs to facilitate computer-aided analysis as needed. The information from my direct observation of the participants during the interview was unsuccessful. I could

not directly observe participants during a phone interview because some participants declined to appear in the video recordings. However, I took some notes during the interview process that helped me with the data organization and analysis.

I organized the study's data to enable the identification of patterns during the research study. The interpretation of the study data depends on the developed patterns from the qualitative information collected from the respondents (Twining et al., 2017). Proper data organization provided the necessary patterns for understanding the study results. I used codes to present the participants' information and maintained the confidentiality of the information by using the assigned codes for each study participant, such as Participant 1, Participant 2, and Participant 3. I used the Zoom application at the time of the interview to capture all the voices of the respondents. Audio-recording of information provides the most effective way to capture participants' information and facilitates the completeness of the study information (Cypress, 2017). I have securely stored the electronic files containing the data on my password-protected computer for five years. After this time, the data will be permanently deleted. Similarly, the hard copies of the data will be stored in a locked cabinet for five years before being securely destroyed.

Data Analysis

Data analysis follows data collection in the research process, which is equally important as the other steps. Data analysis also derives meaning and sense from data through exploration, transcription, interpretation, and understanding (Cypress, 2018). In

data analysis, the initial steps of preparing and organizing the data involve saving digital files using a naming system and securing the data. Data analysis is a multi-step process that entails coding, sorting, and identifying relationships and themes from data (Tomaszewski et al., 2020). Using multiple data sources in the research process supports data triangulation and boosts data quality (Twining et al., 2017). I adopted several data sources, namely, interview data, data from U.S. trade programs, and financial reports to improve the quality of research. To augment the data gathered from participant interviews, I employed methodological triangulation by utilizing document reviews from two distinct sources to provide additional evidence. Methodological triangulation is a process that helps to authenticate the data obtained from various sources relating to a particular phenomenon. (Saks, 2018). The strength of findings and conclusions can be improved with methodological triangulation, often generating more practical results (Cornish, 2020). Collecting data from multiple sources ensures the information is collaborated and validated through different perspectives, thereby increasing its quality.

Engaging in an iterative process of reviewing interview transcripts, notes, and pertinent documents allows researchers to develop ideas about categories, coding, and potential relationships, facilitating the identification of themes within the data. (Zhao et al., 2017). The data analysis files included the interview transcripts saved using Microsoft Word and documents about the companies involved in the study. Organizing data is a relevant pre-step in facilitating data analysis. Codes were created to make sense of multiple data sources, and the codes were reduced to themes regarding strategies required

to gain a competitive advantage. Coding data facilitates data sorting, enabling extracting and examining its segments (Busetto et al., 2020). By grouping data segments with similar codes, researchers can create meaningful themes that encapsulate common elements, ideas, or concepts in the data. Themes are broad data units comprising several codes to form an idea (Cypress, 2018).

A software program can help researchers manage, visualize, and analyze data. Firmin et al. (2017) argued that qualitative data analysis software programs assist researchers in data organization, tracking codes, and data storage. During the data analysis stage, I employed Nvivo 12 software, a qualitative software program that facilitated various tasks such as categorization, tabulation, and data recombination. Using this software, I transcribed the interview data and identified themes based on the responses provided by the study participants. The Nvivo 12 software was utilized in transcribing the recorded interviews, monitoring the emergence of codes, and linking those codes to the themes that were developed. Nvivo 12's auto coding and query-based coding capabilities help researchers navigate through vast amounts of data with enhanced speed and efficiency. I used NVivo 12 software to create nodes that combined the relevant references in the data. These nodes help to categorize and organize the data, enabling researchers to identify patterns and themes more efficiently within the information. Researchers can uncover underlying processes and patterns within the data and group them into significant themes (Zhao et al., 2017).

Furthermore, I utilized the Nvivo 12 software to visualize the data from recorded interviews and identify relevant themes within the reviewed documents. This software also allowed me to integrate all the collected evidence from interviews and document reviews, thus facilitating the process of data recombination. Pattern and Newhart (2017) asserted that it is vital to categorize data and have vivid evidence.

After collecting the data, including the transcription of the interviews, I linked the responses obtained with the existing literature about strategies to mitigate foreign trade regulations and costs that reduce revenues. I directed my attention toward the research question and the conceptual framework to steer the data analysis process. Noble and Smith (2015) stress the importance of exploring topics and using existing research related to their research topic. I continued exploring how the research topic interrelated with emerging findings.

Reliability and Validity

Reliability and validity in qualitative research are critical factors that determine the quality of research. Researchers can apply the concepts of reliability and validity to enhance the quality of their research (Yin, 2018). Noble and Smith (2015) asserted that statistical methods cannot be utilized in qualitative research to establish reliability and validity. Qualitative researchers are unable to use numerical information but can gain value by gathering rich data and discovering patterns from words (Leung, 2015). The requirements for assessing the quality of qualitative research differ from those of

quantitative research. For example, the focus of quantitative research is to ensure the generalizability of the findings.

In contrast, the focus of qualitative research is the usability of the research process in comparable cases (Yin, 2018). I implemented measures to validate the collected data and enhance its transferability as part of this study. To ensure reliability and validity, I adhered consistently to data collection and analysis protocols, utilizing techniques such as an interview protocol and other data collection and validation methods. These procedures helped to ensure the accuracy and consistency of the data collected and analyzed, thereby increasing the credibility of the study's findings.

Reliability

Reliability is one of the measures used to establish the quality of research. Noble and Smith (2015) stated that reliability describes the consistency of the analytical procedures used in the research. Dependability is a term adopted in qualitative research analogous to reliability in quantitative research (Golafshani, 2003). Researchers can ensure reliability by using inclusive and comprehensive data and performing constant data comparisons (Leung, 2015). By gathering data from diverse sources and including multiple perspectives, researchers can obtain a more accurate representation of the phenomenon under investigation. Also, by constantly comparing and cross-referencing the data, researchers can identify any discrepancies or inconsistencies and take steps to address them, thereby increasing the overall reliability of the study's findings.

Golafshani (2003) asserted that dependability could be achieved when researchers seek to verify and examine the data they collect. I used member checking to improve dependability by scheduling follow-up interviews with the participants. Cypress (2017) reported that researchers use member checking and data saturation principles to ensure dependability. Member checking is a process through which researchers share the analyzed data from the interview process (Madill & Sullivan, 2018). Member checking is a useful strategy that allows researchers to confirm their interpretation with the participants (Naidu & Prose, 2018). I shared my analysis of their interviews and confirmed that I had accurately captured their ideas. The interview process should not reveal the researcher's view at the interview to improve reliability, and bracketing can be adopted to prevent this occurrence. Bracketing is a technique that enables researchers to maintain a clear focus on their research topic while ensuring consistency throughout the data collection and analysis process. By setting aside any preconceived notions or biases, researchers can approach the data with an open mind, allowing for a more objective analysis and interpretation of the information gathered.

Validity

Validity covers questions on the research design, sampling methods, and data analysis. Research validity refers to the integrity of the research methods and the accuracy of how findings correctly reflect the data (Noble & Smith, 2015). Validity is the measure of truth for the research findings (Smith & McGannon, 2018). Validity refers to the degree to which a study accurately measures what it was intended to measure. As

such, findings with high validity are deemed to be accurate and reliable. Research findings that have validity possess credibility and are trustworthy. Credibility can be attained through member checking and data triangulation (Saunders et al., 2017). I used member checking by engaging the participants after the initial interview and sharing my interpretation of the interview discussion to obtain their feedback. I used methodological triangulation by collecting data from three data sources: interviews and document reviews from U.S. trade statistics and financial reports of firms involved in the study.

Transferability is related to the usability of research findings in different circumstances. Transferability is the extent to which qualitative research results can be applied in other situations with similar theoretical models (Leung, 2015). I selected the research participants using purposive sampling and probing questions to collect comprehensive responses. The achievement of transferability in research can be facilitated using purposive sampling, thick data descriptions, and robust data (Cypress, 2017). Another measure for testing the quality of qualitative research is conformability. Conformability refers to the level to which the research findings receive the support and approval of others (Leung, 2015). Also, I kept a reflective journal on the data collection and analysis process to audit the research process and identify potential cases of bias. Some of the strategies to ensure conformability are data triangulation and audit trails (Cypress (2017)).

Data saturation can be reached by using adequate data sources and detailed data in the analysis. Researchers adopt data saturation to test whether they have collected

sufficient data. Braun and Clarke (2021) stated that data saturation is the point at which no new themes emerge from the data collected in the research process. I stopped collecting data after collecting suitable information to replicate the study, and no further themes emerged. I used open-ended interview questions for all the study participants to attain data saturation. A researcher should use interview questions that encourage participants to freely share their experiences and address personal bias to reach data saturation (Fusch & Ness, 2015).

Transition and Summary

The intent of this qualitative multiple case study was to understand the strategies that some small business leaders in the medical device and supplies sector use to mitigate the impact of foreign trade restrictions and costs that lead to a decline in revenues. The central research question for the study was: What strategies do some small medical devices and supplies business leaders use to mitigate foreign trade regulations and costs that lead to a reduction in revenues? I explained how I explored strategies some business leaders use to mitigate the impact of foreign trade restrictions and costs that lead to a decline in revenues. Section 2 includes details on the process for selecting participants through purposeful sampling, semistructured interviews, and evaluation of organizational documents. This section contains procedures and plans used to organize and evaluate data. Section 2 also included an explanation of methods for ensuring reliability and validity to establish credibility and dependability of study findings.

In Section 3, I present themes which were identified from the investigation and strategies business leaders use to mitigate foreign trade regulations and costs that lead to reduced revenues. I also describe how these strategies could potentially apply to practices of other organizational leaders in small medical device and supplies organizations and how these strategies can lead to social change. I provide recommendations for action and further research regarding business leaders' strategies to reverse revenue declines, implications for social change, and conclusions.

Section 3: Application to Professional Practice and Implications for Social Change

The purpose of this qualitative multiple case study was to explore strategies that some small medical device and supplies business leaders use to mitigate foreign trade costs and regulations that reduce revenues. I served as the main instrument for data collection; data came from virtual semistructured interviews, documents, member-checking interview summaries, and reflective journal notes. Four themes emerged from data: supply chain management, regulatory compliance, exploring foreign market opportunities, and key resource allocation. The study revealed strategies leaders might use to improve revenues to ensure sustainability.

Presentation of Findings

The primary research question for this study was: What strategies do some small medical device and supplies business leaders use to mitigate foreign trade costs and regulations that reduce revenues? I used the following pseudonyms for participants to ensure their privacy and confidentiality: P1, P2, P3, and P4.

Methodological triangulation, member checking, thematic analysis, and NVivo 12 software were used to analyze data. Coding and analysis of interview transcripts, interview summaries, organization documents, and member checking were parts of the comprehensive data analysis. Four themes that emerged from data analysis were ranked based on codes and total number of quotes received from participants. Codes helped to identify key themes related to strategies that mitigate foreign trade costs and regulations that reduce revenues (see Table 1).

Table 1*Codes*

| Codes | Quotes |
|---------------------------------------|--------|
| Strong customer supplier relationship | 5 |
| Managing supply chain disruptions | 4 |
| Proper inventory management | 2 |
| Reliable global business partners | 1 |
| Strict adherence to FDA regulations | 3 |
| Favourable government regulations | 2 |
| Product safety and quality standards | 1 |
| FDA inspections | 1 |
| Widen the customer base | 1 |
| Entry into foreign markets | 1 |
| Trade agreements | 3 |
| Business resources | 1 |
| Technological tools | 2 |
| Talent management | 3 |

Table 2 includes codes that constitute themes.

Table 2*Codes and Themes*

| Theme Categories | Codes |
|------------------------------|---------------------------------------|
| Supply chain management | Strong customer supplier relationship |
| | Managing supply chain disruptions |
| | Proper inventory management |
| | Reliable global business partners |
| Regulatory compliance | Strict adherence to FDA regulations |
| | Favourable government regulations |
| | Product safety and quality standards |
| Foreign market opportunities | FDA inspections |
| | Widen the customer base. |
| | Entry into foreign markets |
| Allocating key resources | Trade agreements |
| | Business resources |
| | Technological tools |
| | Talent management |

Table 3 shows themes that emerged from data with number of participants that mentioned them.

Table 3*Themes*

| Theme categories | Number of participants |
|--|------------------------|
| Supply chain management | 4 |
| Regulatory compliance | 4 |
| Exploring foreign market opportunities | 4 |
| Key resource allocation | 4 |

Data analysis revealed four themes that leaders use to reverse revenue decline and ensure sustainability: supply chain management, regulatory compliance, exploring foreign market opportunities, and key resource allocation.

Theme 1: Supply Chain Management

Supply chain management was the most referenced theme during interviews. Participants evaluated the importance of maintaining a strong supply chain to mitigate foreign trade costs and regulations. They said promoting and maintaining healthy relationships with suppliers was important to achieve a strong supply chain. This involves regular communication, transparency, and mutual understanding of expectations and requirements. Furthermore, it was emphasized that managing supply chain disruptions is crucial for maintaining a strong supply chain. This includes developing contingency plans and implementing risk mitigation strategies. P2 mentioned developing close relationships with suppliers through regular meetings, getting insights into their operations, and making in-person site visits. P2 said, “The bonding and the level of collaboration are at a level where the partner knows that they are an extension of your business.” Also, P2 said, “It’s not easy to switch from one supplier to the next if there are failures with a particular supplier that supports the production process.” There are huge switching costs, and risks include slowing or closing the production process. P3 said, “Maintaining a close supplier relationship involves establishing clear communication channels, setting expectations from both sides, and regularly monitoring supplier performance.” P3 stated that developing and maintaining good supplier relationships can benefit organizations in

terms of improved product quality, negotiating discounts, and favorable terms. P4 noted that building strong relationships with suppliers and local partners is essential for success in foreign markets. Reliable partners ensure a steady supply of quality products and services while providing access to valuable information and resources. In addition, trusted partners help in terms of navigating cultural and business norms of foreign markets. P4 also shared other benefits of strong relationships include navigating complex foreign regulations more effectively and negotiating favorable pricing terms, which help reduce costs and increase revenues and profits.

All participants indicated factors such as geopolitical risk, climate change, and global pandemics cause supply disruptions in the medical device and supplies sector; thus, having a strong supply chain can help manage these disruptions. P4 mentioned supply disruptions could lead to raw material shortages and shipping delays, affecting an organization's ability to meet customer demands and generate targeted revenues. Disruptions can cause increased costs and uncertainty, making it difficult for organizations to manage their operations effectively. P2 discussed that open lines of communication foster transparency within the supply chain, which enables identifying possible supply chain disruptions and managing results. P1 stated that maintaining appropriate inventory levels can minimize the impact of supply disruptions on organizations. Adequate inventory levels ensure business continuity by meeting customer needs during such disruptions. P1 said, "When we are caught off guard and are unable to increase our inventory before certain things happen, it can impact our revenue." P1's

company monitors its supply chain and inventory levels to ensure emergency preparedness.

Analysis of participants' data showed that proper supply chain management practices helped to reduce foreign trade costs and increase revenues. The data suggests that companies implementing effective supply chain management strategies are better equipped to handle business challenges across international borders. By optimizing the supply chain, businesses can improve their ability to deliver products and services to customers on time and with greater consistency. This can help build customer loyalty and generate repeat business, increasing sales and revenue.

Theme 2: Regulatory Compliance

Regulatory compliance emerged as the second strategy to mitigate foreign trade costs and regulations that reduce revenues. Strict adherence to regulations set forth by the Food and Drug Administration (FDA) is of utmost importance for medical device and supplies companies. Compliance with these regulations ensures that the products are safe and of high quality, thus safeguarding the health and well-being of consumers. Non-compliance can result in high costs to the company, including the need for retesting, fines, and penalties, as well as damage to their reputation. In addition, advocating for favorable government regulations and policies can significantly improve a company's competitiveness in the market. Policies supporting and encouraging innovation, research, development, and adopting new technologies can help companies stay ahead of the curve and adapt to changing market conditions.

P2 noted that the medical device and supplies sector is highly regulated and that vetting suppliers of other medical supplies is important for adherence to good manufacturing practices (GMP). The vetting process includes visiting the facilities to audit their compliance with FDA regulations and inquiring about past and existing FDA investigations to avoid unexpected shutdowns due to non-compliance. P2 said, “It is imperative to avoid compromising quality and regulatory requirements because of the high costs associated.” P3 shared the practice of purchasing from only FDA-approved manufacturers and distributors to ensure that the organization complies with FDA regulations and maintains the safety and quality of the products.

P3 said, “Complying with all the relevant regulations prevents us from incurring hefty fines, retesting costs, and the risk of failing to meet the quality requirements.” P3 asserted that failure to meet the required safety and quality standards might lead to repeating the process, thus leading to additional expenses. P3 also said that using FDA-approved manufacturers can prevent legal complications and potential harm to a company's reputation. P4 noted that the changing regulatory requirements in foreign markets are difficult to navigate due to political instability. The sudden shifts in the political climate of a country lead to significant changes in the regulatory environment, making it harder for companies to comply with the regulations and maintain compliance. The constantly shifting landscape of foreign regulatory requirements can cause significant obstacles for businesses operating in these markets and require companies to stay vigilant and adapt to the changes. P1 reported that his organization actively

advocates for government policies to enhance its competitiveness. P1 said, “The company is trying to engage with policymakers to create a regulatory environment that supports its business objectives, promoting policies that can improve its competitiveness and sustainability.” The goal is to achieve long-term success by creating a favorable environment for the company to thrive. P3’s company documents disclosed that an FDA inspection was conducted in 2023, scrutinizing 350 records and procedures from 2020 to 2023. The inspection was successful due to the company's unwavering dedication to maintaining the highest quality and compliance excellence. This highlights the company's consistent efforts to adhere to regulatory standards and maintain exceptional quality across its operations.

According to data analyzed from interviews and documents, regulatory compliance is important in the medical device and supplies sector. Adhering to regulatory compliance involves following strict guidelines and procedures, including quality control measures, product testing, and reporting requirements, to ensure that products are safe for patients and meet the required standards for efficacy and quality. Companies prioritizing compliance can avoid unnecessary costs arising from non-compliance, such as regulatory fines, product recalls, and reputational damage. Adherence to regulations ensures that high-quality products are produced, leading to increased revenue growth, improved reputation, and customer confidence.

Theme 3: Exploring Foreign Market Opportunities

The third emergent theme was exploring foreign market opportunities. This strategic approach to mitigating foreign trade costs and regulations that could diminish revenues requires commencing trading activities in foreign markets, beginning with regional trade partners such as those in the North American Free Trade Agreement (NAFTA) region and then expanding to other trading partners worldwide. By doing so, it is possible to broaden the customer base and establish additional revenue streams. A review of P2's company documents revealed an unfulfilled demand for medical supplies within the European Union. P2's company discovered a significant unfulfilled demand for medical supplies within the European Union and developed a comprehensive plan to enter the market. The plan includes a detailed analysis of the European market, a targeted marketing strategy, investment in manufacturing capacity and supply chain expansion, hiring experts with knowledge of the European market, and partnering with local distributors. P2's company is committed to providing high-quality medical supplies to its European customers. According to the International Trade Administration (ITA) documents, the United States currently has 14 Free Trade Agreements (FTAs) in place with 20 countries. These agreements allow US companies to avoid paying tariffs when transporting goods between these trading partners. Removing tariff-related costs makes it more convenient and cost-effective for US businesses to export their goods and services to these markets.

P1 and P2 shared a strategy that involves facilitating trade for the United States by taking advantage of existing trade agreements, such as the North American Free Trade Agreement (NAFTA), particularly with countries geographically closer to the US. This move increases trade with Canada and Mexico, both of which are NAFTA signatories and share borders with the US, thus making it easier to transport goods. P1 also mentioned trading with European countries with trade agreements with the United States. By focusing on these markets, P1's company takes advantage of reduced tariffs and other trade-related benefits that come with these agreements, making it easier and more cost-effective to export goods and services to these markets.

P3's company strategically focuses on conducting business transactions within the NAFTA region, encompassing the United States, Canada, and Mexico. The primary objective of this approach is to mitigate the impact of tariffs, duties, and other trade barriers that can significantly increase the costs associated with conducting foreign trade. By limiting its business operations to the NAFTA region, P3's company can minimize its exposure to such trade barriers and enhance its competitiveness in the market. P4's company actively seeks new market opportunities for growth outside the United States. P4 said, "Taking advantage of free trade agreements is a cost-effective way to reduce costs and increase competitiveness in the market."

This strategic approach to exploring foreign markets addresses the obstacles of foreign trade expenses and regulations, allowing businesses to expand their customer

base and create new sources of income. By implementing this approach, companies can decrease reliance on any market and enhance their revenue streams.

Theme 4: Key Resource Allocation

All four participants discussed the importance of allocating key resources to mitigate foreign trade costs and regulations in the small medical device and supplies sector. The highlights of the discussions were investments in talent management strategies, innovative technologies, and supply chain management tools that have supported their firms to navigate regulatory challenges and remain competitive effectively. According to a document released by the Small Business Administration (SBA), acquiring additional funding can be a valuable strategy for small businesses looking to improve their performance. Various funding options are available to small businesses, such as loans, lines of credit, and crowdfunding.

P2 shared that the medical device and supplies sector is capital-intensive, which makes it difficult for many small organizations to survive. P2 said, “Developing a medical therapy or drug takes time and resources.” P2 also mentioned that bringing a new product to market involves a complex process that includes going through clinical trials, obtaining regulatory approvals, and managing the supply chain. These steps are crucial to ensure that the product meets the required quality standards and regulatory requirements. To successfully complete these processes, it is essential to have the right tools and resources at hand. For instance, investing in materials transportation scheduling software can significantly reduce foreign trade transportation costs and increase revenue. P2’s

company uses the software to optimize transportation shipments by identifying the most efficient routes, consolidating shipments, and reducing transit times. Furthermore, P2's company manages its inventory and reduces stock-out risk using materials transportation scheduling software. This software tracks inventory levels and provides real-time updates on the status of shipments, allowing companies to make informed decisions about when to reorder and how much to order.

P3's company implemented document management software to enhance its business operations. This technology enables efficient storage, retrieval, and sharing of relevant documents, decreasing downtime, and increasing productivity. Also, it assists the company in adhering to regulatory requirements associated with transportation and logistics. The software simplifies compliance with regulations by facilitating precise documentation and reporting to prevent expensive penalties. P4's organization utilizes data analytics to examine the performance of medical supplies in foreign markets, to identify patterns and trends, to make informed decisions about their business strategies, and identify opportunities for revenue growth. In P4's organization, data analytics tools and techniques were used to identify revenue growth opportunities, such as expanding into new markets or introducing new products to meet demand. In addition, data analytics provided valuable insights and actionable information to help them make informed decisions and drive revenue growth in their international business operations.

P3's company credits its successful FDA audits to excellent science conducted by its talented staff. Also, the team at P3's organization is responsible for improving its data

quality and enterprise systems. P3 said, “Accommodating shift differentials ensure that operations run smoothly around the globe.” P2 and P3 shared that collaboration between departments eliminated inefficiencies, offered cost savings, and improved performance. For example, some departments that shared resources or coordinated their activities reduced duplication of effort and avoided unnecessary expenses. Furthermore, the collaboration led to teamwork and shared ownership across the organization, leading to a more positive work culture and increased employee engagement. P3 and P4 expressed that offering opportunities for learning and growth is effective in both attracting and retaining high-performing employees and contributes significantly to achieving sustainable success in the long run. By utilizing talent management strategies, innovative technologies, and supply chain management tools, companies can navigate foreign trade costs and regulations and remain competitive in the global marketplace.

Summary of Findings Related to Conceptual Framework

Overall, the data collected and analyzed from the interviews and the organizational documents resulted in the emergence of four themes: supply chain management, regulatory compliance, exploring foreign market opportunities, and key resource allocation. The data collected from multiple sources revealed that leaders of small medical device and supplies companies develop strategies for supply chain management, comply with FDA and foreign trade regulations, explore opportunities in foreign markets, and allocate key resources effectively. The participants agreed that utilizing these organizational strategies was essential for improving organizational

performance. The conceptual framework for the study is based on the resource view of the firm, the study participants' interviews, and reviewed documents showed the relevance of owning and allocating key resources. The implementation of strategies to mitigate foreign trade costs and regulations requires the presence of financial and other essential resources. An organization comprises various resources accumulated to form a competitive advantage (Shan et al., 2019). Freeman et al. (2021) concluded that integrating the accumulation of a firm's resources with the promotion of stakeholder relationships holds the potential for enhanced management practices. Business leaders must recognize the importance of accumulating and allocating a firm's resources to support the organization's initiatives and achieve a competitive advantage.

Summary of Findings Related to the Literature

The literature is connected to the four themes that leaders use to reverse revenue decline: supply chain management, regulatory compliance, exploring foreign market opportunities, and key resource allocation. The existing literature supports the role of continuous innovation, information and communication technology (ICT) utilization, advocating for fair trade policies, supply chain management, and strategic partnerships to mitigate foreign trade regulations and costs. The influence of enabling technologies on business performance is more pronounced in countries with well-developed ICT infrastructure (Karim et al., 2022). According to Martín et al. (2022), the strategic selection of markets and the ability to establish strong networks are essential elements for SMEs to achieve positive outcomes in their international endeavors. Examining

individual digital technologies indicated that only a few solutions could significantly contribute to managing and enhancing circular supply chains (Romagnoli et al., 2023). Business leaders need to adopt strategies that can strengthen the supply chain, enter strategic international markets, and leverage technological and other resources to enhance business practices.

Application to Professional Practice

The research applied to organizational practices to indicate strategies business leaders use to mitigate foreign trade costs and regulations that reduce revenues. To obtain the best practices, business leaders should identify strategies to reverse revenue decline. Global companies can improve the efficiency and effectiveness of their supply chains by implementing important strategies such as redesigning the supply chain, adopting new technologies, and enacting proactive government policies (Xu et al., 2023). The four themes presented based on interviews offer business leaders valuable insight into using effective strategies identified through the study to reverse revenue decline to remain sustainable. The findings provide business leaders with significant insights into utilizing the identified strategies effectively, as presented through the four themes. These valuable findings can be leveraged to reverse the decline in revenue and ensure long-term sustainability for organizations.

The first strategy selected was supply chain management. The study participants used supply management techniques to reduce the impact of foreign trade costs and regulations. This involved streamlining logistics, improving inventory management, and

reducing transportation costs. The participants stated that effective supply chain management strategies can help companies overcome international business challenges. Xu et al. (2023) suggested leveraging technologies to fully utilize global supply chain management to withstand supply disruptions akin to the COVID-19 pandemic. By optimizing their supply chain, business leaders can enhance the capacity of their firms to provide customers with timely and quality products and services.

The second strategy selected for applying the findings of this study was adhering to FDA and foreign trade regulations by business leaders to avoid non-compliance costs and reverse the decline in revenues. Four participants indicated that regulatory compliance is essential for ensuring the safety and efficacy of products. The timely availability of safe and effective medical devices can profoundly impact patients, caregivers, and the overall healthcare burden in the United States (Anderson et al., 2016). The streamlining and optimizing regulatory processes result in expedited access to potentially life-saving treatments and therapies for patients, effectively reducing unnecessary waiting periods (Singer et al., 2022). By emphasizing compliance, business leaders can proactively mitigate the risks of incurring avoidable expenses linked to non-compliance. These expenses may include regulatory fines, product recalls, and reputational damage.

The third strategy selected was identifying potential foreign markets with high demand for medical devices and supplies and developing plans to expand their business in these regions to boost revenue growth. P1, P3, and P4 shared that organizations can

overcome the challenges of declining revenues and expand their customer base by exploring foreign market opportunities. Using international experience to acquire new knowledge and introduce innovations can be effectively employed to enhance overall business performance (Marco-Lajara et al., 2023). Business leaders that explore foreign market opportunities can create new sources of income, reduce their dependence on any market, and increase revenue streams.

The fourth strategy is allocating critical resources, including innovative technologies and personnel, to enhance their business processes, improve competitiveness and achieve long-term success. The four participants mentioned that organizations could stay competitive in the global marketplace by leveraging critical resources such as talent, innovative technologies, and supply chain management tools to navigate foreign trade costs and regulations effectively. Joshi et al. (2022) emphasized that enhancing the capacity of IT governance processes has the potential to enhance IT performance, thereby positively impacting overall business performance. Business leaders who possess the ability to harness crucial resources, such as innovative technologies, can enhance the performance of their firms.

Implications for Social Change

The implications for positive social change include enhancing the health and well-being of citizens in other nations by producing and exporting essential products. A resilient healthcare supply chain can efficiently and promptly deliver high-quality products and services to many patients while minimizing costs (Zamelia et al., 2022).

Positive social change can be brought about by promoting the health and well-being of individuals in other countries by producing and exporting essential goods. For instance, producing and exporting medicine and medical supplies can help individuals in other countries access life-saving treatments they may not otherwise have access to. This can significantly enhance their health outcomes and quality of life.

In addition, improving organizational performance yields several economic advantages, such as higher wages, job security, and continuity. Successful financial outcomes of organizations also translate to more stable job opportunities for employees and contribute to reducing unemployment rates, thus benefiting both the local community and the workforce in the exporting nations. Wei and Yingqiang (2018) observed that commercial activities directly affect regional economic development and indirectly impact local communities. According to Mena et al. (2022), firms engaged in global supply chains are required to adhere to international trade regulations, utilize local infrastructure, and depend on suppliers and customers within the countries they operate. The research can aid future leaders in making informed decisions, presenting them with sustainable alternatives to maintain an organization's financial performance and social standing. This study's findings can equip business leaders with valuable insights to reduce foreign trade costs and navigate regulations, ultimately enhancing organizational performance.

Recommendations for Action

Global trade in healthcare is essential for providing access to essential medical supplies, improving healthcare outcomes, and promoting global economic development. Based on obtained from data collected through interviews and organizational documents, member checking, emerging themes included supply chain management, regulatory compliance, exploring foreign market opportunities, and key resource allocation. Business leaders, front-line, and senior managers can use the strategies to mitigate foreign trade costs and regulations and improve competitiveness.

The initial action recommendation pertains to the management of supply chains. Business leaders must develop lean supply chain strategies that optimize inventory levels, reduce lead times, and minimizes the cost of goods sold. According to Shen and Sun (2023), operational flexibility and collaboration beyond supply chains are fundamental to building resilient supply chain systems. In addition, business leaders should consider utilizing advanced supply chain technologies such as automation and artificial intelligence (AI) to enhance efficiency and reduce costs. Information technology, strong leadership, and collaborative endeavors are key capabilities within a company's supply chain (Gani et al., 2023). Business leaders must collaborate with supply chain partners to identify areas of improvement and implement joint cost-saving initiatives.

The second action recommendation focuses on regulatory compliance. Business leaders must build a strong regulatory compliance program capable of addressing the complexities of foreign trade regulations. A strong regulatory compliance program

requires conducting regular risk assessments and compliance audits to identify gaps and implement corrective actions. The FDA follows a rigorous approval process for drugs, which differs from the process in China (Lythgoe & Sullivan, 2022). Business leaders must invest in training and education programs to ensure their employees understand and comply with relevant regulations.

The third recommendation for action is exploring foreign market opportunities. The world economy is becoming more global due to the formation of entities such as the World Trade Organization (WTO). Business leaders must develop a thorough understanding of the foreign market landscape and tailor strategies to local customers' unique needs and preferences. When firms operate in a highly competitive environment, the sprinkler strategy is more optimal than the waterfall approach for introducing new products in international markets (Cho et al., 2023). Business leaders should conduct market research to identify potential opportunities in foreign markets and develop a market entry strategy that aligns with their business goals.

The fourth recommendation for action is key resource allocation. Business leaders should allocate resources strategically to optimize revenue growth and profitability. Resources can be allocated by prioritizing investments in areas that provide the highest return on investment, such as innovation, IT utilization, and stakeholder management. In response to global supply chain disruptions, certain firms opt for digitalization to ensure their survival (Farooq et al., 2021). Business leaders should consider transforming operations to reduce costs and improve efficiency.

To thrive in international markets, business leaders must thoroughly comprehend the foreign trade landscape and formulate a strategic plan that aligns with their business objectives. It is crucial to continuously monitor and evaluate performance to identify areas for enhancement and make the required adjustments. By implementing these suggestions, businesses can effectively address foreign trade costs and regulations that diminish revenues, fostering success in international markets.

To disseminate the research findings, I will utilize several avenues. The study participants will receive a summary of the study and its outcomes. I intend to present the findings at business conferences and training programs for the healthcare sector. Also, the doctoral study will be published and available for review in the ProQuest/UMI dissertation database.

Recommendations for Further Research

This study focuses on the strategies business leaders employ to counteract a drop in revenue and ensure long-term sustainability, with particular attention to mitigating foreign trade expenses and regulations for enhanced competitiveness. The research outcomes provide insights into effective methods businesses can employ to reverse revenue decline. However, based on its narrow scope, this study has two limitations, which solely encompass this multiple case study of four business leaders from four separate organizations interviewed in the Northeast region of the United States.

This study was conducted with a limited sample size of organizations; therefore, the generalizability of its results may be limited. The recommendation is that future

research expands to more firms beyond the Northeast region to investigate the strategies utilized by business leaders in different regions to address revenue decline and ensure long-term sustainability. Such studies would provide valuable insights into the diversity of approaches and enhance our understanding of the most effective strategies for business leaders to adopt.

Future research should broaden its scope beyond the small medical device and supplies companies and investigate how foreign trade costs and regulations impact businesses in other industries. Additionally, it is recommended that the study examine various leaders' strategies from different sectors to counteract the negative effects of foreign trade costs and regulations, ultimately reversing the decline in profits and ensuring long-term sustainability.

Reflections

Despite facing a lack of understanding from those around me, I pursued a DBA degree. Others could not comprehend why I would devote my time and energy to furthering my education rather than pursuing activities like travel and spending time with family. However, I recognized that my educational journey was personal and not something others necessarily needed to comprehend. Ultimately, I was determined to achieve my goal of earning a DBA degree. At the outset of my DBA journey, I still needed to learn how much effort, writing, and time it would take to achieve my goal. The process has been arduous, but it has also been incredibly rewarding and satisfying. Throughout this journey, I have acquired valuable qualities, such as perseverance and

effective time management skills, boosted self-confidence, and triumphed over numerous obstacles. I feel great pride in reaching this significant milestone in my life.

I gained interest in the subject due to my association with a couple of friends employed in the medical device and supplies sector. This led to my interest in exploring and gaining numerous insights into foreign trade costs and regulations that reduce revenues. I intend to disseminate my study findings among the participants so that they can apply the results in their business practices, should the need arise. My research has allowed me to recognize the strategies that some business leaders use to mitigate foreign trade costs and regulations to reverse revenue decline and improve competitive advantage. My aspiration is to emerge as a leader who specializes in revitalizing organizations engaged in foreign trade, employing a diverse range of strategies aimed at enhancing their competitive advantage. Business leaders are always seeking to comprehend the advantages of managing costs related to foreign trade and complying with regulations, as this is essential for ensuring the long-term sustainability of their organizations.

Conclusion

The data collection method in this study was semistructured interviews and the review of documents from an organization in the Northeast United States. The data were gathered to understand business leaders' strategies to mitigate foreign trade costs and regulations that reduce revenues. The data collection and analysis revealed four themes related to successfully implementing and using strategies to mitigate foreign trade costs

and regulations. The results of this study confirmed that competitive advantage strategies play an essential role in organizational sustainability and that strategy is significant. To ensure their organization's sustainability, business leaders can now directly communicate with their workforce and implement strategies identified by leadership to address declining revenues.

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Appendix A: Interview Protocol

Interviewee:

Time of Interview:

Date:

Position of Interviewee:

I will use a qualitative multiple case study to research strategies that business leaders use for firm sustainability. The interviewees will consist of organizational leaders who have made decisions regarding foreign trade regulations and costs that reduce profitability. The purpose of the research project is to explore strategies to mitigate foreign trade regulations and costs that reduce revenues.

The interview will consist of the following questions:

1. What strategies do you use to mitigate foreign trade regulations and costs to enhance the revenues in your organization?
2. What strategies have you found to work best to mitigate foreign trade regulations and costs to enhance the revenues in your organization?
3. What strategies have failed to mitigate foreign trade regulations and costs to enhance the revenues in your organization?
4. How do you judge the effectiveness of the strategies that mitigate foreign trade regulations and costs to enhance the revenues in your organization?
5. How do you implement the strategies that mitigate foreign trade regulations and costs to enhance the revenues in your organization? Who in the organization is involved?
6. What challenges have you had in implementing the strategies that mitigate foreign trade regulations and costs to enhance the revenues in your organization?
7. What have you done to effectively meet the objectives of mitigating foreign trade regulations and costs to enhance the revenues in your organization?
8. What additional information would you like to share about the strategies used to mitigate foreign trade regulations and costs to enhance the revenues in your organization?

I will thank each participant and remind them that they will be provided a summary of the findings. I will also inform them that I will contact them with my interpretations of their responses, so they can comment on them and provide their feedback about the accuracy of the interpretations.

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