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Impact of EU Medical Device Directive on Medical Device Software

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This is to certify that the doctoral dissertation by

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Abstract

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Dissertation Submitted in Partial Fulfillment

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Abstract

Directive 2007/47/EC of the European Parliament amending Medical Device Directive (MDD) provides medical device manufacturers with a compliance framework. However, the effects of the amendments to the MDD on competition in the U.S. medical device software industry are unknown. This study examined the impact of this directive on the competitiveness of U.S. medical device software companies, the safety and efficacy of medical device software, employee training, and recruitment. The conceptual framework for this study included 3 dimensions of medical device regulations: safety, performance, and reliability. The overall research design was a concurrent mixed method study using both quantitative and qualitative techniques. The qualitative techniques involved case studies of 5 purposively selected companies. Data collection involved both surveys and interviews. The sample consisted of 56 employees within medical device firms with markets around the European regions. Qualitative data analysis consisted of descriptive thematic analysis along the study questions and hypotheses and summative evaluation. Quantitative data analysis included descriptive statistics and correlation to test the 4 hypotheses. The results suggested that the MDD has realigned medical device software manufacturing practices, and US medical device companies have gained global competitiveness in improving product safety and increasing sales revenue. Key recommendations to medical device manufacturers include adopting MDD 93/42/EEC, using model-based approaches, and being comprehensive in model use. Adopting the MDD will provide positive social change to patients, as human safety improves with better product quality while companies experience fewer product recalls.

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Dedication

I am extremely grateful to Dr. Richard Bush and Dr. Diane Stottlemyer for serving on my dissertation committee. I appreciate all that you have shared to make this capstone better. I direct my special thanks to my advisors – Dr. Raghu B. Korrapati and Dr. Irmak Renda-Tanali– for their guidance and encouragement. Thanks for walking with me though these years.

This dissertation is devoted to the following members of my family who have in one way or the other shaped the direction of my life and inspired me to complete a doctorate: my precious children – Jean-Julien Foe Nuphaus and Lea Annick Foe Bodo; my darling wife – Maria Nuphaus, my loving parents – Madeleine Foe Bodo and Jean Foe Owono (of late), my beloved siblings – Georgette Foe Owono (Annick Dioh), Jeanne Diane Owono, Sylvie Foe Owono, Narcisse Mveng Owono, Alfred Leger Foe Nguini, Roger Assanga Foe and Gautier Mveng , and finally to my beloved Grandparents and Great-Grandparents (all of late).

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I would regret my graduate years at the Technische Universität Dresden in Germany if I did not meet my wife and best friend: Maria Nuphaus. She has always been

a constant source of encouragement during my graduate study and very supportive in every step of my life. I could not have achieved this without her support. She is my angel and the mother of our adorable children, Jean-Julien Foe Nuphaus and Lea Annick Foe Bodo.

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Special thanks to Zouameyong Philomene, my spiritual mother, who drew me close to God, and thanks be to God for my bountiful life. May your name be exalted, honored, and glorified.

To the individuals whose names I have left out, your constant words of encouragement were equally invaluable.

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Chapter 1: Introduction to the Study

Introduction

The medical devices market in Europe is one of the sectors actively regulated by directives (European Commission [EC], 2012). The directive regulating the medical devices market is the Medical Devices Directive (MDD) 93/42/EEC, issued on June 14, 1993, by the Council of European Communities and took effect on January 1, 1995. The MDD 93/42/EEC replaced the earlier directive known as the MDD 76/764/EEC as well as amended two other directives, Directive 84/539/EEC and Directive 90/385/EEC, previously used to regulate the medical devices market in Europe (Bright, 1999; EC, 1993).The main objective of this study was to determine the impact of the amendments to Medical Devices Directive 93/42/EEC (MDD) on the U.S. medical device software industry. The medical device industry is a key component of healthcare systems. However, software-containing medical devices are prone to failure and carry inherent risks that can cause injury to the patients, the user, or service personnel. Reports of device failure and glitches in software have been frequent and exemplified by the high rate of recall of medical devices containing software (Halperin et al., 2008). The recall of medical devices is a problem that encumbers the health care industry (Halperin et al., 2008; Maisel, Sweeney, Stevenson, Ellison, & Epstein, 2001). Damaged or contaminated medical device may pose life-threatening injuries. According to the FDA, a Class I recall indicates that there is a reasonable probability that the use of or exposure to a damaged or contaminated product will cause substantial harm or death (FDA, 2014). People who are

injured after using or been exposed to a violative product may make products liability claims. Regulatory agencies may use the statutory and regulatory process that governs product recalls to take action against the manufacturer of a violative product.

As more medical products have become dependent on embedded software, safety regulations for those devices have shifted to the reliability of software systems. The European Union (EU) states that a consistent and coherent implementation of the MDD with amendment 2007/47/EC (M5) is necessary to ensure human health protection. Compliance to the MDD amendment targeting software safety and efficacy is a costly venture before a firm receives certification or accreditation to export to European markets (Panesar-Walawege, Sabetzadeh, Briand, & Coq, 2010). The recent amendment to the MDD by the introduction of M5 tightened the medical device software specifications by requiring medical device manufacturers to provide additional documentation to prove compliance with further safety and efficacy standards. Nitz (2004) criticized the MDD 93/42/EEC for burdening the medical device industry with high approval costs and causing manufacturers to waste time due to the lengthy approval process. Despite actions taken by the EU against nonconforming companies and their products (European Council, 2007), the growth of the medical device software industry correlates with good health and economic outcomes.

The global medical devices market is worth approximately $315 billion (Merritt, 2012). According to researchers at the International Trade Administration (International Trade Administration [ITA], 2012), 76% of global medical device use occurs in the

United States, Japan, Italy, and France, yet these countries account for only 13.1% of the world's population. The United States has the largest medical device market in the world, with an estimated worth of $110 billion, that accounts for approximately 35% of the global medical devices market (U.S. Department of Commerce, n.d.). Estimates by Chase (2004) indicated that the global market for medical devices was worth $169 billion in 2000. In the same year, the US market for medical devices was worth approximately $72 billion and followed by the EU market with an estimated worth of $35 billion. The medical devices market in Japan was worth approximately $25 billion while the rest of the world accounted for nearly $13 billion of the global medical devices market (Chase, 2004).

According to researchers at International Trade Administration (ITA, 2012), the growth of the medical device software industry correlates with good health and economic outcomes. For example, medical devices containing software have played a critical role in reducing the burden of heart disease and improving the quality of life and health outcomes of people with cardiovascular disease. Mortality due to heart attacks decreased by 40% between 1980 and 2000, and researchers have linked the decrease to an increase in the use of devices such as pacemakers, stents, and defibrillators (Myerburg, Reddy, & Castellanos, 2009).

Other benefits from the medical device industry include multiplier economic effects associated with expenditures by the employees in the industry, the procurement of goods and services for use as inputs by the firms in the industry, and revenues and

earnings arising from the sales and marketing of medical devices. According to estimates, employees of medical device firms earn about $24 billion and spend close to $18 billion on consumer goods and services (Lewin Group, 2010). The money spent has multiplier effects on other sectors of the economy. Medical device firm employees spend the remaining $6 billion on taxes, savings, and investments. The data in the Lewin report indicated that each job in the medical devices sector generates another 1.5 jobs (Lewin Group, 2010).

However, software-containing medical devices can expose users to risks that may cause injury or endanger their health. They may also expose users to hackers and breaches of privacy and put their safety at risk. Reports of device failure and glitches in software have been frequent and exemplified by the high rate of recall of medical devices containing software. Maisel et al. (2001) and Halperin et al. (2008) demonstrated that the recall of medical devices is a problem that encumbers health care. Wallace and Kuhn (2001) carried out a study of software-containing medical devices recalled between 1983 and 1997. Wallace and Kuhn identified these recalls by examining the US Food and Drug Administration's (FDA) database of failures of medical devices. According to their findings, 2,792 recalls of medical devices with or without software occurred between 1983 and 1991. Only 165 (6%) of these recalls had computer software. For the entire duration (1983-1997), there were 383 recalls of medical devices containing software. There was a progressive decline in the number of software recalls between 1994 and 1996. Eleven percent, 10%, and 9% of the recalls were for medical device software in

1994, 1995, and 1996, respectively, and attributed to the rapid increase in medical device software (Wallace & Kuhn, 2001). Most of the failures were due to software malfunction (29%) and performance (22%). Sandler, Ohrstrom, Moy, and McVay (2010) reported that the FDA made 23 recalls in the first half of 2010. All the recalls were for Class I medical devices, and six defective devices had flaws in the software (Sandler, Ohrstrom, Moy, & McVay, 2010). Overall, the medical device software sector has helped to improve the economic well-being of the employees, their families, and the communities. Medical device companies usually lead to disposable incomes that are higher than the national average, resulting in higher demand for consumables and other goods, and that lead to the creation of more jobs (Lewin Group, 2010).

This introductory section provided a description of the research problem. The following sections briefly summarize research literature as it related to the scope of the current study, as well as a description of different aspects of the research problem addressed in the study and the gap in knowledge. The purpose of the study contains an indication of the mixed methods paradigm, as well as a description of the study independent, dependent, and covariate.

This introductory chapter provided general information about the current study. Chapter 1 provides the background that undergoes evaluation in subsequent chapters to detail how complying to changes in the MDD 93/42/EEC affects firms' net income and share stock prices, training and recruitment needs, project expenditures, and device recall incidents. The chapter includes the problem, the nature of the study, the purpose of the

study, it significance, the research questions, and hypotheses to guide subsequent chapters. The chapter also includes the scope, limitations, delimitations, and assumptions. The end of chapter includes a summary of the main points of the chapter.

Chapter 2 contains the literature review, which is a critical evaluation of literature on medical device software and its regulation. Chapter 3 includes a discussion on the methods used to conduct the study, while Chapter 4 contains the results and their analysis. Chapter 5 contains a discussion of the findings, as well as the conclusions and study recommendations.

Background of the Problem

The European Union (EU) is a regional economic and political bloc comprised of 27 nations in Europe. Some of the member states of the EU are Italy, Hungary, Austria, Ireland, Belgium, Germany, Bulgaria, France, Denmark, Finland, Cyprus, Estonia, the Czech Republic, and Cyprus. Others are the United Kingdom, Latvia, Portugal, Sweden, Lithuania, Spain, Poland, Slovenia, Luxembourg, Netherlands, Romania, Malta, and Slovakia (EU, 2012).

The partnership between these countries has evolved over time, culminating in the abolition of border controls and the creation of one large market with the euro as the common currency (EU, 2012). Treaties, which are the primary legislation, form the ground rules that govern all the activities of member countries, and the countries must adhere to them. Secondary legislation consists of decisions, directives, regulations, recommendations, and opinions formulated from the objectives and principles outlined in

the treaties (EU, 2012). Regulations are binding legislative acts applied in their entirety in all the member states of the EU. Directives are types of legislation that stipulate a goal that all member states of the EU must attain. However, the member states have flexibility to decide how they are going to attain these goals (EU, 2012).

The Council of European Communities gave member states five years, starting in December 1, 1994, to put devices that conformed to earlier directives (Directive 76/764/EEC, Directive 84/539/EEC, and Directive 90/385/EEC) into the market or into service, after which all products on the market or in service must have met the requirements of MDD 93/42/EEC. For devices meeting the requirements of Directive 76/764/EEC, member states were able to have them in market or in service until June 30, 2004. Amendments to the MDD 93/42/EEC made in 2007 led to a new standard for governing the medical devices market in Europe known as the MDD 2007/47/EC, where EC refers to the European Commission. The MDD 2007/47/EC came into operation March 21, 2010, and introduced changes in MDD 93/42/EEC, Directive 90/385/EEC, and Directive 98/79/EC (EC, 2007, 2012).

The International Electrotechnical Commission (IEC) also instituted a new system controlling software-containing medical devices. The EN/IEC 62304 system is synthesized under an EN, or European Standard, designation. It is the world standard for managing the software development life cycle. The EN/IEC 62304 standard has become a global benchmark for managing the software development life cycle; however, implementation of the standard has been slow. This is due to unintended consequences

including its effect on costs to manufacturers of medical devices, the competitiveness of companies, and the effect on employee training and hiring requirements. Implementation of the MDD 93/42/EEC requirements means that the EN/IEC/62304 requirements have also been met (Hall, 2010).

United States medical device manufacturers selling or marketing their products in the EU must comply with the MDD 93/42/EEC requirements. Nitz (2004) criticized the MDD 93/42/EEC for burdening the medical device industry with high approval costs and causing manufacturers to waste time due to the lengthy approval process. In terms of financial performance, the investment into research and the cost of compliance to EN/IEC/62304 is expensive. Before a firm receives certification or accreditation to export to European markets, safety and efficiency compliance to the MDD 93/42/EEC amendment targeting software is a costly venture (Panesar-Walawege et al., 2010). The recent amendment to Directive 93/42/EEC by the introduction of M5 (2007/47/EC) tightened the medical device software specifications by requiring medical device manufacturers to provide additional documentation to prove compliance with further safety and efficacy standards. This amendment further empowered oversight authorities to take firm action against nonconforming companies and their products (European Council, 2007). Failure to comply with MDD 93/42/EEC will prevent US medical device manufacturers to export to European markets, and to compete in European markets with other firms meeting the MDD requirements. The ultimate objectives of these directives

were to ensure medical devices produced and used in the EU region not only are effective and safe but also provide more benefits to users.

According to Gross and Loh (2006), the growth of the medical device software industry correlates with good health and economic outcomes. Each job in the medical devices sector generates another 1.5 jobs (Lewin Group, 2010). The total global demand for medical devices was approximately $307.7 billion in 2012 (Espicom, 2012). The United States and Europe accounted for 45% and 30% of this demand, respectively (Frost & Sullivan, 2010). This study included a concurrent mixed method study and involved administering questionnaires to a convenient sample of professionals from companies in the medical device software industry.

Problem Statement

This study involved examining how amendments to the MDD 93/42/EEC have affected the competitiveness of the U.S. medical device software industry and their impact on the safety and efficacy, employee training and recruitment of medical devices manufactured in the United States. Wallace and Kuhn (2001) conducted a study of software-containing medical devices recalled between 1983 and 1997, and documented 2,792 medical devices recalls between 1983 and 1991. According to Geissler (2010), balancing safety and effectiveness with security and privacy was a significant challenge facing the development of effective and safe medical device software. Although the MDD 93/42/EEC has helped to make the devices safer, researchers and medical devices manufactured have not done much to investigate the effect of the amendments to the

MDD 93/42/EEC on the market share, employment, and earnings and profitability of US exports to European markets. Databases searched were the Institute of Electronic and Electrical Engineers (IEEE) database, the Science Direct (Elsevier) database, the Wiley Online Library, Google Scholar, Science by the American Association for the Advancement of Sciences, Oxford University Press database, Wiley-Blackwell, Springer Link, ProQuest, EBSCOhost, Sagepub, and JSTOR. The main objective of this study was to determine what impact the MDD 93/42/EEC has had on medical device software in the United States.

Purpose of the Study

The purpose of this concurrent mixed method study was to examine the impact of the EU MDD 93/42/EEC on the U.S. medical device software industry. Specifically, the study involved determining how amendments to the directive have affected the competitiveness of U.S. medical device software companies, the safety and efficacy of medical device software, employee training and recruitment. The mixed method study involved both quantitative and qualitative techniques. The qualitative technique involved systematic literature review, interviews, and case study. This study includes the justification for safety regulations to guide the design and application of the device software in pursuit of better product quality, efficacy, and reliability. For many U.S. medical device manufacturers, regulatory compliance is a considerable effort that requires a great deal of training and expertise, all of which could be expensive. Under the cost aspects, the MDD 93/42/EEC revisions are somewhat uncertain about the

fundamental cost issues of the medical devices because the wordings are ambiguous (Andersson, 2012). This study examined the impact of the MDD 93/42/EEC on the variable costs of employee training and recruitment trends with evidence collated from the interviewees. Compliance with the MDD 93/42/EEC has improved the business results of many companies. Adopting the MDD contributes to social change as human safety improves with better product quality, efficacy, and reliability, while companies experience fewer product recalls. Chapters 4 and 5 contain the results of the findings.

Nature of the Study

The nature of this study was a concurrent mixed method study. The mixed method study involved both quantitative and qualitative techniques. Qualitative research was suitable for this study because it involves narratives instead of numerical data and is based on explanatory rather than exploratory inquiry. However, the results obtained from qualitative studies are not generalizable to entire populations (Maylor & Blackmon, 2005). Quantitative research was suitable for this study because I gathered numerical data, thus enabling the use of statistical techniques to look for relationships between defined variables.

The study examined the impact of the MDD 93/42/EEC on the competitiveness of the U.S. medical device software industry and their impact on the safety and efficacy, employee training, and recruitment with evidence collated from the interviewees. The dependent variable was compliance to the changes in the MDD, and the independent variables were individual company net income and stock share prices, training and

employment needs, compliance project costs, and recall statistics. This study had four main questions and hypotheses addressed by interviews, and a case study of five medical device manufacturers purposively selected. Through case studies, I was able to conduct a first-hand examination of how EU medical directive influences medical device software firms in the United States. I used audiotapes to record the interviews. I analyzed the qualitative data using thematic descriptions along the study questions and hypothesis and summative evaluation. I tested hypotheses using Analysis of Variance (ANOVA), at a 95% confidence level and gathered data from 56 respondents. The statistical software SPSS was suitable to analyze the collected data (SPSS Inc., 2008). I provided a comprehensive discussion of the research design in Chapter 3.

Significance of Study

The study is important because it demonstrates the impact of the amendments to Medical Devices Directive (MDD) 93/42/EEC on the U.S. medical device software industry. Many empirical studies have examined relationships between economic impact of the medical technology industry, healthcare reform, medical devices, dimensions of quality, and safety and effectiveness of medical devices. Pfleeger (2012) proposed a look at safety and effectiveness of software in medical devices. Peck (2011) investigated medical devices security. Werling (2010) analyzed the impact of healthcare reform on the medical device sector. On the other hand, there is little evidence of the relationship between Medical Device Directive (MDD) 93/42/EEC and performance of U.S. medical device companies.

The study offers further support for a fundamental premise, which is that good employee training is necessary to a firm's success. However, because hiring a workforce with previous experience with the MDD 93/42/EEC is often challenging, employees who lack experience with could develop products that do not meet regulatory requirements, thus posing safety or security risks to the users or the patients. Recruiting strategies are critical in attracting the right talent. A successful training can increase products efficiencies and safety, resulting in financial gain.

My dissertation addresses the gap in the current literature on how amendments to the MDD 93/42/EEC have affected the competitiveness of the U.S. medical software industry and their impact on the safety and efficacy, employee training and recruitment of medical devices manufactured in the United States. The results of this study help reduce the gap in the literature and increase the certainty for the safety of medical products dependent on embedded software. I hope to provide the EU Commission Services input to improve the implementation of EN/IEC/62304. Recommendations address legislative weaknesses in the MDD and hence reduce software development costs; reduce time to market; enhance the interoperability, safety, and privacy of medical devices; and enhance compliance with the regulatory requirements. In addition, the recommendations made may help to reduce off-label use and software recalls, which may enhance the competitiveness of the medical device software industry in the United States.

This study evaluated economic and social changes in the medical device industry with regard to providing safe and viable solutions to the health care system. Overall, the

findings in this study help close the literature gap, as the various medical device manufacturers enhance safety and performance of the embedded software. Furthermore, the outcomes of the study are applicable to various medical device manufacturers targeted by the EU MDD (Panesar-Walawege et al., 2010). This study will help to promote the mission of social change by developing solutions to the problems associated with medical devices, thereby helping to improve their effectiveness and the safety factors that will enhance the health and safety of the users of these devices. There is a positive association between enhanced health and safety and better social conditions.

Research Questions and Hypotheses

The following research questions guided the study:

Research Question 1: What is the impact of changes to the MDD to the net income of medical device software firms in the United States?

$H1_0$: There has not been a decrease in the net income of medical device software firms in the United States due to changes to the MDD.

$H1_a$: Changes to the MDD have led to a significant decrease in the net income of medical device software firms in the United States.

Research Question 2: What is the impact of changes to the MDD on the employees training costs for each EN/IEC 62304 compliant software year of medical device software firms in the United States?

$H2_0$: Changes to the MDD have not significantly reduced the employee training costs for each IEC62304 compliant software year of medical device software firms in the United States.

$H2_a$: Changes to the MDD have significantly reduced the employee training costs for each EN/IEC 62304 compliant software year of medical device software firms in the United States.

Research Question 3: What is the impact of changes to the MDD on the project costs for each EN/IEC 62304 compliant software year of medical device software firms in the United States?

$H3_0$: There has not been a significant decrease in the project costs for each EN/IEC 62304 compliant software year of medical device software firms in the United States due to changes to the MDD.

$H3_a$: Changes to the MDD have led to a significant decrease in the project costs for each IEC62304 compliant software year of medical device software firms in the United States.

Research Question 4: What is the impact of changes to the MDD on the recall rate of medical device software firms in the United States?

$H4_0$: There has not been a significant decrease in the recall rate of medical device software manufactured by firms in the United States due to changes to the MDD.

$H4_a$: Changes to the MDD have led to a significant increase in the recall rate of medical device software manufactured by firms in the United States.

Theoretical and Conceptual Framework of the Study

Wallace and Kuhn (2001) carried out a study of software-containing medical devices recalled by examining the FDA's database of failures of medical devices. According to their findings, 2,792 recalls of medical devices occurred between 1983 and 1991. Over the past 20 years, both the United States and the EU have passed legislative reforms in response to the increased numbers of medical incidents and malfunction. These reforms have had the goal of making medical devices safe and effective. (EU, 2012; FDA, 2011). Recent high-profile cases where too many unsafe medical devices, such as hip prosthesis or Poly Implant Prosthèse breast implant for instance, have brought into question the effectiveness of current regulations. To date, failure to comply with these regulatory requirements could results strong sanctions (Great Britain, 2012). However, Medical device manufacturers often perceived these regulatory requirements as government-induced restrictions on international trade. U.S. small and medium-sized enterprises (SME) in the healthcare highlighted a lack of mutual recognition of licensing as a problem that affect exporting to the EU. United States SMEs and related industry associations reported many EU trade barriers, particularly those related to standards and regulations, affect their exports (O'Laughlin, 2014).

The European Council published new methodology of harmonization designed to remove trade barriers within the EU. The result was three new directives governing the safety and performance requirements of medical devices adopted as the benchmark standard for medical devices all over the world. These new directives require that

manufacturers provide evidence that support the safety and efficacy of the medical devices. The following three directives form the EU regulatory framework for medical devices:

1. Directive 90/385/EEC for active implantable medical devices, amended by the Directive 2007/47/EC.
2. Directive 93/42/EEC for medical devices, amended by the Directive 2007/47/EC.
3. Directive 98/79/EC for in vitro diagnostic medical devices.

The MDD 93/42/EEC is the main directive regulating the medical devices industry in the EU. Compliance to the MDD 93/42/EEC amendment targeting software safety and efficacy is a costly venture before a firm receives certification or accreditation to export to European markets (Panesar-Walawege et al., 2010). The recent amendment to Directive 93/42/EEC by the introduction of M5 (2007/47/EC) tightened the medical device software specifications by requiring medical device manufacturers to provide additional documentation to prove compliance with further safety and efficacy standards. Because of the medical device regulations, medical devices companies have more than one overhead with indirect costs. Medical device regulations require that companies provide training on medical device regulations and standards to their employees to ensure regulatory compliance (CENELEC & ISO, 2012). U.S. SMEs argued before the U.S. International Trade Commission that complying with EU regulations was costly for all firms, and that such costs did not take firm's size or export revenue under consideration, and that these regulations affect their exports (O'Laughlin, 2014).

To understand how the 2007/47/EEC amendment to the MDD 93/42/EEC has affected the competitiveness of the U.S. medical device software industry, it is necessary to examine two performance levels, quality performance and business performance. Quality performance measurements focused on the recall rate of medical devices, training and recruitment needs, while business performance was assessed using compliance project costs, company net income and stock share prices. Business performance was important to verify whether changes to the MDD have affected the project costs and the net income of medical device software firms in the United States. Quality performance was important to verify whether changes to the MDD have affected the recall rate of medical device software firms in the United States. The independent variable was compliance to the changes in the MDD 93/42/EEC, and the dependent variables were the competitiveness parameters affected by the directive: (a) individual company net income and stock share prices, (b) compliance project costs. Recall statistics, training and recruitment needs were the mediator variables as shown in Figure 1. According to Baron and Kenny (1986), "a given variable may be said to function as a mediator to the extent that it accounts for the relation between the predictor and the criterion."(p. 1176).

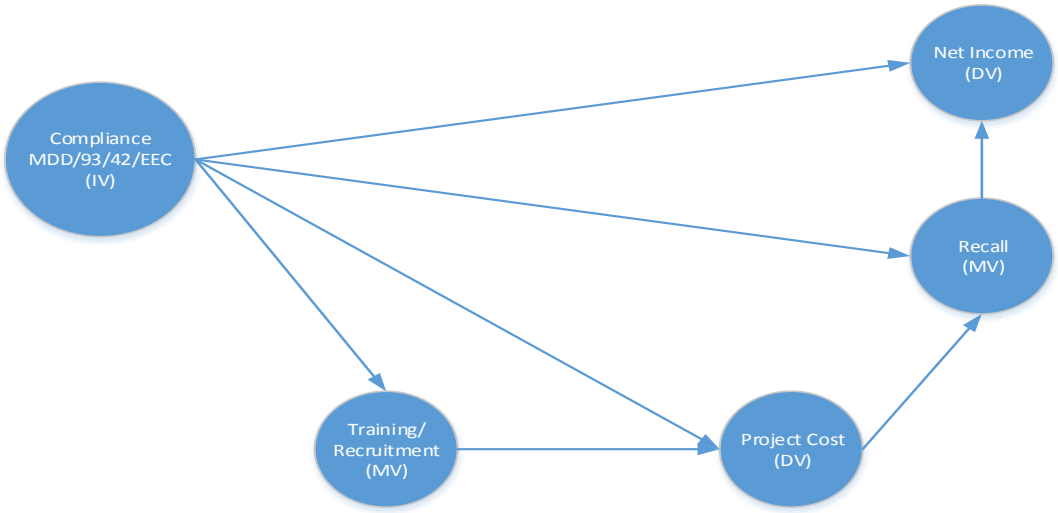

Figure 1. Study conceptual framework.

Definitions of Terms

Article 1 of MDD 93/42/EEC contains the definitions and scope of the directive and states that the stipulations in the directive are to govern the manufacture and sales of medical devices and their accessories.

Article 13 stipulates that at least one qualified person be available in each company to lead compliance with the regulations. The qualified person must have specified academic achievement and not less than 5 years of experience in the medical device industry (Andersson, 2012).

The CE marking: this term indicates a product's compliance with all relevant essential requirements specified in the applicable EU directive(s) and if stipulated in the directive(s), had it examined by an independent notified body (EC, 2014).

Compliance: This term means to abide by the rules, regulations, policies, laws, or values generated from a consensus process or body of authority such as the EU in relevance to this study (Hall, 2010).

Directive: This term refers to a decree or order that stakeholders must follow because there are terms and conditions applicable for nonconformance, for example to MDD 93/42/EEC (EC, 1993).

Intended purpose: This term refers to the intended use for the device according to the data supplied by the manufacturer on the labeling, in the instructions, or in promotional materials (EC, 1993).

Manufacturer: This term refers to the natural or legal person with responsibility for the design, manufacture, packaging, and labeling of a device before it goes on the market under the manufacturer's name, regardless of whether the manufacturer or a third party carries out the operations (EC, 1993).

Medical device. Any implement, apparatus, machine, object, or any other item usable in combination or singly and usable by human beings to diagnose, prevent, monitor, treat, or alleviate a disease; to diagnose, prevent, monitor, treat, or alleviate or compensate for a disability or injury; or to control conception or investigate, replace, or modify an anatomical or physiological feature (EC, 1993). The definition includes any software required for the proper operation of the device.

Placing on the market. Making a device other than a device intended for clinical investigation available for the first time in return for payment or free of charge, with a

view to distribute or use it on the EC market, regardless of whether it is new or fully refurbished (EC, 1993).

Product recall. The process in which a device manufacturer notifies consumers or users of its products to return devices because they have failed a test such as quality, reliability, safety, or durability and hence pose a risk to human health or lives (Sandler et al., 2010).

Patient safety. Prevention of human harm to patients. (Aspden & IOM, 2004).

Quality. The degree to which health services for people increase the probability of desired health outcomes and are consistent with current professional knowledge (IOM & Lohr, 1990).

Reliability: The probability that a product, system or service will perform its intended function adequately for a specified period of time, operating in a defined operating environment without failure (Crossley, 2008).

Performance: The metric against which a complete action is compared (ASQ, 2014).

Software item: Any identifiable part of a software product, including the top and bottom levels (IEC & ISO, 2006).

Software system: A subsystem of the medical device or a medical device by itself (IEC & ISO, 2006).

Software unit: The lowest achievable level of software decomposition for the purposes of testing or software configuration management (IEC & ISO, 2006).

Assumptions

I made the following assumptions in this study: (a) U.S. medical device manufacturers comply with Article 2 and Article 3 of the MDD 93/42/EEC. During this study, I assumed that U.S. medical device manufacturers selling medical devices in the EU comply with Article 2 of the MDD 93/42/EEC, which regulates how to place medical devices into the market and how to put them into service. The regulations state that EU member states should take all the requisite steps to make certain that only those products shown to be effective and safe go into market and into service. Furthermore, I assumed that these medical device manufacturers meet the requirements of Article 3 of the MDD/93/42, which defines the essential requirements that medical devices must adhere to before they can enter the EU market. These essential requirements are in Annex 1 of the directive and include general requirements and requirements guiding the design and construction of the devices. I also assumed that the findings from the case studies and the views expressed by the interviewees would provide a generalization of the medical device industry status. Therefore, the challenges and successes of the companies complying with the changes in MDD 93/42/EEC are shared and replicable with a fair degree of confidence.

Limitations

The limitations of this study were the research methodology and the use of available data. When considering the study findings, a primary limitation of this study was the potential limitation of purposive sampling. While purposeful sampling actively

seeks to enrich the data by including participants with a specific type of experience or understanding of the research topic, the potential disadvantage is the possibility to focus the data collection on the experience of the participants, thus missing the broader picture. The study included stringent inclusion and exclusion criteria to select the respondents, which has led to a limited sample size. A primary limitation of this study was the potential for selection bias and response bias, which might occur if respondents answer questions in a way that is not consistent with their true beliefs. The survey administration was anonymous to help reduce such a bias. The basis of the responses collected from the survey questionnaires was the opinions of the interviewees. These opinions constituted a threat to the overall credibility of the study. Triangulation helped to increase the validity and the reliability of the study results. The duration of interviews with the representatives of the two organizations might have limited the findings in the study. A threat to the external validity may exist due to the convenience method of sampling and the use of archival data.

Based upon the results of this study, I was not able to reject or accept some hypotheses. A plausible explanation for the lack of significant results was the small sample size. Because of the lack of existing research in this area, the sample size further limited this study. The small sample size resulted from the inability to recruit additional participants.

Scope and Delimitations

I limited the scope of this research to studying the impact of the EU MDD on medical device software in the United States. The study included only those firms manufacturing medical devices containing software. The study did not include an attempt to determine the effect of the directive on medical devices that do not contain software. The respondents were from firms within a certain geographical region, which may have led to selection bias with a possible negative effect on validity.

Summary and Transition

The European Council published new three new directives governing the safety and performance requirements of medical devices. These new directives require that manufacturers provide evidence that support the safety and efficacy of the medical devices. This chapter contained an introduction to the study topic and a background that undergoes evaluation in subsequent chapters to detail how complying to changes in the MDD 93/42/EEC affects firms' net income and share stock prices, training and recruitment needs, project expenditures, and device recall incidents. The nature of this study was a concurrent mixed method study involving both quantitative and qualitative techniques. The chapter included the problem, significance, research questions, and hypotheses to guide subsequent chapters. The chapter also included the scope, limitations, delimitations, and assumptions. A primary limitation of this study was the potential limitation of purposive sampling.

Chapter 2 is the literature review and contains a critical evaluation of the literature on medical device software and its regulation. Chapter 3 includes a discussion on the methods used in conducting the study, and Chapter 4 contains the results, their analysis, and the findings. Finally, Chapter 5 includes my conclusions and recommendations for further study.

Chapter 2: Literature Review

Introduction

The main objective of this dissertation was to determine the impact of the amendments to the MDD 93/42/EEC on the United States medical device industry. This chapter reviewed the regulations governing medical device software in the United States, the EU, as well as in other countries. I examined the medical device software industry in the United States using a wide corpus of data from peer-reviewed articles, industry reports, studies by government and quasi-government agencies, and books. The aim was to describe the elemental features that characterize the industry as well as ascertain the competitiveness of this industry while mapping the drivers of growth and the inherent challenges. I looked at the competitiveness of the medical device industry broadly with reference to markets in other countries such as Japan, Canada, Australia, China, Brazil, India, and Member States of the EU. Non-regulatory. I examined the regulatory factors affecting the medical device industry in these countries, and outlined the MDD 93/42/EEC in detail. I conducted the investigation of the impacts of medical devices on the economies of these nations and completed the identification of the amendments to the Directive, and pointed out the weaknesses of the legislation. I provided a description of the outlook of the industry. The literature review serve as a backdrop for the research into the impact of the amendments to the MDD 93/42/EEC on the U.S. medical device software industry.

Literature Search Strategy

I performed a literature review using a collection of materials from peer-reviewed journals, government statistics, databases, online vendors. I used the following databases to identify systematic reviews: the Institute of Electronic and Electrical Engineers (IEEE) database, the Science Direct (Elsevier) database, the Wiley Online Library, Google Scholar, Science by the American Association for the Advancement of Sciences, Oxford University Press database, Wiley-Blackwell, Springer Link, ProQuest, EBSCOhost, Sagepub, and JSTOR. The Food and Drug Administration (FDA) website, the European Union (EU) website, and websites of individual companies manufacturing and distributing medical devices were addition source of information. Reference sources used included the Cochrane Library and textbooks. The scope of the literature search was limited to articles, abstracts, journals, books, theses, conference proceedings, essays, news, editorials, perspectives, and review papers relevant to the topic under investigation. The search terms that were used to query the databases were *medical devices, medical device software, medical device recall, medical device safety, medical devices market, medical devices outlook, EU medical devices, Europe medical devices, US medical devices, Asia medical devices and global medical devices*.

I used the snowballing technique to get more literature. In the snowballing method, the bibliography section of relevant journals and texts already identified was examined and used to locate useful texts and journals, which were then searched in the databases. I used stringent inclusion and exclusion criteria to sort the articles for use. The

criteria entailed inclusion of only those articles published in English and dated between 1974 and 2012. The rationale for setting 1974 as the lower time limit was because the MDD/74/64/EEC originated in that year.

Medical Devices Software: Definitions and Scope

Medical devices are defined by The Federal Food Drug & Cosmetic Act as implements, *in vitro* reagents, apparatuses, implants, contrivances, or other analogous products that are meant for use in the diagnosis, treatment, cure, prevention, or mitigation of disease in humans and in animals and are listed in the United States Pharmacopoeia, legitimate Formulary, or any addenda to these (FDA, 2011). Medical devices can help change human or animal bodily function or structure, but they must not attain their primary effect through their metabolism or chemical action (FDA, 2011).

As opposed to drugs, medical devices do not undergo metabolism in the body and do not undergo or mediate chemical reactions. Accessories are not medical devices except where the manufacturer has intended it used in combination with a medical device to facilitate the attainment of the device's objective (Global Harmonization Task Force [GHTF], 2005). There may be variations in designating certain items as medical devices in different countries. Items that have not yet been harmonized and which, therefore, fall under this category include spare parts for medical devices, aids used by the handicapped and disabled, devices used to diagnose and treat injuries and diseases in animals, and gadgets in which human and animal tissue is integrated and which may adhere to the definitions above, but are regulated by different rules (GHTF, 2012).

According to the European Commission's MDD 93/42/EEC, a medical device is any implement, apparatus, machine, object, or any other item that can be used in combination or singly that is meant for use by human beings to diagnose, prevent, monitor, treat, or alleviate a disease or to diagnose, prevent, monitor, treat, or alleviate or compensate for a disability or injury or to control conception or investigate, replace or modify an anatomical or physiological feature. The definition includes any software required for the proper operation of the device. The device should not attain its main and intended action through metabolic, immunological, or pharmacological effects. In this context, accessories are defined as articles that are not devices but are meant to be made use of in combination with the medical devices in order that the intended use of the device as designed by the manufacturer will be attained. Medical devices also encompass in vitro diagnosis devices and custom-made devices (EC, 1993). Presently, the medical device sector is versatile and besides the more traditional products such as syringes and bandages, it now encompasses modern cutting-edge techniques in the fields of bioinformatics, engineered cells, and nanotechnology (Pammolli et al., 2005).

Classification of Medical Devices

FDA Classification Schemes

The Food and Drugs Administration (FDA) classifies medical devices into three classes (FDA, 2012b). This classification is based on the probable health risks associated with the software-containing medical device and is meant to ensure that the devices are not only effective but are also safe (Peña et al., 2007). The three classes are Class I, Class

II, and Class III. Class I medical devices are devices which are governed by general controls while Class II medical devices are under special controls and stricter regulatory controls. Class III Medical Devices are premarket approval (PMA) devices and these require a premarket approval before their marketing begins. There is inadequate data about these devices to determine their safety or effectiveness. Under this class also are devices that potentially present an unreasonable risk of injury or illness or those devices that are of critical importance in averting harm to human health (FDA, 2012b).

Examples of PMA devices include deep brain stimulators (DBS) devices (Peña et al., 2007). Class I products have a simple design, are not strictly regulated and are not associated with significant risks to the safety or health of users. Crutches are examples of Class I medical devices (FDA, 2012b). Class II products are more complex in design, tightly regulated and pose minimal risks to the users. Examples of Class II devices are magnetic resonance imaging (MRI) systems (FDA, 2012b). Class III products are highly advanced, tightly regulated, devices and can cause significant health and safety risks to users. Pacemakers and cardiac stents are examples of Class III products (FDA, 2012b).

The FDA classifies medical devices by categories. These categories comprised of codes that reflect the medical specialty of the product. The specialties relate to advisory committees that supervise the device regulation. They also include product codes, which relate to the function and features of the devices. The FDA has defined 19 medical specialties, i.e. Anesthesiology, Dental, Hematology, Pathology, or Radiology (FDA, 2012b).

The North American Industry Classification System (NAICS)

The U.S. Census Bureau does not classify medical devices based on the FDA classification system but uses the North American Industry Classification System (NAICS). U.S. manufacturers and government use NAICS to classify business the American medical industry according to type of economic activity. This system classifies medical devices into eight classes as follow: surgical appliances and supplies, surgical and medical instruments, electro-medical equipment, in-vitro diagnostic substances, dental equipment and supplies, ophthalmic goods, dental laboratories, and irradiation apparatus (US Census Bureau, 2012).

Surgical appliances and supplies. The North American Industry Classification System (NAICS) code for surgical appliances and supplies is NAIC 339113. Surgical appliances and supplies refer to wheelchairs, artificial joints and limbs, surgical dressings, surgical kits, orthopedic appliances, surgical gloves, hydrotherapy appliances, rubber medical gloves, stents, and disposable surgical drapes (US Census Bureau, 2012). Surgical appliances and supplies form the biggest subsector in the U.S. medical devices market. According to ITA (n.d.), surgical appliances and supplies comprise 28% of medical devices by value of shipment (VOS).

Surgical and medical instruments. The NAICS code for surgical and medical instruments is NAIC 339112. Surgical and medical instruments include catheters, syringes, blood transfusion devices, anesthesia apparatus, hypodermic needles, and optical diagnostic apparatus (US Census Bureau, 2012). After surgical appliances and

supplies, surgical and medical instruments are the largest subgroup by VOS of medical devices in the United States, as they comprise of 26% of these devices (ITA, n.d.).

Dental goods. Dental goods comprise of dental equipment and supplies and dental laboratories. The NAICS code for dental equipment and supplies is NAIC 339114. Medical devices under this category include dental chairs, drills, dental hand instruments, amalgams, sterilizers, and cements (US Census Bureau, 2012). They form nearly 5% of medical devices by VOS (ITA, n.d.).

Dental laboratories. On the other hand, dental laboratories include orthodontics, crowns, bridges, and dentures. The NAICS code for these devices is NAIC 339116 (US Census Bureau, 2012). They make up 4% of medical devices in the United States by VOS (ITA, n.d.).

Irradiation equipment. The NAICS code for irradiation equipment is 334517 (US Census Bureau, 2012). These devices make up close to 8% of medical devices in the U.S by VOS and include CT, X-ray, and diagnostic imaging equipment (ITA, n.d.).

Ophthalmic goods. The NAICS code for ophthalmic goods is 339115. Ophthalmic goods include lenses, frames for eyeglasses, and other magnification and optical products (US Census Bureau, 2012). They form about 5% of medical devices by VOS (ITA, n.d.).

Substances for carrying out in vitro diagnosis. Substances for carrying out in vitro diagnosis form close to 10% of medical devices by VOS and are identifiable by a NAICS code of NAIC 325413. They include radioactive, biological and chemical

substances used to carry out diagnostic tests using machines, Petri dishes, test tubes, and other devices for diagnostic tests (US Census Bureau, 2012).

Electro-medical equipment. The NAICS code for electro-medical equipment is NAIC 334510. Electro-medical equipment form close to 19% of medical devices by VOS and include pacemakers, ultrasonic scanning devices, MRI machines, patient-monitoring equipment, and patient-monitoring systems (US Census Bureau, 2012). Implantable medical devices (IMDs) fall under this category. These devices are used to examine the physiological conditions in the body and treat them. They are used to treat a variety of conditions such as Parkinson's disease, diabetes, and cardiac arrhythmias. IMDs include neurostimulators, pacemakers, drug delivery systems, and implantable cardiac defibrillators (ICDs) (Halperin, Heydt-Benjamin, Fu, Kohno, & Maisel, 2008b).

EU Classification Scheme

The European Union assigns medical devices into four classes based on their perceived risks to the safety of consumers. These classes are Class I, Class IIa, Class IIb, and Class III (Bright, 1999; EC, 2010). Class I devices are not subjected to the premarket approval process although they must meet the safety and efficacy guidelines when they are being designed, manufactured and labeled (Bright, 1999; EC, 2010). Producers of medical devices belonging to Class II, Class III or Class I devices that have sterility requirements or measuring functions are required to send a Declaration of Conformity to the relevant European Commission (EC) Directives before they can undergo the pre-market approval process. They are also required to submit particulars about the procedure

used to conduct the conformity assessment (Bright, 1999; EC, 2010). Manufacturers of devices that are associated with very high risks are required additionally to submit the relevant EC Certificates originating from a notified body (World Health Organization [WHO], 2003).

Classification of Medical Devices in Other Countries

Classification of medical devices in Canada occurs in four classes namely Class I, Class II, Class III, and Class IV. Class I devices do not require premarket approval although they must meet the requirements for efficacy, safety and labeling (Bright, 1999; EC, 2010). Manufacturers of Class II devices need only to declare that their products are effective and safe before their introduction into the market. Class III and Class IV products are strictly regulated (Bright, 1999; EC, 2010).

Regional authorities usually grant pre-market certification referred to as Todokede to Class I devices in Japan. Regional authorities could also grant pre-market certification to Class II and Class III devices if their efficacy and safety has been proven beforehand. For devices above Class II to be launched into the market however, the central government through the issuance of a license allowing market entry must approve them. The Pharmaceutical Administration Law (PAL) was amended recently in a bid to streamline the regulation of medical devices and make them in line with the principles of GTHF (WHO, 2003).

The Australian Therapeutic Goods Administration (TGA) requires that all medical devices be included in the Australian Register of Therapeutic Goods (ARTG)

before they can be market in Australia. Registrable medical devices are subjected to premarket evaluation prior to their being allowed in the market. There are also devices, which are not regulated as strictly, although they are assessed for safety if concerns have been raised with regard to the devices' risk profile (WHO, 2003).

In order to harmonize the classification scheme, the Global Harmonization Task Force (GHTF) came up with a proposal that would ensure that different countries use the same scheme to group the devices based on a common risk assessment approach (WHO, 2003; GHTF, 2005). The European Commission produced a guidance document that is based on the MDD 93/42/EEC Directive on medical devices for use in classifying medical devices. This classification system aims at ensuring that manufacturers of medical devices apply uniform conformity assessments. It is largely similar to the GHTF classification rules (MEDDEV 2.4/1 Rev 9, 2010) (EC, 2010).

The guidelines require that each medical device meet the minimum requirements of the MDD 93/42/EEC and be subjected to the reporting requirements outlined in the medical device vigilance system notwithstanding its class. The guidelines also require that each medical device with the exception of devices that are designed for clinical investigations and those customized to be affixed with a label that has the "Conformité Européenne" or CE marking. This CE mark means that the product has conformed to European standards and is a declaration that it has satisfied the stipulated regulations and provisions contained in the directive (Kreuzer, 1998; EC, 2010).

Classification of Medical Devices Based on Function

Classification of medical devices containing software can occur based on the main function of the medical device. Under this scheme, medical device software can be categorized as cardiovascular devices, orthopedic devices, diagnostic devices, or general hospital devices. Other categories are surgery devices, radiology devices, anesthesiology devices, and neuromodulation devices. Cardiovascular devices include pacemakers, stents, defibrillators, and cardiac monitors. Orthopedic devices include artificial limbs and artificial joints while examples of diagnostic devices are chemistry analyzers. Electric wheelchairs are examples of general hospital devices while radiology devices include ultrasound imaging systems. An example of an anesthesiology device is the anesthesia gas machine (FDA, 2012b).

Neuromodulation devices include device used in movement disorders and bladder control among others. Many devices that perform neuromodulation for movement disorders utilize Deep Brain Stimulation for the treatment of dystonia, essential tremor, and Parkinson's disease (Jiang et al., 2011). Neurostimulation is also used to assist in bladder control. Urinary retention and overactive bladder symptoms can be minimized through the use of medical device software providing neurostimulation for bladder control. Drug pumps are implantable devices that help manage pain through neuromodulation. They transmit medication for relief against pain to the fluid surrounding the spinal cord. They provide relief using a minimum amount of the dose that would otherwise have been taken orally. There are also several software-containing

medical devices used to perform neurostimulation for gastroparesis. These medical devices transmit weak electrical impulses to the lower stomach thereby providing respite from emesis and chronic nausea originating from gastroparesis caused by diabetes or by unknown mechanisms (Jiang et al., 2011).

Intrathecal baclofen therapy (ITB) Therapy is a neuromodulation technique that involves the delivery of the drug called baclofen to the intrathecal space for the treatment of spasticity (Jiang et al., 2011). Neuromodulation devices have also been used to provide neurostimulation for psychiatric disorders. Surgically implanted devices that resemble pacemakers are used transmit electrical impulses to specific regions of the brain in the treatment of psychiatric disorders such as obsessive compulsive disorder (OCD) (Jiang et al., 2011).

Biomimetic implants are also examples of medical device software used in neuromodulation. Biomimetic implants are software-containing medical devices that are used in the treatment of neurodegenerative illnesses and injuries. Through imitation of the biological world, they substitute lost brain pathways. In the ReNaChip project, interfacing of a synthetic biomimetic chip with the rain allows the completion of neuronal circuits, which are impaired in old age thereby helping in the rehabilitation of behavior among the aged people (Silmon, 2010). Other medical devices used in the central nervous system include cochlear implants for restoration of impaired hearing, neuroprosthetics for impaired movement, and retinal implants for impaired sight. Deep brain stimulation (DBS) has also been used in the treatment of Parkinson’s disease, dystonia, tremor, and

chronic pain. It works through the replacement of lost brain function in which implanted electrodes cause stimulation of the brain but is unsuitable for all neurological conditions since it does not have the necessary specificity that would allow the manipulation of local circuits in the brain. The biomimetic approach offers more promise in the therapy of neurological conditions than DBS (Silmon, 2010).

Implantable medical devices (IMDs) are devices that have found widespread application and are used to monitor and treat physiological conditions inside the body (Halperin et al., 2008). Examples of IMDs include insulin pumps, defibrillators, drug delivery systems, pacemakers, and neurostimulators (Halperin et al., 2008). According to (Hanna et al., 2001), there were more than 25 million Americans in 2001 who depended on medical devices for survival. The first IMD was introduced in 1958 (Leavitt, 2010) and the number of people in US who currently use IMDs is 1.6 million (Leavitt, 2010). Many of IMDs are now linked wirelessly to bedside monitors that transmit information to servers that then make this data available to caregivers. The ZigBee wireless standard is one of the main protocols used by IMDs in data transfer and transmission (Leavitt, 2010). The ZigBee standard is used to specify high-level communication protocols that utilize applications which are built on the IEEE 802 standard and which need secure networking, extended battery life, and low data rate.

The U.S. Medical Devices Industry

According to the United States Department of Commerce (DOC), the United States is the largest market for medical devices in the world. The United States market for

medical devices is worth approximately $110 billion (U.S. Department of Commerce, n.d.). This represented approximately 35% of the global medical device market in 2012. Exports of medical devices from the United States exceeded $44 billion in 2012 (U.S. Department of Commerce, n.d.). This number increased by more than 7% from the previous year.

The number of medical device companies in the United States was approximately 6,500 in 2014 (U.S. Department of Commerce, n.d.). Most of these firms were small and medium-sized enterprises (SMEs) with more than 80% of the companies having fewer than 50 employees (U.S. Department of Commerce, n.d). The percentage of firms in the medical device industry with 100 employees was only 15% (ITA, n.d.). The Lewin Report put the number of workers employed in the medical devices industry at 422,778 as at 2008. The total amount of money paid in wages during the year was $24.6 billion (Lewin, 2010). The report states that each job in the medical devices sector generates another 1.5 jobs. Whereas firms dealing with medical devices were scattered all over the country, there were clusters of these firms in particular areas, which are renowned for their vibrant biotechnology and microelectronics industries. States such as Minnesota, California, Georgia, Michigan, Massachusetts, Pennsylvania, Illinois, New York, and Florida had high concentrations of medical device companies. Some of the leading manufacturers of medical devices in the United States are Medtronic Inc., Abbott Labs, Beckman Coulter, Becton Dickinson, and GE Healthcare Technologies (ITA, n.d.).

Porter (2012) provides a list of the leading global manufacturers of medical equipment. Fifteen firms alone account for 60% of all global sales of medical devices. The market is largely dominated by U.S. companies such as Johnson & Johnson, Baxter Scientific, General Electric, Coviden, Becton Dickinson, and Medtronic among others and European firms most notably Philips, Siemens, and Braun (Porter, 2012). The medical devices industry in the United States has averaged an annual growth rate of 6%. Even in the face of the global economic recession, this industry was able to employ hundreds of thousands of workers and bring more than 1,700 medical products to the market in 2009.

The impact of the global recession on the medical devices industry was significantly less when compared to other sectors of the economy. Whereas employment shrunk by 4.7% and manufacturing payroll decreased by 1.4% in 2009, employment in the medical devices industry reduced by just 1.1% and the payroll by a mere 0.7%. Sales of medical devices rose by 3.05% compared to the 2.8% posted by total product sales in 2009 (Medical Devices, 2010).

The industry contributes immensely to the U.S economy. According to ITA (n.d.), the medical devices industry employed more than 365,000 people in 2007 with average yearly incomes of close to $60,000 (ITA, n.d.). Earnings in the medical devices industry are on average $16,000 more than the average national earnings, bearing in mind that the average national earnings were $42,000. In Arizona, South Dakota, and Wisconsin, earnings in the medical devices industry exceed the national average by more than 50%.

The medical technology industry in the United States also pays higher medical premiums than other sectors (Lewin Group, 2010).

The United States medical devices industry remains highly competitive thru innovation. The future growth remains positive. By 2013, the value of the medical devices market in the United States will be slightly over $120 billion while that of Western Europe will be just over $80 billion (Gross & Loh, 2006; Johnson et al., 2007). Markets in Asia Pacific, Central and Eastern Europe, and the Middle East and Africa Region will be worth about $60 billion, $15 billion, and $5 billion respectively (ITA, n.d.). The top export markets for the U.S. medical products are Japan, Netherlands, Canada, Germany, Belgium, Mexico, China, Australia, United Kingdom, and France respectively. Others are Switzerland, Sweden, Brazil, Korea, and Singapore.

The surgical appliance and manufacturing segment employs the largest number of workers and has the highest amounts of sales in the medical devices industry. According to market analysts at the Lewin Group (2010), manufacturers of surgical appliance employed about 114,500 persons with a payroll of $6.4 billion and sales totaling $35.3 billion in 2008. The surgical and medical instruments segment was in second place with approximately 109,300 employees. This segment has an annual payroll of $6.2 billion and produced sales totaling $33.6 billion (US Census Bureau, 2009; Lewin Group, 2010). The electro-medical and dental laboratories segments employed 65,300 and 50,000 people respectively and their payrolls amounted to $4.8 billion and $1.8 billion

respectively. Sales from the electro-medical and dental laboratories segments were $27.6 billion and $4.7 billion respectively. (Lewin Group, 2010).

California held the highest number of employees working in the medical device industry in 2010. It contributed close to a fifth of all people employed in the industry in 2010 (Lewin Group, 2010). Other states with the highest number of employees include Minnesota, Massachusetts, Pennsylvania, Florida, New Jersey, Indiana, New York, Texas, and Wisconsin. The number of people working in the industry increased by 20% between 2005 and 2007. However, this rate decreased to 12.5% from 2007 to 2008 (Lewin Group, 2010). The decline in employment registered in the medical devices industry in 2008 was just 1.1% and this was smaller than the 4.8% recorded for the entire manufacturing industry in the US (Lewin Group, 2010).

There has been an increase in the use of medical device software in the past few decades. The United States is the world's largest consumer of medical device software. Approximately 1.6 million people in the United States use implantable medical devices (IMDs) (Leavitt, 2010). Hegde and Raheja (2010) estimate that the medical device market in the US is the largest globally and is worth $91.3 billion dollars. This accounts for almost 41% of the total world medical devices market (Hegde & Raheja, 2010). According to Sandler et al. (2010), the total number of pacemakers implanted in the United States was close to 350,000 while that of ICDs was 140,000 in 2009. Estimates by the Freedonia Group (2008) show that the demand for IMDs in the United States will increase by 8.3% every year. Demand for these devices will peak at $48 billion by 2014

(Freedonia Group, 2008). This growth is expected to occur in the backdrop of reduced product recalls arising from enhanced effectiveness and safety. Market research analysts at the Freedonia Group also estimated that cardiac implants in the United States will growth by 7.3% every year and that the revenues will reach the $16.7 billion mark in 2014 (Freedonia Group, 2008).

Growth Trends and Competitiveness of the U.S Medical Devices Industry

The medical device industry in the United States has continued to post good growth. A study by the Lewin Group (2010) indicated a rise of 11.4% in the shipments of medical devices manufactured in the United States from 2005 to 2008. However, there was a 0.7% decline in the value of aggregate earnings for the industry during the same period. This decline was however smaller than the 1.4% decline for the entire manufacturing sector. The report by The Lewin Group also shows that the national earnings premium for the medical devices industry was 40% and this was more than double the national premium, which was just 21%. The higher premium is attributed to the highly specialized skills needed in the industry and this is bound to get even higher as the industry adopts technologies that are highly advanced. However, the average national earnings from some states such as Alaska, Washington DC, Connecticut, Idaho, Louisiana, Virginia, and New York are way above those of employees in the medical devices industry. The biggest differences are seen in New York and Alaska where the average earnings are $56,983 and $39,937 versus earnings of $46,507 and $39,937 for employees in the medical devices industry respectively (Lewin Group, 2010).

The trade surplus enjoyed by the United States in the medical devices market has however declined over the years because of the increase in the value of medical devices imported into the country. The majority of the imports into United States include products such as surgical gloves and instruments (Johnson et al., 2007). According to available statistics by ITA (n.d.), the value of surgical gloves and instruments reached 61.54% between 2002 and 2007. During the same period, imports of these devices grew by more than 2 times. The leading exporter of surgical gloves and instruments into the United States is China. There was also growth in the trade of dental equipment over the same period. The percentage increase in imports of ophthalmic goods was 59.2% while exports grew by 32.7% (ITA, n.d.).

The competitiveness of the medical device industry has been associated with several factors. Increased healthcare spending continues to drive the growth in the revenues of medical device software. According to Keehan et al. (2007), healthcare spending in the United States in 2008 stood at $2.4 trillion and could reach $4.3 trillion mark in 2016. Keehan et al. (2007) estimate that the United States will spend 20% of its GDP on healthcare by 2017.Healthcare expenditure in the United States has largely contributed to the competitiveness of the medical devices market in the country (Johnson et al., 2007).

According to market analysts at AdvaMed (2004), the United States leads the world in the production of medical devices. The investments in R&D, the adoption of high-end technology, high quality products, and a good regulatory end development

environment have made the Unites States medical devices industry very competitive. The United States maintains a competitive advantage in several other industries such as software development, biotechnology, microelectronics, instrumentation, and telecommunications that complement the medical devices industry (ITA, n.d.). Growth of healthcare expenditure in other markets such as China help fuel the demand for medical device software. Factors such as higher life expectancies, enhanced adoption of preventative and diagnostic services, and increased emphasis on geriatric care of the aging baby boomer generation are factors that drive the costs of healthcare up (Keehan et al., 2007; Halperin et al., 2008b).

Challenges and Drivers of the United States Medical Devices Market

A number of challenges facing the U.S. medical devices market have been identified and these include legislation on healthcare reform, which proposes to tax the industry billions of dollars, heightened regulatory oversight, and cost reduction efforts (Gross & Loh, 2006). Other challenges are entry barriers in foreign markets occasioned by lax intellectual property (IP) laws, counterfeits, and laws that have not been harmonized. Reimbursement policies also pose formidable challenges to the U.S. medical devices market. Many reimbursement schemes require that the manufacturers submit dossiers about the safety, efficacy, and quality of their medical devices. The amount of information required is usually burdensome and results in the manufacturers wasting a lot of money and time to carry out extra clinical trials, find out the requirements and pay extra user fees. Such requirements are put in place with the intention of earning the

government income or protecting the local industry. Healthcare reform, access to finances and venture capital funds, industry consolidation, product convergence, demographics, health information technologies, group purchasing organizations (GPOs), and comparative effectiveness are the other challenges facing the medical device software industry in the United States (Gross & Loh, 2006; Johnson et al., 2007; Porter, 2012).

Healthcare Reform. The Patient Protection and Affordable Care Act was passed by the House of Representatives in March 2010 after being approved by the Senate earlier on. The effect of this bill on the medical device industry will be widespread and varied when it comes into full force (Medical Devices, 2010). One of the salient features of the law that has a direct bearing on the medical devices industry is the 2.3% Excise Tax to be levied on sales of the devices as from 2013. The tax is tax deductible and this means that the effective impact of the tax is nearly 1.5%. The tax is expected to bring in $20 billion in taxes over a period of 10 years (Medical Devices, 2010).

This amount is exclusive of medical devices that are bought by members of the public at retail or export sales. The impact of the tax may be small on bigger companies such as Abbott Labs while smaller ones such as Boston Scientific may be affected greatly. The tax is seen to benefit firms that produce proprietary or unique products since they can increase their profit margins. Other beneficiaries of the reform will be manufacturers who deal with medical devices that are directly paid for by consumers. The reforms are expected to have a positive effect on the sales of medical devices that are

used at home. Firms, which are likely to be affected by the tax are those, that produce products that are not differentiated and are costly and commodity-type (Medical Devices, 2010).

The healthcare reform bill also compels everyone to be insured by 2014 else they will be levied penalties. This requirement is projected to add about 32 million people to the insurance plans by 2019 with between 12 and 15 million of the new additions joining Medicaid. Alongside with this, there is a push for the tightening of the minimum medical cost ratios (MCRs) by health management organizations (HMOs) and insurers. This means that insurers will likely have more power when it comes to negotiating reimbursements and rates with doctors and hospitals. This will obviously have an effect on the medical devices manufacturers, as they will be compelled to reduce the costs of their products. If this happens, it is likely that the manufacturers will slash their budgets for research and development and this will hamper innovation (Medical Devices, 2010). The reforms require the firms to make annual reports on "sunshine payments" that are made to hospitals or doctors. The manufacturers are now required to adhere to codes of conduct that guide such payments (Medical Devices, 2010).

Reimbursement. According to Porter (2012), reimbursement is a crucial non-regulatory factor affecting the growth of the medical devices industry in the United States. The Veterans Administration and the Department of Health and Human Services' Center for Medical and Medicaid Services (HHS/CMS) administer reimbursement. Reimbursement is an important non-regulatory factor since it can influence the demand

and price of medical devices. It can also influence the future earnings of manufacturers as well as the incentives to create new products (Baumler, 2008).

Access to Finances and Venture Capital Funds. Most of the firms dealing with medical devices in the United States are SMEs. These firms largely depend on venture capital funding in order to come up with innovative products that can boost their bottom line (Johnson et al., 2007; Porter, 2012). According to ITA (n.d.), the global economic recession negatively affected the funding of these businesses by venture capitalists. The recession led to the withdrawal of many venture capitalists from the early stages of investing and they opted to hold on to their money awaiting the return of better certainty asset valuations. According to reports by the National Venture Capital Association (NCVA), the total amount of money invested by venture capitalists in third quarter of 2009 in the medical device industry was $617 million against $890 million invested in 2008 over the same period (cited in ITA, n.d.). Factors other than the global recession that may have contributed to less investment by venture capitalists include the long reimbursement periods and the drawn out process of product approval (Gross & Loh, 2006).

Industry Consolidation. Mergers and acquisitions are a constant feature in the medical devices industry. Usually, small companies, which are unable to draw large amounts of resources required to roll out innovative products, usually merge with larger companies that have the resources to bankroll such innovations. Such mergers help the bigger firms to obtain novel technologies and hence maintain their share of the market.

The smaller firms get access to resources that help them to actualize their innovations. The global economic recession is one of the factors fuelling increased consolidation of companies in the medical devices market (Johnson et al., 2007). In recent times, firms such as Medtronic, Covidien and Abbott Labs have consolidated their operations. Other forms of consolidation witnessed in the medical devices industry include outsourcing and firms combining their profit centers. There have also been a number of joint ventures between firms located in different countries. Notable examples include the collaboration between firms in China and those in United States. Such operations not only enhance efficiency but also lead to technology transfer and open up new markets for companies. This acts as a driver for the growth of medical devices companies (Gross & Loh, 2006; Johnson et al., 2007; Porter, 2012).

Product Convergence. Product convergence is an important non-regulatory factor affecting the medical devices industry. The convergence of the products of biotechnology and medical devices portend hope that medical devices can be used as delivery systems for these biotechnological products. Convergence between products of nanotechnology and medical devices can enhance the growth of the medical devices market (ITA, n.d.).

Demographics. Demographics are significant drivers for the growth of medical device companies. According to Johnson et al. (2007), one of the most important demographic that continues to shape the medical devices industry is aging. The increase in the average age of citizens both at home and in foreign countries has opened up a big

market comprising of senior citizens and companies are rushing in to serve the health needs of this burgeoning population. The growth in the population of senior citizens has also led to growth in home healthcare (US Census Bureau, 2009). According to Gross and Loh (2007), home healthcare is one of the segments of the medical device industry, which are growing at a very fast rate. As such, many companies are focusing on the production of highly advanced medical devices that patients or unskilled caregivers can use at the patients' homes (Gross & Loh, 2007).

Health Information Technologies. The U.S. government currently fosters the increase use of IT in health, in order to boost the use of medical devices. The American Recovery and Reinvestment Act (AARA) allocated $19 billion in 2009 for the promotion of electronic health records use and for creating boards that would formulate standards and policies that would govern the use of IT in health. The Office of the National Coordinator for Health IT (ONC) under the HHS has also played an important role in drafting rules that govern the use of electronic health records in a consequential manner. In light of these, the medical device industry plays an increasingly pivotal role in the utilization of health IT (ITA, n.d).

Group Purchasing Organizations (GPOs). Group purchasing organizations (GPOs) act on behalf of healthcare provider cooperatives to negotiate contracts with health suppliers. According to Rasmussen (2002), the economic recession has enhanced the role of GPOs since many care providers resorted to cost-cutting measures. In order to

save the hospitals money, the GPOs look for those medical devices that are cost-effective (Rasmussen, 2002).

Comparative Effectiveness. Comparative effectiveness refers to the relative advantages conferred by a particular system as compared to other similar systems. An increase in the costs of healthcare is expected to lead to increased use of comparative effectiveness where research is carried out to compare the clinical efficacy of various devices in order to use solutions that are not only effective but also less costly (Porter, 2012).

The European Union Medical Devices Market

The European Union forms the largest market for medical devices after the United States. France, Germany, Italy and the U.K. form the largest markets for medical devices in the EU. Most exports of devices manufactured in the United States are to the EU. In 2008, the United States exported medical devices worth $13.8 billion (ITA, n.d.). Leading manufacturers of medical devices in Germany are Braun and Siemens while Phillips Electronics is a leading manufacturer in Netherlands. Covidien is a leading manufacturer of medical devices in Bermuda (Johnson et al., 2007).

Factors that have made EU an attractive market for medical devices include a large and aging population. Besides, many countries in Western Europe boast of mature and stable economies, which have consistently performed well on the economic front. This has provided a good market for medical devices. Estimates show that the device markets in most of the western European countries will experience steady growth. There are many

multinationals specializing in medical devices, which have set up shop in these countries in order to benefit from the relatively good market (Gross & Loh, 2006).

Regulations have also contributed to the competitiveness of the medical devices market in Europe. The Medical Device Directives (MDD) regulates the medical devices market in EU (Bright, 1999). These regulations were formulated on the basis of globally accepted standards and were amended to increase the threshold for "clinical evidence" as well as empower the authorities so that they can be better placed to put in place stricter mechanisms for ensuring that only safe, effective and authorized devices are on sale. The large per capita income of many European countries has played a big role in enhancing the growth of the medical devices industry (Bright, 1999; Cookson & Hutton, 2003). Another factor that has worked to the advantage of western European countries is that they are located near the emerging markets of eastern and central Europe. The U.S. is the leading foreign supplier of medical devices in this market (Gross & Loh, 2006; Porter, 2012). In Eastern and Central Europe, the market for medical devices is much smaller but it is forecast to expand. The major supplier of medical devices in this region is Russia while the leading foreign supplier is Germany (Johnson et al., 2007).

China's Medical Devices Market

China has experienced tremendous economic growth over the past few decades. The strong economic growth combined with a large spending class has fuelled the growth of a big market for medical devices (Gross & Loh, 2006). In addition, healthcare reforms have also opened up opportunities in the medical device market. The U.S. is China's

largest supplier of medical devices (Liu & Pecht, 2010). The value of exports from the US to China in 2008 was approximately $1.5 billion and they are expected to increase at a rate of 5%-10% every year (Gross & Loh, 2006). However, factors such as unpredictable regulatory environment, widespread corruption, laws that do not effectively safeguard intellectual property (IP) and massive counterfeiting, and policies that are tilted against foreign players diminish the attractiveness of this market (Luo, 2000).

The Chinese medical devices market is worth approximately $5 billion (ITA, n.d.). Locally, the country is self-sufficient in the production of low-end medical devices such as drapes and gowns, sponges, and dressings. It imports most of high-end medical devices. The Chinese market is still small as it only makes up about 5% of the global demand whereas it has 20% of the global population. In recent years however, the Chinese market has experienced double-digit growth. Estimates indicate that the market will expand at an annual rate of 15% for the next 10 years. This expansion could propel the country to the second largest market for medical devices in the world by 2020 (Gross & Loh, 2006).

Features of the Chinese healthcare system that have significant impact on the country's medical devices industry and affect the imports of these devices have been discussed by several authors. The country's hospital system is one of the factors that continue to impact negatively on China's medical devices industry. The number of private hospitals in china is small compared to that of public hospitals (Gross & Loh, 2006). According to Xinhua (2010), private hospitals are 5,736 in number and make up

just 29% of hospitals in the country. The rest of the hospitals are more than 14,000 in number and are public hospitals run and managed by the country's Ministry of Health (MoH) and other government agencies. There are three classes of hospitals in China: class I, class II, and class III. The quality of healthcare provided, the medical devices used, and the services on offer vary across the three classes. Class I hospitals provide comprehensive healthcare and usually make use of advanced medical devices. The number of beds in these hospitals usually exceeds 500. There are about 1,000 such hospitals in China. Class II hospitals are about 5,000 in number, are medium in size, operate in cities, districts, or counties and have between 100 and 500 beds. Class I hospitals are very limited in the type of services that they provide. Such hospitals are about 12,500 in number and they normally operate in villages or small towns and have old equipment (Yip & Eggleston, 2001).

The poor healthcare infrastructure has considerably affected the growth of the medical devices market in China. Cognizant of this state of affairs, the Chinese government plans to refurbish or build some 29,000 clinics and 3,000 hospitals in China. The plans will lead to an increase in the number of beds as well as better infrastructure including new equipment. This plan can boost demand for medical devices in the country. An uptake of low-end devices is projected to rise due to the expansion of hospitals and improvement of the hospital system (Liu & Pecht, 2009; Merritt, 2011).

Majority (70%) of the Chinese are rural dwellers (Shi, Liu, Zhang, Lu, & Quan, 2008). A report by Epsicom Business Intelligence (Epsicom, 2006) reveals that close to

87% of the rural population in China paid for their medical costs out of pocket in 2000 and that 75% do not have medical insurance. According to Merritt (2011), there were about 700 million in China with no health insurance coverage in 2006. To increase the number of people residing in the rural areas who are covered by medical insurance, the Chinese government reformed the New Cooperative Medical Scheme (NCMS). Other health insurance schemes in the country are the Urban Employee Basic Medical Insurance (UEBMI), which targets employed people living in the urban areas, and the Urban Resident Basic Medical Insurance (URBMI), which targets people who live in urban areas but are not formally employed. There are also medical programs financed by taxes and which target the poor in both rural and urban areas (Yip & Eggleston, 2001; You & Kobayashi, 2009).

To further reform the healthcare system in the country, the Chinese government has announced plans to harmonize the different insurance schemes as well as introduce insurance premium subsidies. These efforts are expected to increase health insurance coverage to 90% of the country's population. By increasing health insurance coverage to 700 million more people, the demand for medical devices in the country will indubitably increase (You & Kobayashi, 2009; Cao, Shi, Wang, & Dong, 2012). The low coverage of the population has negatively affected the growth of the medical devices industry in the country. This is however bound to change as the country has embarked on an ambitious reform program that seeks to have 90% of its citizens covered by medical insurance by 2020 (Cao et al., 2012; You & Kobayashi, 2009). This reform program promises to open

up more opportunities for manufacturers of medical devices not just in the country but also throughout the world (You & Kobayashi, 2009).

Widespread corruption, high taxes, and the collapse of the medical cooperative movement have also removed the sheen off the Chinese medical devices market (Gross & Loh, 2006). Demographics of the country will influence the direction of the country's medical devices market. There are presently more than 160 million people in China whose are 60 years older. This population is projected to increase to 240 million by 2020. The aging population presents new health challenges that provide opportunities for the medical devices industry. With the increase in the population of the aged, it is expected that incidences of stroke, cancer, and cardiovascular diseases will rise. Estimates show that patients with cardiovascular diseases are increasing by a factor of 20-30% every year (Shi et al., 2008; Sun et al., 2011).

Reimbursement is one of the main factors affecting the medical devices industry in China. The Chinese government has put in place several reimbursement schemes in a bid to restrict the prices of medical devices. The limited amount of health insurance funds has necessitated this action. Hospitals are not allowed to buy medical equipment costing more than $250,000 on their own. Instead, they are required to buy such equipment collectively with other institutions to reduce corrupt practices as well as the costs. In addition, the tendering process is centralized and there is a maximum allowable mark up on medical equipment that is meant to keep the prices of medical equipment and devices low. These have had significant ramifications on the Chinese medical devices industry

and have reduced the attractiveness of the Chinese market among foreign manufacturers of these devices (Yip & Eggleston, 2001; Ngorsuraches, Meng, Kim, & Kulsomboon, 2012).

Economic performance is one of the factors that is driving the growth of the medical devices market in China and is expected to improve the sector's fortunes in coming years. China has posted tremendous economic growth over the past few decades (Subramaniam, 2011). The good economic performance is expected to continue in the coming years and this will increase the disposable income of people hence drive up demand for medical devices in the country. This is projected to increase the demand for high-end devices from countries such as US as well as boost the capacities of local Chinese firms to manufacture advanced medical devices (Gross & Loh, 2006).

Another factor that will have a significant impact on the development of China's medical devices market is government policy (Gross & Loh, 2006). The government has formulated the 12th Five Year Plan, which identifies some sectors as being critical to the country's long-term strategic interests. One of the sectors that are identified is biotechnology of which medical devices form a part. Towards this end, the government has initiated plans to provide more support to these sectors. Tax credits are one of the ways through which the sector will be boosted by the government. This is expected to provide Chinese companies with a competitive edge and to increase the barriers foreign firms face in their bid to service the Chinese market (Casey & Koleski, 2011).

Additionally, more stringent regulatory and quality assurance standards are being formulated in a bid to enhance the quality and competitiveness of medical devices produced in China. This is expected to make local consumers have more confidence in goods produced in China and therefore reduce their reliance on medical devices produced in foreign countries. This is expected to pose significant challenges especially to devices made in the US, bearing in mind that the U.S is the leading exporter of medical devices to China. This is especially true since China is able to provide goods that are more competitively priced (Liu & Pecht, 2010).

The Medical Devices Industry in Japan

Japan is the second largest market for medical devices globally with an estimated net value of $23 billion in 2008. It is also the second largest market for U.S. exports of medical devices. The value of exports to this market in 2008 was valued at $3.5 billion (ITA, n.d.). Leading manufacturers in the country include Japan Hitachi, Toshiba, and Medical Corporation (Gross & Loh, 2006). Whereas Japan is the largest market for medical devices in Asia and has a big aging population, the harsh reimbursement and regulatory environment make this market difficult to penetrate for foreign manufacturers (Japan Pharmaceuticals and Medical Devices Agency (PMDA), 2006; Johnson et al., 2007). According to Johnson et al., (2007), the market for medical devices in Japan is projected to drop by 0.9% up to 2013. The only growth is projected to come from devices that are used in the treatment of diseases associated with old age such as orthopedic implants and pacemakers. Besides the aging population, another factor that will

contribute to a growth in this particular segment is the small number of manufacturers making these devices and this will provide opportunities for manufacturers from US to capitalize on the market (Gross & Loh, 2006).

Other large markets in Asia such as Taiwan and Korea also have the same bottlenecks. Australia has a relatively small market for medical devices but its regulatory system favors manufacturers and this has largely contributed to the growth of this sector in the country. Other countries such as Thailand, Malaysia, and Singapore have relatively well-developed markets for medical devices and the improving regulatory environment is seen as a boon for the medical device market in the years to come (Nakai & Yahiro, 2004; Gross & Loh, 2006).

The five biggest countries in terms of population (China, India, Pakistan, Brazil and Indonesia) make up almost 50% of the entire global population but account for just 4.4% of the global medical device use (Gross & Loh, 2006; ITA, 2012).

The Indian Medical Devices Market

India is a country that also has a market that is increasingly growing. According to ITA (n.d.), the medical devices market in the country is growing by double digits every year. The attractiveness of the Indian market is due to the increased uptake in healthcare spending by a fast growing middle class and the private sector. There is a rising demand for high tech products and the per capita expenditure on healthcare is on an upward trajectory. India has not yet fully complied with developing requirements. The US is the

leading foreign supplier of medical devices in India (Economic Intelligence Unit, 2009; Torsekar, 2010).

The Medical Devices Industry in Brazil

Brazil has emerged as one of the fastest growing economies in the world and this has provided immense opportunities for the export of medical devices manufactured in the US. However, the global economic crisis has pushed the economy from the 8th largest economy in the world to the 11th largest. Medical device imports into Brazil have also been hurt by currency devaluations. Brazil's medical device market is one of the largest in the world nevertheless (ITA, 2012). According to ITA (2012), this market is the 8th largest globally. Local companies supply close to 70% of medical devices with the rest being supplied by foreign companies. The US is the biggest foreign supplier of medical devices in Brazil and demand for foreign devices is mostly for high-tech imports (Brito, 2004).

The Medical Devices Industry in Canada

Exports of medical equipment to Canada have expanded over the past 5 years and the trend is expected to continue largely because of the country's highly developed and affluent market. Besides, healthcare in the country is for the most part bankrolled through the public service. However, the US is facing stiff competition from manufacturers in Japan and other European countries. Though stable, the Canadian market has relatively low yearly growth rates that do not exceed 5% (Johnson et al., 2007; Porter, 2012).

The Medical Devices Industry in Mexico

Mexico forms the second largest market for medical equipment in Latin America after Brazil. Trade between the United States and Mexico has significantly increased since North American Free Trade Agreement between the United States, Canada, and Mexico (NAFTA) became effective (Office of the United States Trade Representative [USTR], 2014). U.S. companies dominate the Mexican market for medical devices. Another factor that has benefitted manufacturers of medical devices in America is the absence of a well-developed medical device industry in Mexico. This has opened up sales opportunities for U.S. firms (ITA, 2005; Johnson et al., 2007; Porter, 2012).

Impacts of Medical Device Software

Positive Impacts of Medical Devices

Medical devices play a very important role in boosting the health and economic fortunes of millions of people around the world. Medical devices have greatly helped to boost health outcomes (Ceer, 2006; King, 2006). For instance, devices such as pacemakers, stents, and defibrillators are critical in reducing heart attack mortality. Mortality due to heart attacks fell by 40% between 1980 and 2000 and this decline is attributed to an increased use of cardiovascular medical devices. Estimates show that the devices have helped to reduce mortality due to cancer by an estimated 20% between 1980 and 2000. The number of deaths due to stroke also reduced by 37% between the same period and this has been largely attributed to the increased use of well designed medical devices (Calfee & Sudduth, 2011).

Besides saving lives and improving the quality of life of the sick, medical devices also provide economic benefits to millions of people around the world. These devices improve the economic wellbeing of the employees and their families and the communities in which the firms manufacturing them are located (Ceer, 2006). In many areas, medical device companies have led to higher disposable incomes, which in turn have resulted in higher demand for consumables and other goods leading to the creation of more jobs. Other benefits that accrue from the medical device industry include multiplier economic effects associated with expenditure by the employees in the industry, procurement of services and goods for use as inputs by the firms in the industry, and revenues and earnings arising from the sales and marketing of medical devices (Nixt, 2004; Pammolli et al., 2005; Porter, 2012). According to estimates, employees of medical device firms earn about $24 billion and spend close to $18 billion on consumer services and goods. These employees spending have multiplier effects on other sectors of the economy. The remaining $6 billion was spent on taxes, savings, and investments (Johnson et al., 2007).

Calculations by the Lewin Group (2010) use the example of California to demonstrate the economic benefits associated with the medical devices industry. The state has about 84,000 employees working in the industry with a combined payroll of $5.3 billion. Sales of the devices in the state total to about $26.3 billion. Based on these figures, the Lewin Group determined that the job, payroll, and sales multipliers for the industry in California are 3.5, 2.3, and 2.2 respectively. This means that each job in the

medical devices industry in California generates 210,000 other new jobs, an extra $6.9 billion in payroll, and an additional $31.6 billion in sales (US Census Bureau, 2009; Lewin Group, 2010). In Oklahoma, the jobs multiplier is 2.48. The job multiplier is between 2 to 2.4 in 13 states, between 2.5 to 2.9 in 14 states, between 3 to 3.4 in 8 states, between 1.5 to 1.9 in 1 states, and between 1 to 1.9 in 2 states.

The highest multipliers in the medical device industry in the US are the electro-medical and in-vitro diagnostics. The median job multipliers for these two sectors are 2.99 and 2.95 respectively. Multipliers for surgical and medical instruments, irradiation, and surgical appliance and supplies sectors are 2.53, 2.50, and 2.46 respectively. The sectors that have the least job multipliers in the medical devices industry are dental equipment and supplies, ophthalmic, and dental laboratories which have median rates of 2.23, 2.02 and 1.77 respectively (Johnson et al., 2007; US Census Bureau, 2009; Lewin Group, 2010).

Negative Impacts of Medical Software

Health and Safety Risks. Whereas medical devices are associated with many benefits, use of these devices can potentially endanger the lives of users by exposing them to various risks. These risks include the risk of device failure, hacking, breach of privacy and safety, and security risks. The following is a review of these majors risks.

Device Failure. One of the most dangerous risks associated with use of software-containing medical devices is the risk of device failure. This is a prevalent risk going by the number and rate of recalls done for software-containing medical devices. There has

been an increase in the rate and number of recalls of software-containing medical devices (Lee et al., 2006). According to Maisel et al. (2001) and Halperin et al. (2008), recall of medical devices is a big problem encumbering healthcare today. Recalls are usually done and advisories issued against particular medical devices due to product malfunctions or glitches. A study by Maison et al. (2001) showed that 41% of all recalls of medical devices by the FDA since 1990 were because of firmware malfunction. Wallace and Kuhn (2001) carried out a study of software-containing medical devices that were recalled between 1983 and 1997. They identified these recalls by interrogating FDA's database of failures of medical devices. According to their findings, a total of 2,792 medical devices with or without software were recalled between 1983 and 1991. Only 165 (6%) of these recalls had computer software. For the entire duration (1983-1997), Wallace and Kuhn (2001) found out that there were 383 recalls of medical devices containing software. There was a progressive decline in the number of software recalls between 1994 and 1996. As found out, 11%, 10%, and 9% of the recalls were medical device software in 1994, 1995, and 1996 respectively. This decline was the result of the fast increase in the number of medical device software (Wallace & Kuhn, 2001).

Wallace and Kuhn (2001) grouped the recalls according to the main function for which the medical devices were indicated. According to their findings, majority of the recalls were for radiology devices (30%) followed by cardiology (21%) and diagnostic devices (19%). Recalls for devices for general hospital, anesthesiology, and surgery constituted 10%, 10%, and 3% of the recalls respectively. High failure rates for radiology

and cardiology devices were the results of the relative complexity for their development (Wallace & Kuhn, 2001).

Based on the problems displayed by the failed devices, Wallace and Kuhn (2001) were able to define 13 symptoms and classify the 383 recalls by their symptoms. According to their findings, most of the failures were due to software malfunction (29%) and behavior (22%). Others were because of failure of output (19%), service (10%), display (8%) input (4%) and response (3%). Failure due to data, quality, user instruction, timing, and system each constituted 1% of the total recalls (Wallace & Kuhn, 2001).

According to Sandler et al. (2010), there were 23 recalls made by the FDA in the first half of 2010. All the recalls were for Class I medical devices and six of the defective devices were due to errors in the software (Sandler et al., 2010). Increased use of medical device software is associated with an increase in the frequency of fatal incidences and malicious attacks (Sandler et al., 2010). In a study on defects in medical devices spanning a 15-year period, Dolores and Kuhn (2001) noted that there was an increase in the incidence of recalls due to flawed software during the later years. Dolores and Kuhn (2001) attributed the increase in the incidence of recalls to the increase in the number of medical device software with time (Dolores & Kuhn, 2001).

According to Dolores and Kuhn (2001), 2,792 defects in medical device software led to these devices recall between 1983 and 1997. Out of these defects, 383 were due to defective software while 21% of the recalls were due to faulty cardiovascular devices. Dolores and Kuhn (2001) also found out that 98% of the software defects could have

been uncovered through elementary testing techniques. There were nearly 56,000 adverse events reported from the use of infusion pumps between 2005 and 2009. These adverse events included death and injuries and most were due to flawed software. The total number of infusion pumps recalled during this period was 87 and the recalls were due to concerns about the safety of these devices. According to Hauser and Kallinen (2004), 212 deaths resulted from the use of implantable cardioverter defibrillators (ICDs) in the United States between 1997and 2003. Inspections, specifications-based testing, flaw hypothesis penetration testing, and failure modes and effects analysis are techniques available to ensure the quality and reliability of software (Wallace & Kuhn, 2001).

Risk of Hacking. Medical devices are increasingly becoming vulnerable to hackers (Peck, 2011). According to Peck (2011), medical devices expose their users to potential hacking attacks. There is a possibility of hackers intercepting communications between medical devices and other equipment and transmitting injurious data to the devices. Hackers can also steal confidential patient data (Peck, 2011).

Leavitt (2010) demonstrated that it is possible to use computer and radio equipment to reprogram medical devices as well as gain access to patient data (Leavitt, 2010). Solutions to prevent against hacking include encryption, use of patient-centered approaches, and zero power defenses (Peck, 2011). According to Geissler (2010), encryption is one of the ways to limit or prevent hacking of medical device software. Encryption can be useful against hacking since it can restrict unauthorized access as well as conceal the commands used by medical device software. The main problem associated

with this approach is that it can increase computing complexity thereby imposing additional system requirements. In particular, inadequate computing and battery power can hinder implementation of complex encryption algorithms (Geissler, 2010).

Patient-centered techniques are available to prevent hackers from interfering with software-containing medical devices. Empowering patients can help to minimize or eliminate incidences of hacking. One of the ways this can happen is by encouraging patients to use strong passwords, which must be entered before access to the medical device software can be granted. To enable doctors gain access to the IMDs during emergencies, the passwords can be encrypted inside bracelets worn by the patients or tattooed as barcodes that can only be seen under ultraviolet light (Juels, 2006).

According to Halperin et al. (2008a), zero power defense is being considered as an appropriate strategy for preventing hacking attacks since it does not impose additional resource requirements on the IMDs. The objective is to make the medical devices safe from hackers without utilizing more energy from the gadget's battery. According to Geissler (2010), this approach involves the use of a computer to harvest energy and serve as a gateway device. Radio transmissions from people who need to access the medical device are used to power this gateway device. The gateway device thereafter initiates a challenge-response protocol requiring people to verify that they are authorized to make contact with the medical device. People who are unauthorized do not therefore use any of the device's battery power as they are stopped by the verification process (Geissler, 2010).

Privacy Issues. Use of software-containing medical devices can potentially expose the patient to breach of privacy. Medical device software can potentially place the users' safety and privacy at risk since the conventional techniques for imparting safety such as redundancy and use of unique identifiers are ineffective against deliberate security and privacy attacks and failures. Moreover, knowledge about the safety and privacy of medical device software is still limited and this is largely due to the isolation of the devices from interoperable networks (Rieback et al., 2005).

According to Halperin et al. (2008), there is limited knowledge on how the use of software-containing medical devices affects the privacy and security of users. This is largely due to the separation of medical devices from networks thereby limiting their inter-operation (Halperin et al 2008). The limited knowledge further compounds the observation that currently available methods for forestalling attacks such as use of unique IDs and redundancy are not fail-safe mechanisms for stopping unintentional attacks or providing security. In addition, medical devices deployment over the network has increased thereby creating new challenges associated with user security (Geissler, 2010). Halperin et al. (2008) and Geissler (2010) documented several privacy goals for medical device software and include device-existence privacy, device-type privacy, specific-ID privacy, bearer privacy, measurement and log privacy, and integrity of data. The following is a brief description of challenges associated with user security.

Device-existence privacy. This privacy feature refers to the inability of unauthorized people to make out remotely the medical devices implanted in a patient.

This is because the unauthorized person may be an adversary such as a prospective worker who is keen on perpetuating discrimination against the patient or a member of a criminal group looking to sell some costly device (Geissler, 2010).

Device type-privacy. According to Halperin et al. (2008), device-type privacy is an important feature that medical device software should have. This feature means that medical devices must not disclose their type to unauthorized persons even though it discloses its existence. This is important because patients with implantable devices may be unwilling to let others know that they have these devices for reasons such as to avoid stigma associated with their condition, to prevent other people from knowing that they have a terminal condition, or because the device may be too costly and may attract criminals on the prowl for such devices (Juels, 2006).

Specific-device ID privacy. The goal of specific-device identification (ID) privacy is to stop unauthorized people from tracking individual medical devices using wireless techniques such as Bluetooth, 802.11 media access control (MAC) addresses, and Radio-frequency identification (RFIDs). If this happens then the location privacy of the patient can become compromised (Juels, 2006).

Bearer privacy. Bearer privacy is also an important feature of privacy in medical device software. Bearer privacy means that adversaries must not take advantage of the features of medical devices to pinpoint the identity of the patient or dig up patient-related information such as the patient's medical history, demographic data, or medical history (Geissler, 2010).

Measurement and log privacy. Medical device software should be designed and configured such, that hackers cannot breach the privacy of the patient by accessing measurement or log data stored in the device. It should also be impossible for the adversary to dig up or intercept patient-related information that is being transmitted (Schneier & Kelsey, 1998).

Integrity of data. Protection of patient safety and privacy also involves ensuring that the integrity of the data that is stored or being transmitted is not spurious. Consequently, medical device software should be designed in a way that prevents unauthorized people from interfering with previous measurements or log files, modifying the physiological features, or deleting and insertion of events. The demographic information and other data that has been stored should not be amenable to modification (Juels, 2006).

Security Issues. One of the most important features of medical device software is safety. Safety means that the harm caused by the devices should be minimal or non-existent while its benefits should be greater (Halperin et al., 2008). All medical devices have an inherent form of risks to the safety of their users. Device safety is usually determined through risk assessment studies. In the US, medical devices are classified into 3 classes based on the risk that they portend to the health of the user. Other countries use different methods to classify medical devices based on their safety risks (WHO, 2003).

According to Geissler (2010), one of the foremost challenges facing the development of effective and safe medical device software relates on how to balance

safety and effectiveness with security and privacy. With regard to safety, these devices should permit access to the data only by authorized persons. Measurement and storage of data should be highly accurate and authorized persons ought to be able to identify the device without much difficulty as well as configure the settings of the device. It should be possible to update the software and the operational history of the device ought to be auditable in the event of device failure. In addition, safety of medical device software includes the ability of the device to interact or coordinate with other devices and it should be efficient in terms of utilization of resources (Geissler, 2010). Security goals of medical device software include authorization, availability, device software settings, and identification and containment of adversaries (Juels, 2006).

Authorization. The safety of medical device software largely depends on authorization. There are different levels of authorization and these include personal authorization, role-based authorization, and selection. Personal authorization refers to the ability of the system to allow only certain people to carry out some defined tasks. The device authentication scheme integrates the rights of different sets of people to perform the tasks. Role-based authentication allows people to perform particular tasks based on their roles and access to the system could be role-based. With regard to selection, the devices ought to be able to communicate with only intended devices. Authentication and authorization of medical device software are highly contextual processes. Consequently, the rules can be set to relax in emergencies in order to protect the patient from grievous harm arising from non-intervention due to the strict authorization rules. The devices

ought to have the capacity to ensure that the authorization rules are stringently enforced (Geissler, 2010).

Availability. Availability is another important feature of medical device software security. It specifies the ability of the device to thwart attempts by adversaries to execute successful denial of service (DOS) attacks against the device (Halperin et al., 2008).

Software and settings of the device. For safety purposes, only approved persons should be able to configure, modify, or carry out actions on the medical devices that would lead to alteration of behavior. Accordingly, settings configuration by the device manufacturers and physicians should be in such a way that patients cannot deliberately or accidentally place themselves in danger. For instance, the drug delivery system configuration should not enable patients to increase the dose of their morphine medication. Additionally, access by physicians to debug modes or audit logs should be restricted and the devices ought to receive only firmware updates (Forsstrom, 1997; Juels, 2006).

Adversaries. Adversaries are people or actions that can compromise the safety and privacy of patients using medical device software (Geissler, 2010). According to Halperin et al. (2008), adversaries can be classified as insiders, active adversaries, passive adversaries, or coordinated adversaries. Insiders may include patients, software developers, healthcare providers, and hardware engineers and can potentially sabotage the effective functioning of medical device software thus placing the patients using these devices under great risk. Passive adversaries can breach the safety and privacy of patients

using medical device software by listening in on signals that are being sent or received by the devices (Halperin et al., 2008).

Besides listening in on transmissions, active adversaries can also set off malicious communications with peripheral equipment and other medical devices as well as cause interference with legitimate communications (Juels, 2006). Coordinated adversaries utilize collaboration between two or more adversaries in order to carry out an activity that can cause risks to the safety and privacy of patients using medical device software (Halperin et al., 2008). In performing attacks, adversaries may either use standard or custom equipment. Standard equipment are those that are commercially manufactured while custom equipment are those that are developed at home and used for active attacks and listening in (Geissler, 2010).

While enhanced security is desirable for software-containing medical devices, it could also lead to reduced system performance and increase in costs. Enhanced security of software-containing medical devices can also necessitate the purchase of new equipment. For instance, implementation of security measures requiring two-way communication in medical devices based on unidirectional equipment would compel the users to acquire bidirectional equipment (Leavitt et al., 2010). Enhancement of security in software-containing medical devices is faced with challenges in coming up with solutions that do not only work but are also acceptable to patients themselves.

Directions in Enhancing the Safety of Medical Device Software.

As noted before, safety and privacy issues are increasingly becoming important in the development of medical device software. Halperin et al. (2008), provide several research directions for minimizing or eliminating threats to safety and privacy in medical device software. These directions include use of fine-grained access control, open access with revocation and second-factor authentication, shifting of computation to external devices, authorization using secondary channels, use of secondary channels to let the patients know about their security status, and integration of accountability into the system (Halperin et al., 2008). These are briefly discussed in the sections that follow.

Use of fine-grained Access Control.

Fine-grained access control can help to resolve the conflict between predefined authorization and authentication rules and open access in the event of emergences. This approach resembles the Grey system where programmers examine the serial number, model, and primary-care center of the patient in an emergency and use the information obtained to get in touch with the manufacturer of the device and request access to specified functions for a particular duration of time. The manufacturer than evaluates the request and decides whether to give access rights to the programmer through issuance of a signed credential. The main feature of this approach is that the ultimate power on deciding which device interacts with a given device rests with the manufacturer. The main undoing of the approach is that it does not fully support specific-ID privacy and can

raise safety issues if the internet link between the manufacturer, emergency programmer, and primary care center is broken, cut off or slow (Bauer et al., 2005).

Open Access with Revocation and Second-Factor Authentication.

Another approach that is being considered for use in ensuring safety and privacy of patients using medical device software involves allowing unlimited access to medical devices and revoking or restricting access to these devices when they get stolen or lost. Access restriction or revocation might be done through the use of certificates that expire automatically. To make the system work properly, it would be difficult for one to regain the certificates without the right medical. Distribution of the certificates should be done in a hierarchical manner and they should be stored in safe places. The main drawback of this approach is that the devices are exposed to equipment that can be compromised for small periods and exposes the healthcare provider to DOS attacks due to the certificate distribution procedure. Additionally, the approach requires that the devices have a robust time notion (Halperin et al., 2008).

Another way of implementing this approach in medical device software is to restrict access to the device through the use of tokens to authenticate the identity of authorized users. The main undoing of this approach is that it might limit interventions during emergencies. Integration of federated identity management systems in the devices can also help to overcome the safety and privacy concerns associated with the devices (Geissler, 2010).

Shifting of Computation to External Devices.

Use of cryptography to initiate DOS attacks against the battery, processors, or communications of medical device software is a possible mechanism that can be used by adversaries to carry out actions that can compromise the safety and privacy of patients using medical devices. Adversaries can also utilize methods based on asymmetric cryptography to mount DOS attacks. These attacks can be minimized or eliminated by expanding the protocols and devices. This can however result into a bigger computing base that might render the system difficult to secure (Juels & Brainard, 1999; Juels et al., 2005).

Authorization using Secondary Channels.

Secondary channels can be used to authorize access to the medical device software. Wands located close to the chest have been used to activate ICDs through near-field communication. Once activated, the medical device can then be programmed by the healthcare provider for a greater duration of time. Alternatively, accelerometers integrated in medical devices can be used to halt communication whenever it becomes apparent that there is a considerable change in the patient's environment. These approaches are effective at curtailing breaches to the patient's security and privacy because they restrict lengthy exposure to situations that may compromise the safety and privacy of the patient. Research approaches also propose the use of encryption keys indented on medical-alert bracelets or cards to secure the communications between medical devices and the programmer. The main drawback of this method is that the

patient may be exposed to safety risks if the bracelet or card are forgotten or lost and there is need for emergency interventions (Halperin et al., 2008; Geissler, 2010).

Use of secondary channels.

Some of the currently available medical devices enhance the safety of the patient by issuing out audible alerts upon depletion of their battery. According to Halperin et al. (2008), secondary channels can be used to better notify the patients about the security status of their medical device software. These channels include environmental factors such as mobile phones, watches, and monitors located in the house. These channels can be used to transmit tactile, auditory, or visual information whenever there is a change in their environment. Whereas these alerts cannot by themselves stop malicious attacks, they can inform the patient about the threatening situation and thereby cause them to put in place protective measures (Halperin et al., 2008; Geissler, 2010).

Integration of Accountability into the Medical Device Software System.

Accountability measures can go a long way towards making medical device software safer and confidential. This can involve recording all the malicious activities and associating them with a particular person or event. The activities can be identified by reviewing the cryptographic audit log (Schneier & Kelsey, 1998; Halperin et al., 2008).

Risks Associated with Off-label Use.

According to David and Hyman (2007), off-label use of medical devices refers to the use of the device for reasons that are not listed as indications by regulatory authorities such as the EC and the FDA. It involves the use of medical devices for indications other

than those in the approved device labeling list of the EC and FDA. Off-label uses of these medical devices may include applications that are contraindicated or expressly forbidden thereby exposing the users to grave danger. According to Lee et al. (2006), medical devices are increasingly becoming networked and this has created challenges that make it difficult to make sure that there is uniformity in health safety.

There are many ways in which the use of medical devices can be referred to be off-label use. Reuse of devices, which are designed and labeled for single use only, is one example of off-label use that is widely practiced by many people (David & Hyman, 2007). The use of substances such as the human growth hormone and erythropoietin by athletes is an example of off-label drug use. Off-label use of medical devices may also be due to misapplication as a result of lack of knowledge, or flawed analysis. It may also be due to carelessness. In some instances, manufacturers may fail to obtain clearance from regulatory authorities due to the costly nature of clinical trials, sufficient prior familiarity with similar devices, or unprejudiced data that lend credence to labeling claims. Risks associated with off-label use include injuries, death, and incapacitation (David & Hyman, 2007).

Legislation of Medical Devices Software

Increase in the number and rate of recalls and the risks associated with use of software-containing medical devices-brought into the fore the importance of legislation with regard to these devices. For a long time, the regulations governing the production and marketing of software for medical devices was lax and the Medical Devices

Directive had not officially classified software as a medical product. In addition, previous regulations were only ideal for those devices whose risk levels were comparatively low. Medical devices that were used for critically important physiological functions and whose failure could lead to serious harm or even death were not covered adequately by the regulations. However, all this has changed and a new system controlling software-containing medical devices has been instituted. The system is the EN/IEC 62304 and is the world standard for managing the software development lifecycle. Although EN/IEC 62304 standard has been embraced as a global benchmark for management of the software development lifecycle, implementation of the standard has been slow due to unintended consequences including its effect on costs to manufacturers of medical devices, the competitiveness of companies, and the effect on companies arising from requirements touching on training and hiring of employees (Hall, 2010).

Regulation is done at the following levels: conception and development, manufacturing where good manufacturing practices (GMP) must be followed, packaging and labeling, advertising, sales, use, and disposal. Regulation involves the manufacturer of the device, the vendor, the user, the public, and the government. Regulation is done at 3 levels namely pre-market review, product representation, and post market surveillance.

Pre-Market Review

Pre-market review is carried out on the medical device before it can be brought into the market. The objective is to ensure that only products that meet the regulatory requirements eventually get to the market.

Product Representation

This involves the regulation of devices during the advertising and sales periods in order to ensure that vendors do not only operate from established premises but also fulfill their after-sale obligations and do not use advertisements that are either misleading or false. The objective is to protect the users from being exploited by insincere vendors.

Post-Market Surveillance

Post-market surveillance involves the continuous monitoring of products already approved to be in the market. The objective of post-market surveillance is to ensure that the safety and efficacy of the products being sold is maintained as time passes by. In the US, medical devices are highly regulated by the Food and Drug Administration (FDA). The FDA is responsible for ensuring that the health of members of the public is protected by ensuring that medical devices, drugs, cosmetics, radioactive products, food supply, and biological products are not only safe but are also effective and secure (David & Hyman, 2007).

Standards for Quality Assurance of Medical Devices

Quality systems refer to the resources, organizational structure, methods, processes, and tasks required in the execution of quality management (WHO, 2003). The ISO defines standards as accepted agreements that comprise of technical plans or other clear-cut principles that are meant to be used always as definitions of features, guidelines, or regulations to ensure that services, products, materials, and processes are suitable for their purpose.

Increasingly, generic standards that are universal standards that can be made use of by any company regardless of the products or services being produced or provided have gained prominence. Standards are of utmost importance in the medical devices industry for several reasons. First, they provide a benchmark that must be attained by a process, service or product thereby ensuring that the medical devices produced are of high quality. Secondly, they guarantee consumers that the features of services or products in the market are not only reliable but also consistent. Third, standards avail data that can be used to improve the trustworthiness, performance, and safety of processes, products, and services. Additionally, quality standards provide more choices to consumers by allowing the products of a particular company to be combined or replaced with those of a different company (WHO, 2003).

In the medical device industry, standards that are largely used to regulate the quality of products are ISO 13485 and ISO 13488. Different countries make use of different quality systems as shown in the table below (WHO, 2003).

Table 1

Quality Standards Used in Different Regions.

Region / Country	Standards	Conformity Assessment
Canada		
	ISO 13485, ISO 13488	Third party (Conformity Assessment Bodies)
Japan		
	GMP#40 ordinance GMP#63 ordinance QS standard for medical devices #1128 notice	Government
Australia		
	ISO 13485 ISO 13488	Third party and government
United States		
	QS (21 CFR part 820)	Government
EU		
	ISO 13485 ISO 13488	Third party (notified bodies)

Note. Source: World Health Organization (WHO), 2003.

Standards may contain different types of specifications and these may be prescriptive, performance, design, or management specifications. Prescriptive specifications detail the desirable features in a product while performance specifications guarantee that a prescribed test such as the capacity of a battery is met. Design specifications stipulate the

particular technical or design features of a product whereas management specifications spell out the requirements for the procedures and methods firms establish. Standards may have different sets of specifications (WHO, 2003). Since medical devices manufactured in one country can be used by people in many other different countries, it is of critical importance that the quality standards used in different jurisdictions be harmonized in order to ensure the consistency of these devices and avoid endangering the health of patients (WHO, 2003).

Harmonization of Quality Standards for Medical Devices.

The GHTF comprised of Australia, the United States, Japan, Canada, and the EU. Pre-market approval involves the issuance of the Australian Register of Therapeutic Goods by the Therapeutic Goods Administration in Australia and the PMA or 510(k) by the FDA in US. A Device License is issued by the Therapeutic Products Directorate in Canada while the Pharmaceutical and Medical Safety Bureau of the Ministry of Health, Labor, and Welfare issues a Shounin in Japan for devices that have been granted pre-market approval. In the EU, the manufacturer is given an EC certificate and is thereafter required to pin the compliance label (CE mark) on the devices for sale. The table below describes the tools and requirements applied in regulating the medical devices sectors in those countries:

Table 2

Tools and Requirements Used in Regulation of Medical Devices in Different Countries.

Region/ country	Tool showing pre-market approval	Requirements for placing device on market
Australia	ARTG number	Enterprise identification (ENTID)
US	PMA or 510(k)	Establishment registration
Canada	Device Letter	Establishment license
Japan	Todokede (notification) or Shounin (approval)	Yunyu Hanbai-Gyo or import license, Seizo-Gyo or manufacturer license, and Hanbai Todoke or sales notification
EU	Compliance label (CE mark)	Registration of responsible person

Source: WHO (2003)

Conformity Assessment.

Conformity assessment refers to the procedures, methods, and processes that are carried out in order to ascertain whether a particular product adhere to the specifications of a certain standard. Conformity assessment can be done using any of 4 recognized methods. Direct testing is the most commonly used method to determine conformity to quality standards. Other methods are auditing, accreditation, or registration. Firms that meet the management standards receive a registration certificates from Management Registration agencies. The following table shows the organizations responsible for ensuring that medical device software comply with quality standards in different countries as well as globally.

Table 3

Different Standards Organization.

Region/Country	Standards Body
Canada	
	Standards Council of Canada (SCC)
European Union	
	European Committee for Electrotechnical Standardization (CENELEC) European Telecommunication Standards Institute (ETSI)
	Comité Européen de Normalisation (CEN)
United Kingdom	
	Medicines and Healthcare products Regulatory Agency (MHRA)
Germany	
	The Act on Medical Devices(Medical Devices Act) (Medizinproduktegesetz - MPG)
US	
	American National Standards Institute (ANSI)

International Standards Organizations		
Organization	Domain	Standards
International Organization for Standardization (ISO)	Electrical and electronics engineering	ISO 13485, ISO13488
International Electrotechnical Commission(IEC)		IEC 60601-1, IEC 61010-1, IEC 60601-2, IEC 62304(2006)
International Telecommunication Union (ITU).	Telecommunications	

Source: WHO (2003)

Voluntary Standards.

Voluntary standards refer to standards that have been developed and ratified based on broad participation and compromise by all stakeholders. Voluntary standards are useful because they involve the participation of many experts from diverse fields and who have access to cutting edge technologies and other resources present in industry and other professional bodies. Such standards are also beneficial since they enable the government to overcome its weaknesses such as limited resources and come up with extensive and well-thought out specifications for products and services. In addition, they enable accredited third parties to conform to standards besides harmonizing different regulations in different nations. Voluntary standards help in technology transfer to less developed nations because standards are updated without much difficulty as new technologies are adopted. Voluntary standards provide manufacturers with the flexibility to select suitable standards or comply with regulations (WHO, 2003).

According to the GHTF (2012), following "Essential Principles of Safety and Performance of Medical Devices" are instrumental when developing standards in order to ensure that they comply with the. New medical devices standards should also be based on internationally accepted standards and regulatory authorities are required to make available a system for identifying international standards so that manufacturers are provided with a means of proving that they have complied with the aforementioned essential principles. However, full application of an international standard is not mandatory so long as the firms can demonstrate compliance to the essential requirements

of the standard. Additionally, GHTF required that international standards be used to harmonize different regulations but still provides room for the use of regional or national standards in order to demonstrate compliance.

Product Standards.

The EN/IEC/62304 is a harmonized standard for the design of medical device software. The US and EU have adopted this standard. Since this is a harmonized standard, manufacturers using the standard are able to comply with the requirements of MDD 93/42/EEC and the M5 (2007/47/EEC) amendment. The standard requires that medical device software manufacturers assigned safety classes to the medical device software. Medical device software can be classified as Class A, Class B, or Class C (IEC & ISO, 2006). Class A devices are those that have no potential of causing an injury or damage to health while Class B devices can potentially cause an injury that is not serious. Class C represents medical device software that can possible cause serious injury or even death of the patient (IEC & ISO, 2006). In this context, serious injury is defined as an illness or injury that can threaten one's life, can cause a body structure or function to be permanently impaired, or occasions an intervention that is surgical or medical in nature and which is necessary in order to stop a body structure or function from becoming permanently impaired. Permanent injury means that a body structure or function has been damaged or impaired in a permanent manner (Hall, 2010).

After classification of the software into the appropriate class, the next step as specified in the EN/IEC/62304 is to decompose the software into items and units. A

software item refers to a component of a computer program that can be identified. On the other hand, software units are indivisible software items. The units and items can be typifies using an architectural diagram and this can also be used to relegate the safety classification of certain parts of the software so long as they are separable or can be segregated. Segregation can involve using different processors to execute software items. This means that it is possible to break up safety-critical software into items. The items may be classified differently (Hall, 2010).

Other product standards used in the design of medical devices are IEC 60601-1, which is a standard for medical electrical equipment safety, IEC 61010-1, which contains specifications for electrical equipment safety requirements, and IEC 60601-2, which has specific requirements for medical electrical equipment safety.

Management Environment Standards.

The International Organization for Standardization (ISO) has provided several standards for medical devices. Standards for the management of the environments for the manufacture of medical devices include ISO 13485, ISO 13488, ISO 14971, and EN/IEC 62304: 2006. The latter standard has harmonized all the other standards for software-containing medical devices. The United States and the EU have both adopted the standard. Adoption of EN/IEC 62304: 2006 by manufacturers ensures that they comply with the requirements for software development as contained in MDD 93/42/EEC and MDD 2007/47/EC. This standard enforces strict guidelines for medical device software and classifies software as a medical product (Hall, 2010). The ANSI/AAMI/IEC

62304:2006 standard, which is indistinguishable from the EN/IEC 62304: 2006 variants is also adopted in the United States (Hall, 2010). Standards for medical device software life cycle processes include ISO/IEC 90003: 2004 and the IEC 60601 series.

EN ISO 14971 was developed by the International Organization for Standards (ISO) and seeks to provide guidance to manufacturers on conducting analysis, evaluation, and control of risks. This is important in risk management especially when designing, developing, manufacturing, and monitoring the safety and functionality of medical devices after they have been sold (WHO, 2003).

On August 30, 2012, the updated "EN ISO 14971:2012 standard was published as harmonized to the Medical Device Directive (MDD) 93/42/EEC, and became effective immediately without a transition period. Three annexes ZA, ZB, and ZC were added to be used by Notified Bodies to assess compliance with the Essential Requirements of the Medical Device Directive (MDD) 93/42/EEC. There has been no change to the normative text of the standard.

The Food and Drug Administration (FDA) and Regulation in the US

The Food, Drug, and Cosmetic Act granted FDA limited powers to regulate medical devices in 1938. The agency can confiscate devices that have been adulterated and misbranded as well as prosecute the companies responsible for producing the products. The authority of the agency to exert control over medical devices became increasingly lame as technological advances took place resulting in devices that are not only complex and advanced but also which placed the health and safety of individuals at

significant risk. Consequently, FDA requested more regulatory authority over medical devices. Subsequently, the Bureau of Radiological Health received congressional authority over radiological devices such as x-rays and merged with the FDA in 1971.

Due to a number of scandals associated with medical devices, there was a public outcry demanding a strict regulation of the medical devices industry. This outcry led to the formulation of the Medical Device Amendments in 1976 that gave the FDA more authority to control the way the devices are designed, labeled, marketed, produced and distributed. The new regulation also gave rise to the formation of a classification system, which specified the process for registering and approving new medical devices. The FDA formed expert advisory committees made up of medical specialists to help examine the devices as well as to advise on policy matters. The FDA's regulatory systems include the classification, device approval, and reclassification systems (FDA, 2011; FDA 2012, FDA, 2012b).

Regulatory Systems. The FDA classifies medical devices based on their class and category. Classification by class involves grouping medical devices into 3 groups referred to as Class I, Class II, and Class III. Class I products have a simple design, are not strictly regulated and are not associated with significant risks to the safety or health of users. Class II products are more complex in design, but could pose minimal risks to the users. Class III products are highly advanced devices are very tightly regulated and can cause significant health and safety risks to users. Medical devices are also classified based on codes that reflect the medical specialty of the product and contain two letters.

The specialties relate to advisory committees that supervise the device regulation. They also include product codes, which relate to the function and features of the devices and which consist of three letters.

System for Approval of Devices. Pre-market notification or pre-market approval (PMA) process is required for FDA clearance to market. Class I medical devices does not require approval as they are associated with little or no risk to the safety and health of consumers. On the other hand, Class II medical devices require submission of a pre-notification for FDA clearance to market. In this process, the manufacturers are required to fill 510(k) for new products or whenever they carry out significant alterations on the labeling and design of existing devices. This process requires that companies demonstrate that there is "substantial equivalence" between their product and other products in the same category, which were manufactured earlier or specified standards formulated by the FDA for that particular category. Demonstration of "substantial equivalence" usually involves the presentation to the FDA of aspects of the device's design and testing information (FDA, 2011; FDA 2012, FDA, 2012b).

For Class II devices, manufacturers must present their devices for approval through the PMA process. This particular process requires that manufacturers provide copious amounts of materials that support the safety and efficacy of the device. Such materials may include data from clinical tests demonstrating that the devices are both effective and safe. There are two types of PMA, one original and the other supplementary. The original PMA is filled anytime a new medical device is being

launched while supplements are filled whenever changes are made in the design, manufacturing process, manufacturing location, and labeling (FDA, 2011; FDA 2012, FDA, 2012b).

Reclassification System. Over the years, there have been many changes made in the classification of medical devices by the FDA and this has led to the reclassification of hundreds of medical devices. Most of the reclassifications have involved the movement of Class III medical devices to either Class I or Class II hence the replacement of PMA requirements with 510(k) requirements. Reclassifications are carried out through Congressional mandates, petitions made to the FDA by concerned parties, and by FDA through the agency's own initiative. Before reclassifications occur, the FDA seeks advice from the concerned advisory committee and other specialists. The agency also broadcasts the proposed rules for reclassifications a couple of months prior to the reclassification in order to enable the public to make their contributions to the proposed reclassification (FDA, 2011; FDA 2012, FDA, 2012b).

The Center for Devices and Radiological Health (CDRH) is the division of the FDA that regulates manufacturers of medical devices in the United States (Bartoo, 2005). In 2009, CDRH received nearly $43 billion from the $325 billion allocated to FDA (ITA, n.d.). The CDRH carry out premarket review of medical device software in order to determine the efficacy and safety of the devices. The review of the device includes evaluating artifacts for the software development life cycle in order to make out the suitability of the device's quality assurance features. CDRH also performs post market

surveillance after the device has been placed in the market. Market surveillance involves evaluating the performance of the device. Whenever reports about grievous harm or deaths due to the device are received, CDRH carries out a health-hazard evaluation. This evaluation may result in a full-scale investigation referred as forensic analysis to determine the cause of the malfunction or failure. Depending on the outcomes obtained, the center can decide to either recall the devices or compel the manufacturer to institute corrective measures (Jetley, Iyer, & Jones, 2006).

According to Jetley, Iyer, and Jones (2006), these processes by CDRH are usually effective for the processes involved in production of the devices. However, they are not adequate in evaluating software. This is because most manufacturers do not use the model-based approach when developing their software. Rather, they develop their software based on the product requirements. As a result, it is not possible to detect some errors and bugs during the premarket assessment stage because model-checking methods or white-box testing techniques cannot be applied to the software. In addition, determining the source of software defects during forensic analysis is a very difficult undertaking. This is because the defects are usually non-deterministic and are largely system-dependent thereby making their reproduction a difficult if impossible task. Review of the software's source code is thus the only way to identify the defects and this is a laborious and difficult task because third parties usually perform the reviews and they often lack prior understanding of the software (Jetley, Iyer, & Jones, 2006).

The FDA has recently embarked on a drive to grow the number of electronic submissions for approval. The FDA launched in May 2008 the Sentinel Initiative to create a national electronic system that would enable FDA to look for safety data on medical devices approved by FDA in existing databases. In addition, the agency seeks to streamline existing good manufacturing practices (GMP) in order to forestall inconsistencies arising out of ambiguities in the GMP requirements that could lead to health and safety risks (ITA, n.d.).

Other initiatives by the FDA geared towards tightening the regulation of medical devices include re-examination of the 510(k) process. The 510(k) is a process that allows the FDA to determine substantial equivalence evaluation for premarket notification (510(k)) submissions. The intend of the re-examination is to get rid of ambiguous and unclear requirements as well as decide if restrictions should be placed on the kinds of products that can be subjected to the 510(k) clearance procedure (ITA, n.d.).

Based on Congress' request, the Government Accountability Office (GAO) carried out a study on the 510(k) process. According to the recommendations made by GAO, the FDA should establish regulations for a small set of PMA devices that get into the market via the 510(k) process. Re-evaluation or down-classification of the devices should follow the strict PMA procedure for class III products. Based on this directive, the FDA conducted a reevaluation of a type of artificial hip joints, pedicle screw spinal systems, external counter-pulsating devices, intra-aortic balloon and control systems, and implanted blood access devices. The FDA ordered manufacturers to send data about their

class III devices on the efficacy and safety of the devices prior to the amendment (FDA, 2011; FDA 2012, FDA, 2012b).

To further strengthen the regulation of medical devices, the FDA collaborated with other stakeholders in order to put in place a Unique Device Identifier (UDI) system for medical devices. The system is expected simplify the process used to recall products, reduce medical errors, enhance the reporting of adverse events, and improve the post-market surveillance of medical devices. Further, the FDA made it compulsory for manufacturers of medical devices to submit electronic copies of adverse event reports (AERs) to CDRH. This is expected to cut costs and enable CDRH to carry out safety reviews faster since the previous method involved submission of paper reports that were then fed into the Manufacturer and User Facility Device Experience (MAUDE) database (ITA, n.d.; FDA, 2011; FDA 2012, FDA, 2012b).

The Medical Devices Directive (MDD 93/42/EEC)

The Medical Devices Directive 93/42/EEC is the main directive regulating the medical devices industry in the EU and is the benchmark standard for medical devices all over the world. Other directives include Directive 90/385/EC, which regulates active IMDs and Directive 98/79/EC, which regulates in-vitro diagnostic devices. The MDD 93/42/EEC aims at ensuring that medical devices manufactured and used in the EU are not only effective but are also safe (EC, 1993). It comprises of 23 articles, which specify the regulations that medical devices must meet.

Amendments to MDD 93/42/EEC

Amendment M5 (2007/47/EC) came into operation in 21st March, 2010 and introduces changes to the MDD 93/42/EEC. Amendments of the MDD 2007/47/EEC include the following changes. First, standalone software is specifically included in the definition of medical devices. Secondly, the amendments require providing the proof of the clinical efficacy for Class I devices and all other devices. The amendments do not exclude medical devices that also happen to be machines as described by the Machinery Directive (2006/42/EC) from assessment of their efficacy and safety. In addition, MDD 93/42/EEC was amended to state that the Personal Protective Equipment Directive 89/686/EEC must be used to evaluate medical devices, which offer protection to the user or operator. Moreover, the amendments make it mandatory for all customized medical devices to undergo post market surveillance. It is also required that the patient for whom the device was customized should be given particular information.

Other amendments state that manufacturers are required to appoint Authorized Representatives to act on their behalf if they are not located in the EU. Additionally, trending has been included as part of the post market surveillance processes and the list of incidents reportable to the Medicines and Healthcare products Regulatory Agency (MHRA) have been expanded to include birth defects, congenital abnormalities, and fetal distress and death. MHRA is the UK government agency, which is responsible for ensuring that drugs and medical devices sold in the UK are safe and effective. The amendments also require that information about the technical factors and characteristics

identified as hazards that can cause risks upon reuse of the medical device should be clearly indicated and accompany single use devices and that manufacturers must ensure that Declaration of Conformity and Instructions for Use are controlled documents in the quality management system of the manufacturer.

Other inclusions are that processes that outline the post market surveillance activities related to the device must be included in the quality management system for most devices, the technical file must contain data from clinical evaluations, and that the notified body ought to monitor third party subcontractors carefully. In the new rules, reclassifications occur continuously and all stakeholders are therefore required to keep themselves updated. Finally, the EC requires that new devices comply with the most recent standards since the harmonization of standards is a continuous process (Conformance, 2012).

Legislation of Medical Devices in Developing Countries

Developing countries cannot sustainably grow their medical devices industries unless they adopt and enforce standards for risk management, regulatory approval, and quality. They also need to harmonize their local standards so that they attain world best practices established on the guidelines set by the Global Harmonization Task Force (GHTF) (ITA, n.d.). The GHTF was a task force that comprised of industry players and regulators. It was a voluntary body that comprises of Australia, Japan, Canada, the United States, and the EU. Its main objective was to streamline and harmonize regulations. Developing countries such as Brazil, South Africa, Chile, and Mexico participated in the

GHTF through the Latin American Harmonization Working Party (LAHWP) while China, Vietnam, Indonesia, Malaysia, and Thailand participated through the Asian Harmonization Working Party (AHWP) (ITA, n.d.).

Legislative weaknesses

One of the biggest weaknesses of the regulations governing medical devices is that approval is very costly. Before Class III products can get PMA approvals, manufacturers are required to submit copious amounts of materials that can prove that the devices are safe and effective. Detailed data from clinical tests are some of the information required. The clinical tests are very expensive to conduct. Class II products also require huge amounts of money to push through the PMA process although the cost is not as large as that for Class III products. This is because the regulations for Class II devices are not as strict and the company is only required to demonstrate "substantial equivalence" between its devices and other devices of the same category, which exist in the market (Lee et al., 2006).

Secondly, approval takes a lot of time. The PMA approval process often requires the submission and resubmission of material and this usually takes a lot of time. (Lee et al., 2006). Thirdly, some of the provisions are very difficult to enforce. According to Donawa (2010), enforcement of the legislation for medical devices in Europe is not always effective. Enforcement occurs through market surveillance program, which enable the authorities to detect firms, and devices that are not up to standard and take the appropriate action to protect the consumers form these companies and products.

Conformity assessment and post market surveillance are also difficult to conduct and unscrupulous traders can find loopholes.

Another weakness associated with the regulations is that source code for the medical device software remains the exclusive property of the manufacturers. The legislation covering these devices does not regulate source code. Therefore, patients and doctors do not have access to the medical device source code and cannot test the security of these devices. However, manufacturers have the option of submitting their source codes to FDA for analysis by its specialists in order to uncover any flaws before premarket review. This requirement is nevertheless optional and not compulsory (Sandler et al., 2010).

The regulations have also failed to protect users and members of the public effectively. In a precedent set in 2008 in the Riegel vs Medtronic Inc., the United States Supreme Court ruled that patients injured by medical devices sanctioned by FDA and recalled in 2005 were ineligible to pursue compensation from the manufacturers. The court removed the product liability lawsuits that were the only protection for people using IMDs thus exposing them to potential harm. This is an example of an area in which the legislation does not effectively safeguard the interests of patients using medical device software (Sandler et al., 2010). Another weakness is that the regulations do not have adequate safeguards to protect users against threats to their privacy (Leavitt, 2010). Other weaknesses of the regulations include lack of standardization in the security properties of medical devices and ambiguities in the requirements for clinical evaluation.

Additionally, the regulations create entry barriers that lock out small companies that cannot afford to go through the approval process (Higgs, 1995). They increase the sunk costs and since sunk costs are the main determinant of the economies of scale, the number of companies capable of returning profits in a particular market is limited by high sunk costs. There is a correlation between high sunk costs on one hand and lessened competition and fewer companies on the other hand (Sutton, 1991; Nixt, 2004). A study by Nixt (2004) shows that reduction in sunk costs lead to the increase by more than 100% of the number of companies entering the market each year. It is also associated with an 80% rise in the rate of new products launched into the market every year. The increases are not short lived; rather, they are long-term and take effect instantly. Nixt (2004) also found out that reductions in sunk costs have considerable effects on the rate at which medical devices are patented. One of the possible effects of sunk costs on the rate of patenting is that it can affect the value of patent protection and hence the tendency of companies to seek for patent protection. It was found out that reclassification by FDA does not only lead to a reduction in the rate of patenting but also enhances the quality of patents given. This implies that high sunk costs lead to an improvement in innovation (Nixt, 2004).

Nixt (2004) also investigate the effect of sunk costs on the entry of firms in the medical devices industry. A key factor of the medical devices market is the repeated entry resulting from the innovations taking place in the industry. The results of the study indicate that fewer new companies enter into the medical devices market when the sunk

costs are high and vice versa with a decline in the sunk costs. The same situation obtains with incumbent companies (Nixt, 2004). The findings suggest that entry barriers are critically important factors in the long-term success of firms in the medical devices industry. Since these entry barriers are largely determined by the existing regulations, the inescapable conclusion is that the success of new or incumbent firms or that of products entering a market depends on the regulations governing these companies and products. The literature suggests that the FDA regulations create entry barriers that hinder the entry of new firms (Nixt, 2004). Finally, the regulations have limited innovation.

Future Outlook of Medical Devices Software

According to Halperin et al. (2008), the future of medical devices is bright. High demand for these devices is expected to persist in the coming year due to factors such as the aging baby-boomer generation and the emergence of novel therapies. Aging of the baby-boomer generations bound to increase the demand and use of medical devices as they increasingly seek geriatric care. Emergence of novel therapies for chronic ailments such as sexual dysfunctions, anorgasmia, and juvenile diabetes continue to increase the demand for medical devices. Technological advancements that will aid the increased use of software-containing medical devices and medical devices will increase in complexity. The outlook for the medical device software also shows that there will be an increase in the miniaturization of medical devices leading to a decrease in the size of software-containing devices (Halperin et al., 2008).

According to Hegde and Raheja (2010), one of the factors that will power the growth of the medical devices market is increased healthcare spending. According to estimates, healthcare spending in the United States stood at $2.4 trillion in 2008 and was forecast to stand at $3.1 trillion in 2012 and $4.3 trillion by 2016. Healthcare expenditure is forecast to constitute a fifth of America's GDP by 2017 (Keehan et al., 2008). According to Chase (2004), beneficiaries of Medicare are projected to exceed 75 million people by 2030. Increased healthcare expenditure will lead to an increase in the consumption of medical device software (Hegde & Raheja, 2010).

Favorable demographics in the United States and other major markets for medical device software will also play a role in enhancing the use of these devices. According to Gibbs (1994), there's a doubling in the quantity of software present in consumer products every 2 to 3 years and this will also aid the growth of the industry to a larger extent. Increased inter-communication between medical devices through high-bandwidth and long-range wireless links – for instance, IMDs can now support the transfer of telemetry for remote monitoring using wireless means and at higher bandwidths and longer read ranges (Halperin et al., 2008). The US healthcare system is largely ineffective, costly, and is encumbered by an acute shortage of healthcare providers and an increase in the population of senior citizens. This provides a backdrop for the increased use of medical devices (Lee et al., 2006).

The 2005 High Confidence Medical Device Software and Systems (HCMDSS) workshop identified several critical issues to the future development of software-

containing medical devices. These issues include certification and validation, environmental concerns due to climate change, integration of medical devices, modeling and simulation of patients, and embedding of networked system infrastructure in a real-time manner. Validation and certification are required before legislative authorities can grant manufacturers of medical devices the go ahead to market their devices.

According to Lee et al. (2006), the certification is about to reach a limit due to the increasing complexity of the devices and their overreliance on embedded software to attain important functionality. Current validation and certification processes not only highly inflate the costs of medical devices but also increase the time to market and enhance the likelihood of device failure leading to higher recall rates and liability costs (Lee et al., 2006). There is need to review the current validation and certification processes to ensure that they not only protect the consumers of the products but also do not unjustifiably increase manufacturing costs and time.

Integration of medical device systems will shape the medical devices industry to no small extent. Currently available medical devices are not highly distributed and have poor safety, privacy, extensibility, robustness, mobility, and interoperability characteristics. In addition, there is a disconnect between treatment and diagnostic systems that needs to be addressed for them to work together effectively. (Lee et al., 2006). Modeling and simulation of patients is another factor that will have a bearing on the future outlook of medical device software. Software containing medical devices are more and more effective because of the increased use of simulation and modeling.

Embedding of networked system infrastructure in a real-time manner will help to enhance the role and effectiveness of medical device software. The outlook of software-containing medical devices is that they will comprise of persistent networked systems that provide safe, dependable, cost-effective, high-quality, confidential, and personalized healthcare (Lee et al., 2006).

Regarding global warming and climate change, environmental concerns are increasingly shaping the direction of medical device software. Future medical devices will need to be made of environmentally friendly materials (Woo & Woo, 2010). These concerns have led to the discontinued use of chlorofluorocarbon (CFC) in cleaning the medical devices as well as that of lead in the assembly of electronic instruments. More and more medical devices are manufactured using metallocenes and polyolefins such as cyclic olefin copolymers (COC) and cyclic olefin polymers (COP) in place of Polyvinyl chloride (PVC). In addition, sterilization using ethylene oxide gas has considerably reduced and replaced with ionizing radiation (Woo & Woo, 2010). Health concerns about these materials are also influencing the selection of materials for manufacturing medical devices. Concerns about the health risks posed by the use of PVC and di (2-ethylhexyl) phthalate (DHEP) led to their elimination in the manufacture of medical devices (Woo & Woo, 2010).There is also concern that the continued use of bisphenol A (BPA) in the manufacture of medical devices could pose health risks to consumers. This is borne out of the observation that BPA can imitate some hormones resulting in detrimental effects on expectant women and their children (Woo & Woo, 2010).

Emerging technologies such as nanotechnology drive the growth of medical device software. Innovation, increased uptake and improvements of technology, and biomaterials are also important factors as are micro-electro-mechanical systems (MEMS) and improvements in manufacturing processes. Trends in lifestyle will also have an impact on the future outlook of medical device software. Lifestyle changes are one of the main contributors to the growth of the medical device software market. For instance, people with sedentary lifestyles have a higher risk of obesity and diabetes mellitus and this determines demand for insulin pumps. More and more people perform sports and outdoor activities. These activities are bound to lead to body injuries and necessitate use of medical devices such as prosthetics.

Design issues such as increased use of computer-aided design (CAD) and computer-aided manufacturing (CAM) coupled with better technology will make medical devices more compatible with a larger subset of the population and this has not only widened the consumer base but also reduced the age threshold for their use. Other important factors that will determine the future outlook of medical device software are new product development, establishment and growth of public health insurance, demographics especially aging populations, rising levels of income in developing nations and harmonization of legislative requirements and standards worldwide (ITA, n.d.).

Chapter Summary

The medical device market has expanded exponentially over the past decade. The US has the largest market for medical devices globally followed by the EU and Japan.

However, markets in countries such as China, India, and Brazil have continued to exhibit robust growth and they will become very important markets in future. Factors that will drive growth in many markets include expanding health insurance schemes, demographics, increased healthcare expenditure and harmonization of regulations, changing lifestyles, and better economic conditions among others. There are many positive impacts of medical device software such as improved health and economic fortunes. However, these devices expose users to many health and safety risks and can render them susceptible to loss of privacy as well as lead to deaths and injuries due to device failure.

The objectives of standards are to ensure that the medical devices are not only effective but are also safe. The MDD 93/42/EEC is an example of a regulation formulated specifically for this purpose. There is still a high rate of software recall due to device failure. The regulations have also increased the sunk costs and the approval time to market medical devices. There is need to determine the exact impact that the MDD 93/42/EEC has had on medical device software and to address any regulatory and legislative weaknesses. This will not only enhance the efficacy and safety of medical device software but also make the medical industry more competitive. Arising from this literature review, very few sources discussed the impact of the Directive on medical device software, and the impact to firm competitiveness remains to be ascertained. The next chapter will present the methodology of investigating the research questions and hypotheses postulated from chapter 1.

Chapter 3: Research Methodology

Introduction

This study involved examining the impact of the amendments to the MDD 93/42/EEC on the U.S. medical device software industry. The purpose of the study was to evaluate impact of the changes in the MDD 93/42/EEC on the net income and share prices of the compliant firms; the training cost for each EN/IEC/62304 compliant software year; project cost for each EN/IEC/62304; and the recall rate of devices manufactured by firms in the United States. This chapter includes the research methods used to conduct the study. This chapter outlines the nature of the study, its appropriateness to the research, and the population, sampling, and data collection criteria. This chapter also contains measures used for ensuring the reliability and validity of the study, evidence of trustworthiness, a description of the data analysis methods, ethics, and data management methods. The research questions and hypotheses formulated were as follows:

1. Research Question 1: What is the impact of changes to the MDD to the net income of medical device software firms in the United States?

   ***H*1$_0$-Null Hypothesis:** There has not been a decrease in the net income of medical device software firms in the United States due to changes to the MDD.

   ***H*1$_a$-Alternative Hypothesis:** Changes to the MDD have led to a significant decrease in the net income of medical device software firms in the United States.

2. Research Question 2: What is the impact of changes to the MDD on the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States?

   ***H*2$_0$-Null Hypothesis:** Changes to the MDD have not significantly reduced the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States.

   ***H*2$_a$-Alternative Hypothesis:** Changes to the MDD have significantly reduced the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States.

3. Research Question 3: What is the impact of changes to the MDD on the project costs of medical device software firms in the United States?

   ***H*3$_0$-Null Hypothesis:** There has not been a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States due to changes to the MDD.

   ***H*3$_a$-Alternative Hypothesis:** Changes to the MDD have led to a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States.

4. Research Question 4: What is the impact of changes to the MDD on the recall rate of medical device software firms in the United States?

***H*4$_0$-Null Hypothesis:** There has not been a significant decrease in the recall rate of medical device software manufactured by firms in the United States due to changes to the MDD.

***H*4$_a$-Alternative Hypothesis:** Changes to the MDD have led to a significant increase in the recall rate of medical device software manufactured by firms in the United States.

Research Design and Rationale

The nature of this study was a mixed methodology of qualitative study and quantitative techniques. The main objective of conducting a qualitative study was to understand and decipher subjective meaning from the point of views of the participants of the study. The quantitative techniques involved testing closed ended questions under a multivariate analysis framework. The significance of means from the participants was suitable to accept or reject the given alternate hypotheses and their null statements (Tabachnick & Fidell, 2001).

Appropriateness of the study method chosen

The qualitative technique involved systematic literature review, interviews and case study for the following reasons: (a) the qualitative method enables researchers to discover the problems under investigation (Bryman & Bell, 2011), and (b) this approach was preferred since the technique leads to the discovery of feasible solutions for the problems at hand (Coffey & Atkinson, 1996). The method does not only allow the researchers to devise novel concepts and ideas related to the issues under investigation

but also enable the analysis of lots of information (Bryman & Bell, 2011). In addition, compared to other methods, it was relatively cost-effective. Moreover, the method allows rapid turnaround time and the outcomes can be obtained within a short time (Dawson, 2013). The qualitative method was suitable since it enables the gathering of large amounts of background information quickly and without much difficulty (Coffey & Atkinson, 1996).

The quantitative method was suitable for its simple correlation, descriptive and Analysis of Variance (ANOVA) capabilities of the given factors and hypotheses (Tabachnick & Fidell, 2001). The simple correlation measured the sampled firms performance attributes before and after the implementation of the EU MDD such as net income, stock values, project costs and impact on revenue and employee numbers. The descriptive analysis was suitable to evaluate the demographic and operational key performance indicators of the various firms whose representatives participated in the survey. The ANOVA was appropriate for testing the hypotheses significance against p=0.05 (SPSS Inc., 2008).

Rationale for Selection of the Mixed Method

The mixed method design was suitable for this study due to the following considerations:

1. I was able to explore the issues under study using both qualitative or narrative and quantitative or numerical forms thereby enabling a systematic and complete

appreciation of the research problem and expansion of the breadth and scope of the investigation (Borkan, 2004)

2. The mixed method study approach allowed the collection of useful primary data on the impacts of the MDD 93/42/EEC directive on medical device software which would otherwise be impossible if other methods such as meta-analysis were used due to the scarcity of current and conclusive data
3. In mixed method studies, researchers have recourse to different feasible alternatives (Zikmund, 2010). The main objective of this study was to determine the impact of the EU Medical Device Directive on medical device software and hence infer possible solutions to solve identified problems. I used of the mixed method approach not only to identify the problems and drawbacks associated with the MDD 93/42/EEC but also to propose viable alternatives that could be used to redress these problems. From the foregoing therefore, it is evident that the mixed method was a more useful approach than either the explanatory or the descriptive approach for this particular study.
4. The mixed method approach allowed the outcomes and questions of one method to be recasted with those of the other method thus enabling the discovery of novel perspectives, contradictions, and paradoxes (Zikmund, 2010)
5. Exploratory research is advantageous when mixed method studies are conducted. I was able to build theory as well as obtain a profound understanding of the issues I investigated. In particular, mixed method studies are beneficial during the early

phases of research. The use of the mixed method approach helped formulate theories on the impact of the EU Medical Device Directive on medical device software and hence provided a comprehensive and well-supported framework on the research topic.

6. A major goal of this study was to identify problems associated with the EU Medical Device Directive on medical device software. Studies conducted using the mixed method approach have been instrumental in deciphering problems facing important regulations and directives in the medical field. Therefore, I was confident that the correct use of the mixed method approach in this study would similarly enable the identification of any problems associated with the EU Medical Device Directive on medical device software.
7. The mixed method approach promotes the creation of new novel ideas. This study sought to come up with new ideas about the role, place, impact and possible effects of the EU Medical Device Directive on medical device software. The mixed method technique was also preferred because it enhances complementarities, validity and reliability of the study (Green et al., 1989).

Program Evaluation

Summative evaluation was suitable to determine the impact of EN/IEC/62304 of Medical Software. Summative evaluation is a method of assessing the value of a program against its specification. It provides information on the capability of the program to meet the expectation of performance. Singleton and Straits (2010) describe two types of

summative evaluation used in this study: (a) Effect assessment evaluated whether the Medical Device Directive was achieving its intended effects and (b) efficiency assessment evaluated the cost and benefit values of the Directive. Summative evaluation included descriptive statistics. Considering that significance in summative evaluations is not an expression of randomness, the issue of randomness was not an important aspect of the measure, since the concern was for the impact of EN/IEC/62304 on firm performance.

Role of the researcher

Denzin and Lincoln (2003) consider the research as a human instrument of data collection. The role of the researcher in this study necessitates the identification of personal values, including any assumptions and biases, any expectations and experiences at the outset of the study (Greenbank, 2003). The researcher is a Biomedical Engineer with decades of experiences in the medical devices manufacturing industry. He is a current member of the American Society of Quality Assurance (ASQ) and has extensive experience in the European Medical Device Directive 93/42/EEC as well the U.S. Code of Federal Regulations for medical devices (Title 21 CFR part 820).

I believe that my professional experience provides firsthand knowledge, and sensitivity to the topic examined in this study. Although I made every effort to ensure objectivity, personal bias may have shape the way I viewed and understood the data collected and their interpretation.

The interview participants were purposefully selected because of their unique expertise in their respective fields. I did not have supervisory or instructor relationships involving power over the participants. The interviewees worked for different firms. I conducted the study using combination of questionnaires and structured interviewing techniques; asking the participants open-ended questions about their unique expertise with the research topic. I reduced researcher bias by administrating the survey anonymously using SurveyMonkey.com. Based on the ethics review, as part of this study, I assigned the study participants pseudonyms and the data collection occurred in total confidentiality.

Population

The target population included employees at selected medical device manufacturing companies. My preliminary investigation established that there were at least 265 firms in the medical device industry with business interest reaching the EU regions. I conducted interviews with managers at the following firms: Organization X and Organization Z. Organization X employs about 250 employees, and Organization Z employs about 85 employees. References to these organizations as Organization X and Organization Z are for purposes of confidentiality. Each of these companies was listed either in the New York Stock Exchange or NASDAQ or in terms of size, their market capitalization ran into millions of dollars. The study involved qualitative case studies of five medical device companies that have been in operation since the publication of the EN/IEC/62304 standard in 2007.

Sampling Methods and Procedures

For both the survey and interviews, the sampling frame consisted of senior and middle level managers of the companies listed in the preceding section. This study included a concurrent mixed method study and involved administering questionnaires to a convenient sample of professionals from companies in the medical device software industry. The population size consisted of 256 potential respondents targeting at least 1 in each firm. I used the purposive sampling technique to select respondents for the study. I selected the respondents in a non-random fashion based on the qualities that I deemed were suitable for attaining the ends of the study. The method was suitable since I was able to select respondents well versed with the issues under investigation. In particular, the purposive sampling technique allowed the selection of respondents based on their easy availability and more importantly because their experiences and perspectives provided useful information critical in answering the research questions (Saunders et al., 2009).

Since the study survey was administered online, I adopted convenient sampling of the respective firms' managers. Eventually, I managed to get interviews from two managers of the cited firms and while the survey managed to get feedback from 56 firm representatives. This is equivalent to 21.87% response rate. According to Kaplowitz et al., (2004), this response rate is admissible for an online survey first due to the geographical dispersion of the respondent and second due to difficulties of contacting the respondents. For years, observers assumed that higher response rates guaranty more

accurate survey results (Aday, 1996; Rea & Parker, 1997). However, very few studies have documented the consequences of lower response rates. A study by Visser, Krosnick, Marquette and Curtin (1996) indicated that surveys with lower response rates (closed to 20%) yielded more accurate results than did surveys with 60 or 70% response rates. A study by Curtin et al. (2000) on the effect of lower response rates found no effect of excluding respondents who initially refused to cooperate on estimates of the Index of Consumer Sentiment using monthly samples of hundreds of respondents. On the other hand, a low response rate is likely to give rise to sampling bias. Holbrook et al. (2005) found that surveys with much lower response rates decreased local representativeness within the demographic range examined, but not significantly. Data saturation was not addressed in this study. Due to resource constraints, the sample respondents for qualitative data capture was done purposively. The following criteria were suitable to ascertain the eligibility of participants in the study:

Inclusion criteria

1. Study participants were willing to take part in the study
2. They must have worked in the medical devices software field for a period not less than 5 years
3. Their company must have released a EN/IEC/62304 compliant software since the publication of the standard in 2007
4. They must be able to speak and write in English

Data Collection Methods

Primary Data

I collected primary data using surveys, in-depth interviews, and case study and systematic literature review (Saunders, et al., 2009).

Survey Instruments. I used survey instruments since they allow me to collect information in an inexpensive manner and without much difficulty. The study involved collecting primary data using SurveyMonkey.com. This method was ideal for administering the surveys because of a variety of reasons including its low cost especially where the target population resides in remote or distant geographical areas and the ease of administration to large populations. Use of the web surveys enabled instant transmission and reception of the questionnaires. Web surveys allowed enforcement of anonymity. No staff time was required with this method (Kaplowitz, et al., 2004). The questionnaire was designed using tools provided in the website and is attached as shown in the appendix. The survey questions probed the effectiveness Medical Devices Directive MDD 93/42/EEC, the impact of the MDD 93/42/EEC on medical devices costs and firms revenues. Other questions focused on process improvement of conformity assessment and the legal impact of the MDD 93/42/EEC.

In-Depth Interviews. The study involved performing in-depth interviews. These were open-ended, detailed, discovery-oriented and unstructured data collection tools (Guion, 2006), According to Zikmund (2010), in-depth interviews are qualitative research

methods that allow a one-on-one discussions. The main objective of the in-depth interviews was to understand the impact of EU Medical Devices Directive on medical device software by assessing the answers provided by the respondents when questioned (Zikmund, 2010). The chief characteristic of in-depth interviews was the use of open-ended questions in which the respondents provided responses to the questions that I posed in an open and free manner (Zikmund, 2010). In-depth interviews consisted of seven steps namely thematization, designing, interviewing, and transcription. Others were analysis, verification, and reporting (Kvale, 1996 cited in Guion 2006 p.2).

I adopted good interviewing skills in order to ensure that the responses obtained were accurate. I prepared an exhaustive interview guide comprising of a list of questions and follow-ups in order to keep interviewees from digressing. The guide also helped to provide a summary of the question, ensured that questions followed a sequential order, and ensured consistency in during the interviews. I used reasonably acceptable standards and formats during the preparation of the interview guide and I utilized a detailed face sheet to log in the date, demographic data of the participants, time of the interviews, and interview location. I also made use of good interviewing practices like patience, flexibility, and active listening to ensure optimum process and quality responses obtained. I used audiotapes to record the interviews after obtaining permission from the respondents. The objective was to store information for future reference as well as to enhance the interview precision.

The interview questions assessed the impact of EN/IEC/62304 on organization, and explored ways in which EN/IEC/62304 has been effective in enhancing the safety of medical devices, and whether or not medical device software produced under the guidance of EN/IEC/62304 provides firms with a competitive advantage.

Case Studies. I reviewed cases of financial performance of purposively selected companies in the medical device manufacturing industry, which are Artventive Medical Group Inc., Varian Medical, Mindray Medical, Abiomed and CryoLife. The purposive sample relied on the assurance that these medical device companies have embedded software and export products to EU markets. I retrieved case study information was from Securities and Exchange Commission (SEC) and Yahoo Financial data, both which are free access for public viewing. The justification of case studies was that method used collation first-hand information from medical devices software firms in the United States on the impact of EU medical Directive on these devices. Net income, shares stock price trends and the cost of implementation of the standard in terms of R&D served as the basis to examine participating firms' competitiveness after the implementation of the changes in the MDD 93/42/EEC. According to Yin (2009), case studies are appropriate when there are structured data and information about organizations or system whose variable comparison is under investigation.

Secondary Data.

According to Saunders, et al. (2009) use of different sources of secondary enables researchers to address successive gaps raised by every other. I developed and used the

systematic literature review method to gather literatures, theories and positions of various issues in the study such as MDD 93/42/EEC, medical device industry and various Standard Operating Procedures (SOP) which assign labels on medical devices as mark of quality and certification. Systematic literature review provided evidence about trends and acquires higher reliability if corroborated by different sources (Hiladgo, et al., 2011). Systematic Literature review provided information about policy, laws, practices and the impact to stakeholders (Evidence for Policy and Practice Information and Co-ordinating Centre, 2007). Systematic literature review is appropriate for studying robust supply chains such as envisaged in the medical device industry of interest in this research (Colicchia & Strozzi, 2012). The secondary data I collected included the net income for each company under study and the percent changes in training cost for each EN/IEC/62304 compliant software year. Secondary data also included the percent changes in project cost for each EN/IEC/62304 compliant software year and the percent changes in net income for each EN/IEC/62304 compliant software year. These data were obtained from company reports, Hoovers database and Yahoo Finance. Secondary data were also collected from the internet, peer-reviewed articles, premium content databases such as the IEEE, online vendors, books, market research reports, government reports and white papers, books, market research reports, standard reference works, and libraries.

Validity and Reliability

Validity is a measure used to determine how accurately a particular tool assesses what it is supposed to assess (Zikmund, 2010). It indicates the degree to which collected data is a reflection of reality and therefore determines how useful a particular outcome is.

Threats to Validity

The convenience method of sampling and the use of archival data potentially limited a generalization of the findings (Creswell, 1998). The overall strategy was a mixed purposeful sampling composed of convenience sampling and purposive sampling. While these types of sampling techniques use small sample sizes, the goal was credibility, not representativeness. The respondents were from firms within a certain geographical region, which may have led to selection bias with a possible negative effect on validity. A low response rate is likely to give rise to sampling bias.

Due to the different level of experience of the respondents, the selection maturation effect could have threatened the validity of the study. To reduce this threat, one of the inclusion criteria for the study was that participants must have worked in the medical devices software field for a period not less than 5 years. Data collected from participants during the interviews, and survey included opinions that could have also threatened the credibility of the study.

Issue of Trustworthiness

Guba (1981) proposed four constructs for judging the trustworthiness of qualitative research: credibility, transferability, dependability and confirmability. In

addressing credibility, I used data triangulation: collecting both quantitative and qualitative data from both primary and secondary sources. Trustworthiness of interpretations was enhanced through triangulation of quantitative financial data on the performance of the five medical device companies, in depth interviews with two experience managers in regulatory affairs and quality assurance. Member checking was included as a validity strategy. I conducted a follow-up meeting to give them the opportunity to verify the transcripts. On the issue of reflectivity, Creswell (1998) believes that all researchers have personal biases that can influence their interpretation of data. I believe that my professional experience provides firsthand knowledge, and sensitivity to the topic examined in this study. Personal bias may have influenced my interpretation of the data collected.

To allow transferability, specific criteria were defined (P. 117) to ascertain the eligibility of participants in the study. In addition to being a U. S. medical device companies marketing products in the EU, and the detail description on the research methods, these criteria provide sufficient details for a reader to be able to decide whether the findings can justifiably be applied to the other contexts or settings.

In addressing the issue of dependability, I used triangulation and audit trail. I provided a detail report of the research design and study results. The meeting of the dependability criterion should enable a research to repeat the study in the future.

Finally, to achieve confirmability, the findings of this study are the result of the experiences and opinions of the participants. The findings emerged from data collected

from literature reviews, interviews and case study of five U.S. medical device companies. I have provided evidence in Chapter 4 on procedures I used in this study to increase trustworthiness of the research.

Minimization of Bias

Questionnaire bias was reduced by administering the questionnaires to people meeting the inclusion criteria, and standardization of the questionnaire. Learner bias was avoided by randomizing the order of questions asked. Researcher bias was reduced by administrating the survey anonymously using SurveyMonkey.com. The data collection occurred in total confidentiality.

Research Strategy and Time Frame

The entire study took place over a period of 12 months. Following the review of literature, the design of questionnaires was done and participants for the study recruited thereafter. Administration of questionnaires, and in-depth interviews were conducted subsequently. Completed questionnaires were collected and data verification and transformation thereafter performed. The data were then analyzed and the final report compiled. The following convergence table was used to present results of the triangulation.

Table 4

Convergence Table for Presenting Triangulation Results

Research question	Results		Comparison / convergence
	Quantitative	Qualitative	
What is the impact of changes to the MDD 93/42/EEC on medical device software?	Summary	Summary	Summary of whether the results converged or failed to converge
What is the impact of the MDD 93/42/EEC on Europeans medical device manufacturer's competitiveness?	Summary	Summary	Summary of whether the results converged or failed to converge

Data Analysis

Qualitative Data Analysis

The qualitative data analysis was done using thematic descriptions along the study questions and hypothesis and summative evaluation (Coffey and Atkinson, 1996). In the case studies, descriptive statistics involved univariate analysis in which measures of central tendency, namely the mean and mode, were computed and displayed graphically (Saunders, et al., and 2009). The interviews were analyzed thematically with relevance to the research questions (Gillham, 2005). The secondary data and information were analyzed by summative evaluation to document whether EN/IEC/62304 is meeting its objectives, and whether there are any unintended consequences. Summative evaluation involves making judgments about the efficacy of a program at its conclusion (Bryman & Bell, 2011). It provides information on EN/IEC/62304 's efficacy and its ability to do what it was designed to do.

Quantitative data analysis

The quantitative financial data analysis were analyzed using excel to extrapolate the trends and measures from central tendencies (Saunders, et al., 2009). Additionally, I tested the hypotheses by data entry into SPSS tool, which is versatile in univariate and multivariate correlations (SPSS Inc., 2008). The ANOVA method was preferred to test the data along the Five Point Likert scale for their significance on the benchmark of p=0.05 (Tabachnic & Fidell, 2001).

Table 5

Quantitative Data Analysis.

Hypotheses	Dependent variable	Independent variable
$H1_0$: Changes to the MDD 93/42/EEC have led to a decrease in the net income of medical device software firms in the US	Net income for the firms in 2011	Average net income for the firms (2005-2009)
$H2_0$: Changes to the MDD 93/42/EEC have led to a decrease in the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the US.	Training costs for the firms in 2011	Average training costs for the firms (2005-2009)
$H3_0$: Changes to the MDD 93/42/EEC have led to a decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the US.	Project costs for the firms in 2011	Average project costs for the firms (2005-2009)
$H4_0$: Changes to the MDD 93/42/EEC have led to an increase in the recall rate of medical device software manufactured by firms in the US.	Average percent recall rate (2011)	Average percent recall rate (2005-2009)

Constant comparison was at the core of the data analysis. A convergence table was used to present results of the triangulation (p. 124).

Ethical Considerations

A letter of participation was email to the heads of the Quality Assurance department of participant firms (see Appendix G). I subsequently sent an email with the consent form (Appendix H) to the participants after I received a positive response to the letter of participation.

Ethical considerations were taken into account in order to comply with the demands of good research and to protect the privacy and rights of the participants (Saunders, et al., 2009). Privacy was enhanced by use of unique codes instead of the participants' names. Permission was obtained from the university's Institutional Review Board (IRB) before commencement of the study and full disclosure was made to all participants in order to comply with ethical requirements. The IRB approval number for the current study issued by Walden University is 09-20-13-0109393 and expired on September 19, 2014 (see Appendix E).

In addition, collection of data through interviews was also done in an ethical manner. From the outset, I acknowledged and respected the respondents' right to privacy and therefore avoided asking questions that overstepped the limits of personal privacy (Trochim, 2001).

I also took steps to safeguard the respondents' anonymity and sought informed consent prior to the administration of the questionnaires. This involved explaining the purpose of the study to the respondents and giving them a clear description of the aims and objectives before requesting for permission to take part in the study. I also informed

the respondents that they could opt to discontinue the study at any time. I carried out the interviews openly without any concealment or dishonesty and I adhered to the letter the code of ethics guiding research from the National Institutes of Health (NIH) Office of Extramural Research (Certification Number: 853619). I used safe filing cabinet and strong password to store data ensured that the privacy of the participants was safeguarded. Privacy of the respondents will also be guaranteed by destroying the data 60 months after completion of the study through shredding or formatting the hard disk. The nature of the data gathering process did not require a formal procedure for exiting the study. All participants were thank for participating in the study.

Data Entry and Management

Quantitative data entry was through typing and scanning of financial data into a Microsoft Excel spreadsheet to extrapolate the individual company performance then comparison is conducted across the firms. Data validation was done to ensure that no questions have been skipped and that all important demographic and background information has been supplied. I contacted the participants for clarification to correct incomplete questionnaires. In line with good research practices, I made use of a codebook to store pertinent information about the research and the collected data. Each anonymous interview respondent was accorded their wish as prerequisite for participating in the study.

Summary

This chapter has outlined the research strategy, which was comprised of mixed qualitative methods of systematic literature review, interviews, online survey and case studies. I adopted convenient sampling to get interviews from two managers and while 56 firm representatives participated in the online survey. I conducted the case study of ArtVentive Medical Group Inc., Varian Medical, Mindray Medical, Abiomed and CryoLife companies. The chapter has defined each strategy and justified choices of each method. The chapter has also defined the data and information analysis methods suitable for triangulation of these three methods to ensure the outcomes are replicable and validated. I have outlined ethical factors that had impact on the study. The next chapter will provide interview, case study and literature findings followed by analysis and interpretation along the research questions and hypothesis.

Chapter 4: Results, Data Analysis, and Discussion

Introduction

The main objective for this study was to determine the impact of the amendments to the MDD 93/42/EEC on the U.S. medical device software industry. The purpose of the study was to evaluate the impact of the changes in the MDD 93/42/EEC on the net income and share prices of the compliant firms, the training cost for each EN/IEC/62304 compliant software year, project cost for each EN/IEC/62304, and the recall rate of devices manufactured by firms in the United States. This chapter is organized around the research questions identified in chapter 1, the methodology defined in chapter 3, the interview findings followed by case study results, analysis, and discussion along the research questions. The chapter also contains a brief recapitulation of the latest proposed amendments in the MDD 93/42/EEC on cost, safety, quality, and reliability aspects. The final section contains a summary of the results pertaining to each research question.

Settings

The nature of this study was a concurrent mixed method study involving both quantitative and qualitative techniques. The qualitative phase involved systematic literature review, interviews and case study of five medical devices companies selected by purposive sampling. The study involved recording interviews on tape and collecting surveys using surveymonkey.com. Each of the interview items answers are sub-questions from the main research questions. I adopted convenient sampling to get telephone interviews from two managers and while 56 firm representatives participated in the

online survey. This is equivalent to 21.87% response rate. The survey participants represented several different organizations. The quantitative phase involved the collection of financial data on the performance of the five medical device companies. There were no known current personal or organizational conditions that influenced participants or their experiences that may have affected the study results. The same was true of the participants in the quantitative phase.

Demographics

I gathered survey results from 56 respondents via mail (71% male and 29% female). Study participants were limited to individual who have worked in the medical devices software field for a period not less than 5 years. The study also involved submitting the questionnaire and survey to two managers with experience in the medical device industry working at Company X and Company Z. The first participant was the manager of quality assurance and regulatory affairs at Organization X (MOX), and the second was the senior director of clinical affairs working at Organization Z (DOZ). MOX had been working in the medical device industry for 21 years. DOZ had 18 years of experience in clinical affairs management.

Data Collection

This study had four main questions and hypotheses addressed by surveys, in-depth interviews, a case study of five U.S. medical device manufacturers purposively selected and systematic literature review. Permission was obtained from the university's Institutional Review Board (IRB) before commencement of the study and full disclosure

was made to all participants in order to comply with ethical requirements. The IRB approval number for the current study issued by Walden University is 09-20-13-0109393/

I gathered survey results from 56 respondents via mail. The study also involved submitting the questionnaire and survey to two managers with experience in the medical device industry. These managers worked for two different medical devices manufacturers located in the San Francisco Bay Area. Interviews lasted one hour, with a planned ninety minutes minimum time. The interviews were tape-recorded and I transcribed from the audio recording taken. Primary data were collected using SurveyMonkey.com. The survey questions probed the effectiveness Medical Devices Directive MDD 93/42/EEC, the impact of the MDD 93/42/EEC on medical devices costs and firms revenues. Other questions focused on process improvement of conformity assessment and the legal impact of the MDD 93/42/EEC. The study involved performing in-depth interviews. The main objective of the in-depth interviews was to understand the impact of EU Medical Devices Directive on medical device software by assessing the answers provided by the respondents when questioned (Zikmund, 2010). I used audiotapes to record the interviews after obtaining permission from the respondents. The objective was to store information for future reference as well as to enhance the interview precision. I reviewed cases of financial performance of purposively selected companies in the medical device manufacturing industry, which are ArtVentive Medical Group Inc., Varian Medical, Mindray Medical, Abiomed and CryoLife. The purposive sample relied on the assurance that these medical device companies have embedded software and export products to EU

markets. The entire study took place over a period of 4 months. There were no variations from the data collection plan presented in Chapter 3, and no unusual circumstances occurred.

Research Questions

This section includes data from surveys and survey, market capitalization for each company under study, mean changes in stock company performance for each EN/IEC/62304 compliant software year, mean changes in project cost of R&D for each EN/IEC/62304 compliant software year, and mean changes in net income for each EN/IEC/62304 compliant software year. The investigation for each research question involved administering qualitative telephone-administered surveys to the various companies affected by the MDD 93/42/EEC amendments. The targeted population consisted of medical equipment companies. To determine the impact of the MDD 93/42/EEC on the safety and reliability of software systems, and the impact on training and employee recruitment, the research questions and hypotheses formulated were as follows:

Research Question 1: What is the impact of changes to the MDD to the net income of medical device software firms in the United States?

$H1_0$: There has not been a decrease in the net income of medical device software firms in the United States due to changes to the MDD.

$H1_a$: Changes to the MDD have led to a significant decrease in the net income of medical device software firms in the United States.

Research Question 2: What is the impact of changes to the MDD on the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States?

$H2_0$: Changes to the MDD have not significantly reduced the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States.

$H2_a$: Changes to the MDD have significantly reduced the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States.

Research Question 3: What is the impact of changes to the MDD on the project costs of medical device software firms in the United States?

$H3_0$: There has not been a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States due to changes to the MDD.

$H3_a$: Changes to the MDD have led to a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States.

Research Question 4: What is the impact of changes to the MDD on the recall rate of medical device software firms in the United States?

$H4_0$: There has not been a significant decrease in the recall rate of medical device software manufactured by firms in the United States due to changes to the MDD.

$H4_a$: Changes to the MDD have led to a significant increase in the recall rate of medical device software manufactured by firms in the United States.

Interview Results

The study involved submitting the questionnaire and survey to two managers with experience in the medical device industry working at Company X and Company Z because these individuals indicated during my initial phone call that they were the persons to review and approve my request to conduct the research study. During the phone calls, the managers requested that I e-mail them in advance all documents associated with the research, including the questionnaire. After reviewing the documents, they indicated that they would be the sole participants. References to these organizations as Organization X and Organization Z are for purposes of confidentiality.

The two participants completed a 60-minute survey online and two interviews took place during 60-minute phone calls. The first participant was the manager of quality assurance and regulatory affairs at Organization X (MOX), and the second was the senior director of clinical affairs working at Organization Z (DOZ). The study involved triangulating the interview data by conducting case studies of financial data, stocks, and R&D competitiveness of selected companies.

My first contact was with MOX. MOX was the manager of quality assurance and regulatory affairs at Organization X, a company that manufactures medical therapy apparatus software. MOX had been working in the medical device industry for 21 years.

Organization X has approximately 250 employees worldwide. This interview took place on December 12, 2013, at 10:30 p.m.

The second participant, DOZ, was the senior director of clinical affairs working at Organization Z. Organization Z is a medical device company specializing in the manufacturing of wound healing technologies. DOZ had 18 years of experience in clinical affairs management. This survey took place on December 10, 2013, at 7:35 p.m. Organization Z has approximately 85 employees worldwide.

As previously stated, the purpose of the study was to evaluate the impact of the changes in the EU MDD 93/42/EEC on medical software and firm competiveness. The two interviews captured various areas where medical device software is applicable. The interviews and surveys indicated various departments existed within the medical device companies, including hardware engineering, software engineering, project management, regulatory affairs, operations, manufacturing, and others. Each department has close relations to the overall software product and standardization, hence the importance of capturing their supply chain value systems.

The interviews captured various demographic factors that may have a direct or indirect impact on the employee characteristics and organizational structure. Both interview participants were males, aged between 36 and 55 years. Both respondents had been with their current employer less than 10 years.

Research Question 1

Research Question 1 was as follows: What is the impact of changes to the MDD to the net income of medical device software firms in the United States? MOX indicated that the value of Organization X's exports to Europe from March 24, 2011, to March 24, 2012, exceeded US$1 million. DOZ did not disclose information on the value of the company's export to Europe between March 24, 2011, and March 24, 2012. DOZ had no opinion regarding whether the amendments had a significant impact on competitiveness of the company. MOX reported that leaders of Organization X implemented EN/EN/IEC/62304 in early 2013 using a third-party consultant to speed up the software life cycle, and the organization has benefited from various competitive advantages such as validated performance and reliability compared to other types of devices measurable in financial metrics.

The survey on the impact on European market-share changes since March 24, 2011, indicated 50% have not changed while 50% decreased. Neither respondent indicated the percentage change by increase or reduction of the European market share since March 24, 2011. The question whether medical device software produced under the guidance of EN/IEC/62304 provides firms with a competitive advantage had affirmative responses. MOX confirmed, "It will provide competitive advantage, because it is a harmonized standard. That means the scientific community is behind it." MOX reiterated that EN/IEC/62304 is useful in the "safety and efficacy" of the medical device that was a troubled link from product standards.

Research Question 2

Research Question 2 was as follows: What is the impact of changes to the MDD on the training costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States? MOX commented, "We have implemented 62304 fully, we are practicing fully. All our procedures have been revised, and people have been trained. We have spent $100,000 on training. We have about 265 associates globally." MOX stated that the number of new employees increased by 10% since March 24, 2011,while the number of old employees decreased by 15% since March 24, 2011. DOZ did not disclose any data associated with changes to the MDD 93/42/EEC on the training costs. When asked what organizational leaders could do to increase the implementation speed of EN/IEC/62304 and employee retention, MOX responded that the company had "invested nearly $100,000 on training."

I commented that EN/IEC/62304 outlines the software development life cycle by defining the majority of verification activities, which has an impact on training needs at various stages of best practice such as software devices planning, requirement analysis, implementation and verification, integration, and software release at different phases within the organizations. In terms of demonstrating compliance with these standards, DOZ commented, "Again right now, everybody is going through a learning curve. It is an excellent process, well-structured." MOX noted that the entire workforce has received training on the EN/IEC 62304 standard for efficiency and competitiveness in operations.

Research Question 3

Research Question 3 was as follows: What is the impact of changes to the MDD on the project costs of medical device software firms in the United States? The survey finding on the costliness of the MDD 92/42/EEC approval process was that MOX and DOZ indicated Class I and Class IIa devices were 100% and 50% not costly, respectively, and both participants indicated Class IIb and Class III were 100% costly. The findings on the effects of the amendments on the cost of approval were split, with MOX indicating "increased costs" while DOZ indicated "do not know." With regard to the question about the duration of the approval process for medical devices, both respondents indicated a "long time more than 90 days."

During the probe regarding any effects of the implementation of EN/IEC/62304 on software costs and employee training, MOX indicated a concern about the cost of compliance, stating, "If you are selling a product to the EU, you are required to comply with 62304; otherwise, you might not be able to sell the product." MOX noted that sales fluctuations affect company labor planning. Consequently, regarding the impact of EN/IEC/62304 on changes of the number of employees since March 24, 2011, MOX indicated a 50% increase while DOZ indicated a 50% reduction. There was mixed feedback about the changes on employee numbers.

Research Question 4

Research Question 4 was as follows: What is the impact of changes to the MDD on the recall rate of medical device software firms in the United States? A review of FDA

data between 2002 and 2010 revealed recalls for approximately 1.5 million software-based medical devices. That 8-year period had more than twice the number of software device recalls compared to the previous 8-year period. DOZ indicated there were no recalls of devices after June 30, 2004. However, the survey responses identified various areas with potential causes of product recall such as initial software malfunction, behavior failure, failure of output, service failure, delay failure, input failure, response failure, failure due to data, user instruction failure, timing failure, system failure, quality failure, and others. During the interviews, MOX attributed the previous high percentages of software recall to poor risk analysis, which was "inconclusive during the development, verification, and validation stages instead of a complete life cycle." MOX emphasized that risk analysis should start at the initial phase and cover supply chain, manufacturing, design transfer, software integration, and transfer to manufacturing before aligning with the post market surveillance operations.

Probing the occurrence of any unintended consequences associated with the implementation of EN/IEC/62304, MOX stated, "So far, we have not seen any adverse event report." Similarly, with regard to the survey question on whether any of the organizations had any recalls after March 21, 2010, both respondents indicated none, as the same types of potential causes for device recall apply, as indicated in the previous questions.

MOX did not comment on what could be done to improve the process of conformity assessment. However, with regard to what could be done to improve the

designation and monitoring of notified bodies, MOX called for random observers' participation during audits. With regard to what could be done to make the clinical evaluation requirements clearer, MOX called on the establishment of requirements and usability studies. When indicating what could be done to improve the process of conformity assessment, DOZ called for reducing clinical data requirements. DOZ was not sure which actions would improve the designation and monitoring of notified bodies and was uncertain on how to make the clinical evaluation requirements clearer.

The survey question on what could be done to improve process conformity assessment did not receive any feedback from MOX and DOZ. According to the FDA, software validation is imperative for software in medical devices and applications, whether during the production stage or during the launch of the devices for quality purposes. The intention for EN/IEC/62304 was to make medical device software validation safer. The interviewees agreed with this goal because achieving various documentation standards serves to address previous product safety gaps and reduce recalls.

The survey question on what could be done to improve the designation and monitoring of the notified bodies did not receive feedback from the respondents. The EN/IEC/62304 introduction is useful for classifying software into A, B, and C categories. MOX indicated a concern regarding the possibility that designers under classify medical device software to avoid meeting the stringent documentation requirements. To that

effect, the MOX recommended, "The process should be applied the same to all classes, so that you have a standard practice. Otherwise, people may slip."

MOX reaffirmed the need to validate medical devices to "ensure accuracy, reliability, consistent . . . performance" and minimize recalls. A general belief is that the EN/IEC/62304 has met expectations in enhancing the safety of medical devices. DOZ noted, "Classification of software highlights the defects and the software damages that may occur in future." I further highlighted the importance of keen audits to capture problems not discovered during manufacture that have a likelihood of causing product recall and that warrant additional classification procedures. With regard to what could be done to make the clinical evaluation requirements clearer to reduce recalls and whether medical devices produced under the EN/IEC/62304 are much safer during use, MOX responded that safety is in "the complete software design development documentation, the software architecture, the risk analysis, the V&V [verification and validation]."

The question on how to improve the process of post market surveillance to reduce device recalls received mixed feedback. I stated, "Although EN/IEC 62304 standard has been embraced as a global benchmark for management of the software development lifecycle, implementation of the standard has been slow." In probing the causes of the slow adoption especially post market surveillance, the interviewees responded that misunderstanding the standard and the lack of availability of the template were hindrances. Basing the argument on company experience, MOX added that people do not know "what should go in the design and development software document."

The question on whether the approval process aimed at reducing device recall is transparent received 100% agreement from both interviewees. The question on how to improve the transparency of the approval process to reduce device recalls did not receive any feedback from the respondents. The interviewees agreed that the approval process was already transparent enough.

The question on whether the organization has a specific work instruction or SOP for EN/IEC/62304 received an affirmative response from MOX, who added, "We have a procedure for software development life cycle, and we revised it last year to comply with 62304." MOX expressed concerns with SOUP [software of unknown provenance]: "We do not have a procedure on how to manage SOUP. That is one area where regulatory agencies will look into," and this can be a potential problem leading to product recalls.

The International Electrotechnical Commission introduced EN/IEC/62304 to medical device manufacturers to address some of the major concerns such as rampant product recall and lack of documented procedures when changes in software designs take place. I noted ["to the participants"], "The FDA and the EU have observed an increase use of off-the-shelf software (SOUP) in automated medical devices prior to the introduction of EN/IEC/62304." MOX underscored the need for documented processes to be part of the design process in all activities to create a significance level of accountability during product recall. MOX added, "The software design document, SDDs, must clearly document what off-the-shelf commercial software we are using."

The topic of one survey question was the effectiveness of MDD 93/42/EEC enhancing the efficacy of medical devices, and both respondents indicated that Class I, IIa, IIb, and III devices were "100% effective" in managing potential product recalls. In response to the survey question on the effectiveness of the MDD 93/42/EEC enhancing the safety of medical devices responsible for various recalls, respondents indicated Class I devices are "100% very effective," Class IIa devices are "50% very effective" and "50% effective," Class IIb devices are "100% effective," and Class III devices are "100% effective." MOX acknowledged that EN/IEC/62304 was a good standard for the medical device industry to reign in the problems leading to product recall. MOX added, "The only thing is that we need guidance and more, . . . for example, sample templates. If the standard is requiring a software architecture document, they should be guidance at the minimum what the content of the software architecture should be"

Case Studies on the Financial, Stocks, and Research and Development Competitiveness of Selected Companies

This section contains an analysis of the case studies of five medical device companies that have been in operation since the publication of the EN/IEC/62304 standard in 2007. The companies, selected by purposive sampling, are ArtVentive Medical Group, Varian Medical Systems, Mindray Medical, Abiomed, and CryoLife. These companies export medical software devices to Europe and other continents. The data in this section include the company size, net income, closing share prices from Q4-2009 to Q3-2013, and EN/IEC/62304 standard R&D expenditures. I could not access data

for each of the five companies on training costs for each EN/IEC/62304 compliant software year or on project cost for each EN/IEC/62304 compliant software year. However, I assumed that these figures were a percentage of expenditures for each EN/IEC/62304 compliant year in research and staff development. The section contains a summative evaluation of net percent changes for data category per year since 2009. The following is a brief description about each of the five case study companies.

ArtVentive Medical Group

ArtVentive Medical Group has a market capitalization of $48.87 million (ArtVentive Medical Group, 2013). The company manufactures medical devices with a focus on endoluminal occlusion devices (EOS). Since listing in the New York Stock Exchange, the company files their accounts according to SEC regulations (ArtVentive Medical Group, 2013).

ArtVentive leaders pursue manufacturing innovations and intellectual property rights to introduce and market their medical devices. ArtVentive devices have an exceptional performance in invasive medical diagnoses and procedures that target various health problems that were previously a challenge to many practitioners. The ArtVentive medical devices have high industry demand, including women's health care, surface and neurological problems, and cardiovascular diagnosis. Among the various accomplishments is the subsidiary incorporation of ArtVentive Women's Health Group. Other than manufacturing medical devices for human health care, ArtVentive leaders have diversified into animal health as well, and the products conform to Directive

93/42/EEC and the FDA, among other standards. The company leaders adhere to regulations and procedures for raising equity for expansion and research; hence, in 2001, the safety and operational standards achieved the EOS device classification (ArtVentive Medical Group , 2013).

In terms of financial performance, the company has been facing some liquidity problems because the investment into research and the cost of compliance to EN/IEC/62304 are expensive. Thus, ArtVentive leadership has been struggling to balance the company balance sheet to profitability. In Q3-2013, ArtVentive had negative capital of -$17,748 in the balance sheet and a yearly total deficit of $6,998,014. As a remedial step, ArtVentive leaders had elaborate plans to raise more capital via equity finance to ease the operational pressures and ensure the company remained competitive for the next year. It is possible for ArtVentive to revive from the current financial problems as long as the company leaders obtain timely financial capital partners, improve the research efficiency, and innovate more medical device products that can compete with existing market offers in price, quality, and efficacy. Consequently, ArtVentive management recently announced that they would seek more equity finance via public and private expression of interest for offers.

An independent audit report by Anderson Bradshaw PPLC published with Mergent (2013) indicated that ArtVentive's performance from 2011 to 2013 conformed to rules and regulations in the United States. The report had various concerns because ArtVentive was making a loss since the company's inception. The report further

indicated that ArtVentive could be having some internal operations problems that were preventing the achievement of financial performance goals (Mergent, 2013).

Data analysis revealed ArtVentive's financial performance problems were an indication of management issues. The decline in net income was a red flag that management needed to address; otherwise, the company would fail to attract potential strategic investors for a merger or an acquisition due to its uncertainty trends. Analysis indicated that the stock's performance gained marginally from 2009 to 2011 before worsening in 2012, which indicated that public investors were wary about the company's stocks with marginal trading in prospects.

Varian Medical Systems

The headquarters for Varian Medical Systems is in Palo Alto, California. The company is a leading medical device software manufacturer targeting cancer therapy, radiology, radiosurgery, proton therapy, and brachytherapy (Varian Medical Systems, 2013). Varian also manufactures data software for cancer care in clinics and major hospitals around the world, including Europe. The company manufactures X-ray tubes and other hardware for imaging and diagnostic operations. Varian is a leading venture in scientific innovations that solve many cancer problems in the medical industry (Varian Medical Systems, 2013). Varian Medical Systems was initially Varian Associates, founded by Russell H. Varian, Sigurd F. Varian, William Webster Hansen, and Edward Ginzton in 1940 (Varian Medical Systems, 2013).

One of the greatest Varian software innovations is the noninvasive stereotactic ablative body radiotherapy suitable alternative to surgery in lung cancer called TrueBeam. This technology is useful for targeting patients with lung cancer at the early stages. Various studies on the effectiveness of this medical software have consistently shown that the technology is useful for increasing the survival rate of patients and reducing their healing time because of the noninvasive techniques compared to the normal open surgery approaches (Varian Medical Systems, 2013).

In a study of 3,771 patients involving 45 research associates, 3,201 patients indicated a longer survival by at least 2 years when targeted by TrueBeam. The study also showed that complete healing occurred in approximately 70% of the patients, including the ability to manage 91% of tumors. This finding was better than the 68% survival rate of 2,038 patients for whom health care professionals managed their cancer infections using traditional surgical methods (Varian Medical Systems, 2013).

The noninvasive stereotactic ablative body radiotherapy as a suitable alternative to surgery for lung cancer has thus proved to be a major breakthrough in modern cancer management where there is the lowest need for an operation as the patients are at primary stages. Moreover, the Varian cancer-treating device, TrueBeam, is useful for reducing the side effects that some patients' experiences due to the procedures of managing such ailments as administered by oncologists in open surgery methods. Researchers from Harley Street and University College Hospital London conducted the study involving

Varian Medical Systems and used patients with radio surgery and conventional methods as controls (Varian Medical Systems, 2013).

According to analysts at Market Grader (2013), Varian's performance in Q3-2013 was below expectations, as reflected in its revenue growth at $770.43 million compared to $755.86 million in 2013, which reflected a 1.93% change in growth as opposed to projections of nearly 4% growth. Sales were worth $2.94 billion in Q3-2013 and were 24.77% better than Q3-2011. To improve the company's revenue performance, analysts at Market Grader (2013) recommended that Varian cut cost in various operational areas such as shortening the research life cycles. Additionally, the analysts at Market Grader (2013) speculated that Varian stock earnings could go either way in Q4-2013, with the Q3-2013 price being 19 times the listing share price, which indicates that Varian stocks have been increasing in value 8.97% annually. Overall, the analysts at Market Grader (2013) viewed Varian's financial trends as promising and demonstrating stable business performance.

Data analysis indicated Varian Medical System financial trends were increasing every quarter and year. Therefore, Varian leaders must keep an eye on the operating expenses as they research and launch more products. Data analysis further indicated that the stock's diluted value has been strong year on year, and the company leaders need to maintain the positive market outlook that will sustain investor confidence for future performance.

Mindray Medical International

Mindray Medical is a Chinese-owned but New York Stock Exchange listed firm that manufactures various medical devices and software targeting human and animal medicine practice (Mindray Medical International, 2013). The company began in 1991 and has over 6,000 employees. Mindray has three major operational divisions: Patient Monitoring & Life Support, In-Vitro Diagnostic Products, and Medical Imaging Systems. Some of Mindray's Medical device products include patient monitors, ECG machines, pulse oximeters, telemetry, ultrasound systems, anesthesia delivery systems, hematology analyzers, chemistry analyzers, regents, and veterinary equipment. Most of Mindray's device manufacturing takes place at Shenzhen, China, with satellite stations around the world, including New Jersey (Mindray Medical, 2013).

The Patient Monitoring & Life Support Department manufactures multiparameter patient monitors, biotelemetry systems, anesthesia delivery systems, defibrillators, ECG machines, pulse oximeters, hospital beds, and other support structures. Market research analysts at Frost & Sullivan recognized Mindray Medical in 2007 for the innovations in Patient Monitoring & Life Support with the Global Excellence Award following an audit. In 2008, Mindray Medical acquired the Datascope Corporation at $2009 million to improve their market share in China. The In-Vitro Department of Mindray Medical is responsible for data management from various human body fluid tests. This department also works on various laboratory analyses that blend manual and automatic tests (Mindray Medical, 2013).

According to Jayson (2013), Mindray Medical International has not been performing according to investors' expectations and investors did not expect performance to improve during Q4-2013. Various indications that Mindray would have another low quarterly earnings were the poor performance of accounts receivable and revenue. These performances could have a role in the Mindray stocks. Jayson (2013) indicated concern about Mindray debts and slow-moving inventory, as some of the factors affected the company's financial performance. Mindray leaders might have been remiss in collecting money owed to the firm or lining up for strategic changes such as acquisition. Similarly, it was possible that Mindray device prices had a problem that needed urgent attention to increase the revenue growth track.

Data analysis indicated that Mindray leaders must increase revenue targets and assign sales staff to report targets to ensure timely action by the senior management. Moreover, Mindray leaders would need to improve the current average inventory period from 64.4 days, including the quarterly figure of 59.7 days. The analysis revealed that Mindray leaders must overhaul the business model to a more stable approach that will ensure sales attain quarterly targets. Income and stocks data were below expectations because since 2012, revenue increased by only 10.5% while the debt owed increased by 20.6% (Jayson, 2013). Mindray leaders might also increase their accounting surveillance to ensure investors have the correct information.

Abiomed

Abiomed is a company that manufactures medical devices for circulatory system and medical care in the category of acute heart failure management. The company launched in 1981 with headquarters at Danvers, Massachusetts, and appears on the NASDAQ. Abiomed market capitalization is $1.067 billion (Abiomed, 2013). Abiomed products include, the Impella 2.5 catheter, a percutaneous micro heart pump with integrated motor and sensors for use in interventional cardiology; and Impella 5.0 catheter and Impella LD, which are percutaneous micro heart pumps with integrated motors and sensors for use primarily in the heart surgery suite. The company also manufactures and sells the AB5000 circulatory support system and the BVS 5000 biventricular support system for temporary support of acute heart failure patients in profound shock, including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock, or myocarditis. In addition, it offers AbioCor implantable replacement heart, a self-contained artificial heart for end-stage biventricular heart failure patients. (Abiomed, 2013).

On August 1, 2013, Abiomed leaders reported revenues of $42.7 million for Q1-2014, which is 10% more than the same period in the previous year of $38.8 million. Nevertheless, the company still register a loss of $1.7 million, which was equivalent to $0.04 per diluted share but an improvement from the previous year at $3.1 million, and $0.80 per diluted share in Q1-2013. The improved performance of Abiomed is from the increased global sales of Impella, which the company expected to rise to $38.7 million or

12% revenue compared to Q1-2013 from $34.7 million. Overall, the Impella sales in the United States alone were up by 7%, equivalent to $35.4 million, compared to $33.0 million in Q1-2013 (Abiomed 2013).

The use of Impella by U.S. patients rose by 12% in Q4-2013. In the same period, at least 27 medical clinics bought the Impella device, thus reaching 775 units sold in Q4-2013. Furthermore, 66 clinics acquired the Impella CP, to increase the Q4-2013 sales to 172, which indicated that the distributions of Impella 2.5 and CP are 2.4 units per clinic and not much different from Q1-2013 (Abiomed 2013).

Market analysts at Zacks (2013a) noted that Abiomed would continue its positive performance buoyed by the new products development and device trials at clinics despite the poor performance in the 4 years preceding 2014. Market analysts at Zacks (2013a) justified their assessment of Abiomed with caution following the decline in stock earnings by nearly 76.9% by Q4-2013 compared to a 13% decline in Q4-2012. Furthermore, the analysts at Zacks (2013a) appreciated Abiomed's net income growth by nearly 19%, which was within the projections, and continued the 4-year income trends in double digits, supported by the increased demand of the Impella device in successive financial quarters.

Demand for the Impella device is likely to increase in 2014, as the leaders of many hospitals adopt the heart pump devices that are applicable in many remedial cases of heart failure. Nevertheless, Abiomed's operational expenditures decreased by nearly 5%, whereas approximately 8% of expenses were for legal services, compliance

submissions, and supply chain development, including R&D. Overall, the increasing operational costs have had pull-down effects on Abiomed's bottom line prospects, and analysts are watching the trend (Seiffert, 2013).

Data analysis indicated that Abiomed leaders have managed to stabilize expenditures on R&D each year, and Abiomed's net income has been improving. Thus, Abiomed is efficient in resource use in successive years as the returns on investment improve. Analysis also indicated that Abiomed's stock performance is flat, despite the improving net income, which indicates that investors have stable demand for Abiomed stock.

CryoLife

CryoLife is a company that manufactures and distributes medical devices for cardiovascular and vascular transplant operations and that trades at the New York Stock Exchange (CryoLife, 2013). CryoLife has a market capitalization of $298.75 million and has several subsidiary companies, including Natus Medical, Cryosure, Heart International, AngioDynamics, Accuray, Teleflex, Echo Therapeutics, and MAKO Surgical. The average CryoLife enterprise value in the past 5 years was $146.74 million (CryoLife, 2013).

CryoLife operates and specializes in preservation and logistics of human tissues for various transplant needs other than manufacturing medical devices for sales to hospitals. Some of the devices are the CryoValve SG pulmonary valve and the CryoPatch SG pulmonary cardiac patch tissue; the management of each involves using CryoLife

SynerGraft Technology. In mid-2011, CryoLife bought Hemosphere, which sells Hemodialysis Reliable Outflow, a technology for grafting final stages of renal diseases. In Europe, the company sells medical software devices via CryoLife Europa (CryoLife, 2013).

CryoLife has many other products and devices sold around the world, including Europe. SynerGraft Technologies is among CryoLife's patented products for aiding medical implants of biological cells and organs. This technology limits a cell's pathogen-causing cells while vital tissues are healing. Therefore, the SynerGraft Technologies aid in the lowing cases of human leukocyte antigen Class I and II antibodies which pulmonary tissue growths. The application of this technology reduces chances of a patient requiring a heart transplant. The device is useful for monitoring the advances of panel reactive antibodies, whose excessive presence in the body can lead to emergency operational risks to the patient (CryoLife, 2013).

According to market analysts at Zacks (2013b), CryoLife's improved performance on revenues was due to the Q3-2013 growth surpassing expectations. Specifically, the CryoLife revenue for Q3-2013 improved to $18.8 million compared to Q3-2012 at $16.9 million. The gross income was up by 81% in Q3-2013 compared to 82% in Q3-2012. The higher sales of revascularization devices and laser devices, whose revenues rose by 14.3% at $2.4 million in the Q3-2013, accounted for these positive trends. Moreover, the shortage of some alternative medical device shipments increased demand for CryoLife devices. Also during Q3-2013 period, the preservation devices sales

increased by 6.1% to 17.4 million, which led to better margins by 46% compared to 45% in Q3-2012. Specifically, vascular device sales increased by 8% due to new service fees occasioned by the shortfall of substitute shipments used for vascular grafts (Zacks, 2013b).

CryoLife's share price rose by nearly 50% in Q3-2012, by which was $0.12 compared to an $0.08 increase in Q3-2012. This trend beat Zacks Research Market predicted 43.8% increase. The CryoLife net income increased by 11% to $3.2 million in Q3-2013 compared to an increase of 6% to $1.5 million in Q3-2012. The CryoLife revenues also had an impressive performance, increasing by 8% to $36.3 million in Q3-2013 from $33.4 million in Q3-2012. This growth was due to strong sales of BioGlue and revascularization devices (Zacks, 2013b).

Data analysis revealed that CryoLife's increasing investment in R&D would improve the company's performance. Analysis further indicated that the trends in investments in R&D are matching the net income growth. This implies that CryoLife management is efficient in resource management.

Survey Results and Hypothesis Tests

From the possible working population of 256 organizations in the medical device industry with business interests within the EU region, I gathered survey results from 56 respondents via mail (71% male and 29% female). I evaluated the respondents' experiences in the medical device industry and established the outcomes seen in Figure 2.

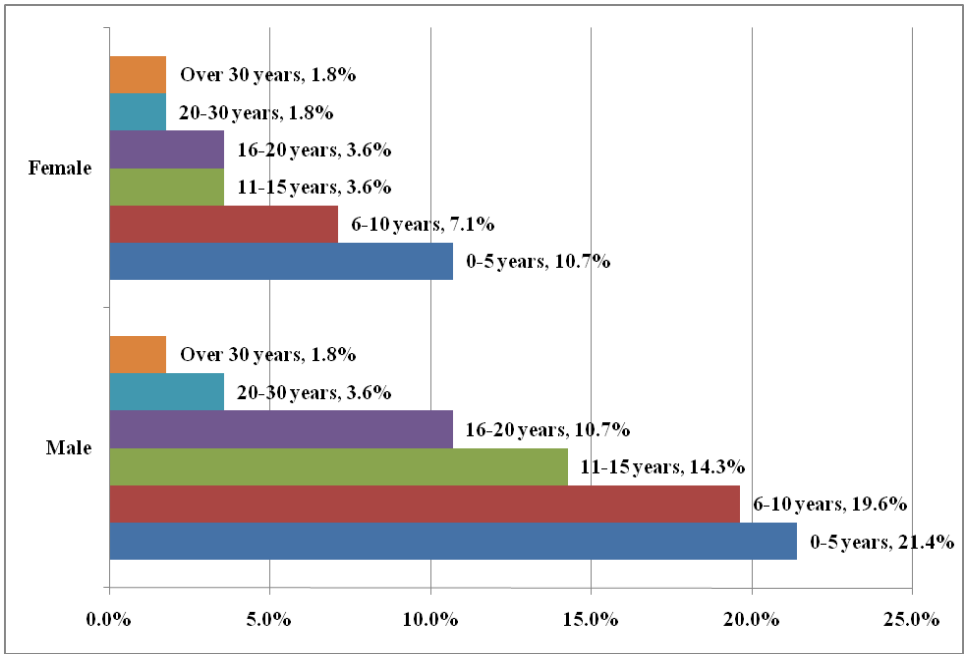

Figure 2. Gender versus experiences in the medical device industry.

The cross-gender analysis indicated that the high durations of services or attachment to the medical device industry has fewer respondents while the males had more experience than the females. The analysis also involved evaluating the professional spread for the combined genders, which revealed that 31% were in software sales or marketing management, 24% were in finance and accounts management, 21% were designer engineers, 14% were in operations management, and 10% were in other unspecified positions. The findings on the current job titles appear in Figure 3.

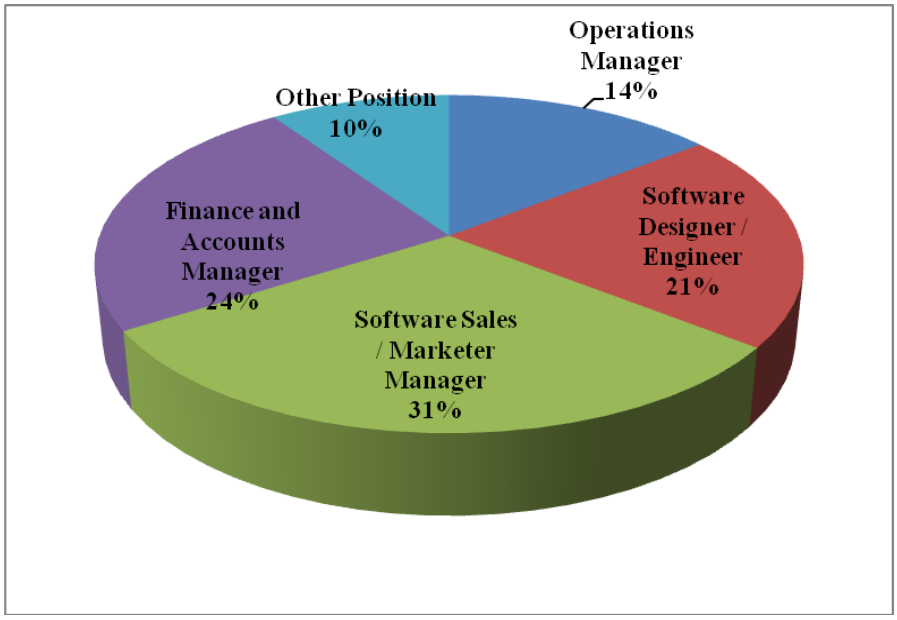

Figure 3. Professional roles of the respondents.

In terms of efficacy, the study involved evaluating the effectiveness of various devices along their classifications after the introduction of Directive 93/42/EEC. I found that only Class I devices had some incidences of not being effective at all at 5%. Additionally, Class IIb devices had the highest efficacy rate of performance at 73%, followed closely by Class IIa at 64%, Class III devices at 63%, and Class I at 46%. Figure 4 contains these findings.

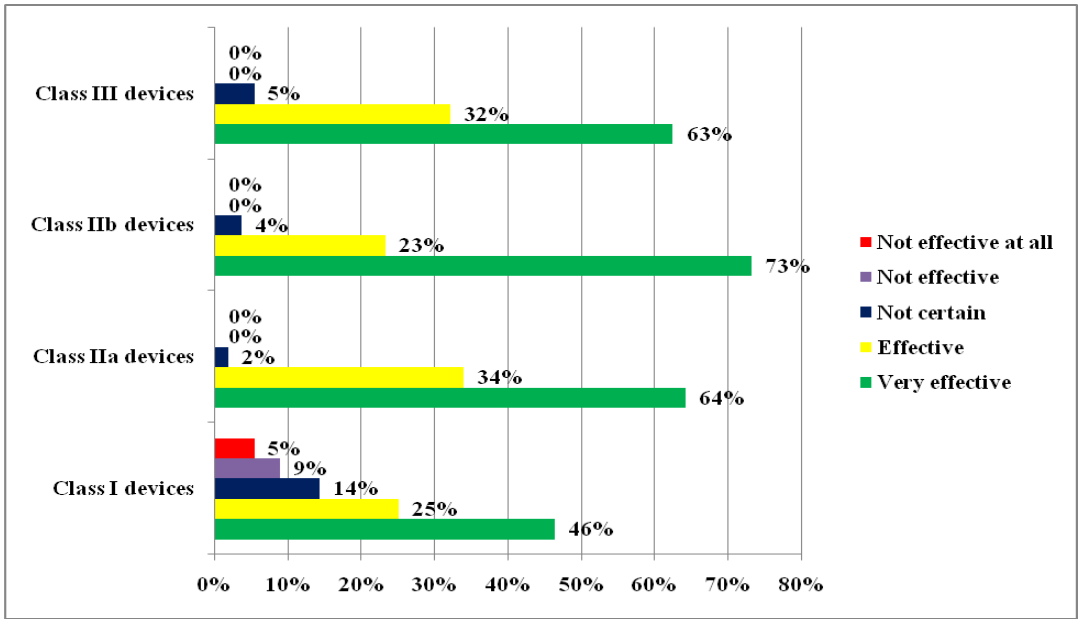

Figure 4. Device efficacy along class types for implementation of Directive 93/42/EEC.

In terms of safety, the study involved evaluating the different device classes following the implementation of Directive 93/42/EEC. The findings indicated that only Class I devices registered incidences of not being effective at all (4%). Class III devices had the highest safety rating of 75% being very effective, followed by Class IIa at 64%, Class IIb devices at 61%, and Class I at 54%. Figure 5 contains the findings.

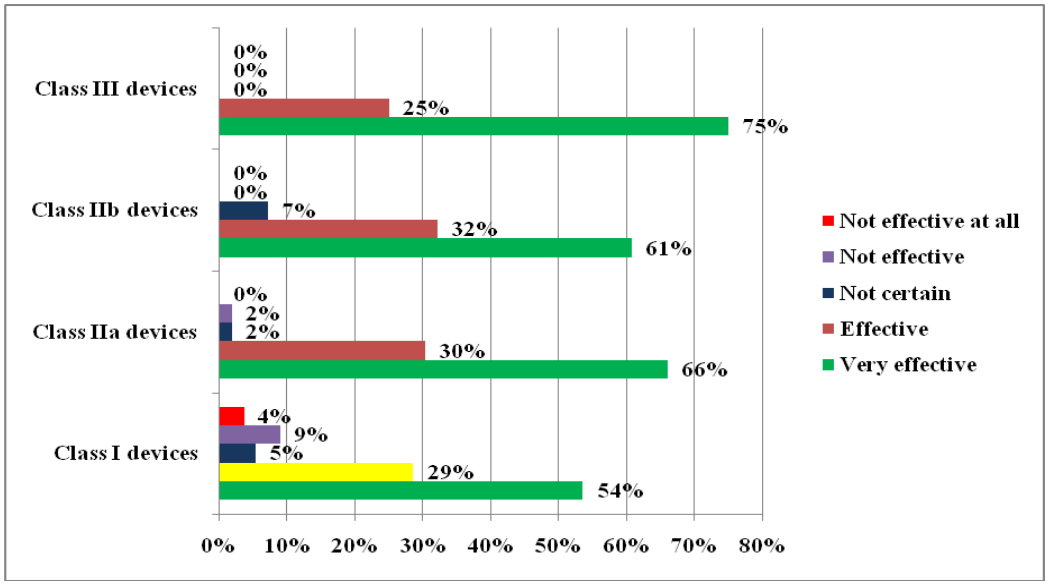

Figure 5. Device safety long class types for implementation of Directive 93/42/EEC.

Following the implementation of Directive 93/42/EEC, cost implications were likely. I surveyed the respondents on the cost impact and found that the highest cost reduction was with Class III devices at 5%. The most maintained low cost from previous period was 9%, also with Class I devices. The highest percentage of cases with no cost effects was Class III devices at 5%. The most maintained high cost from previous period was with Class I devices at 25%. Finally, the most increased cost was with Class IIa devices at 77%. Figure 6 contains these findings.

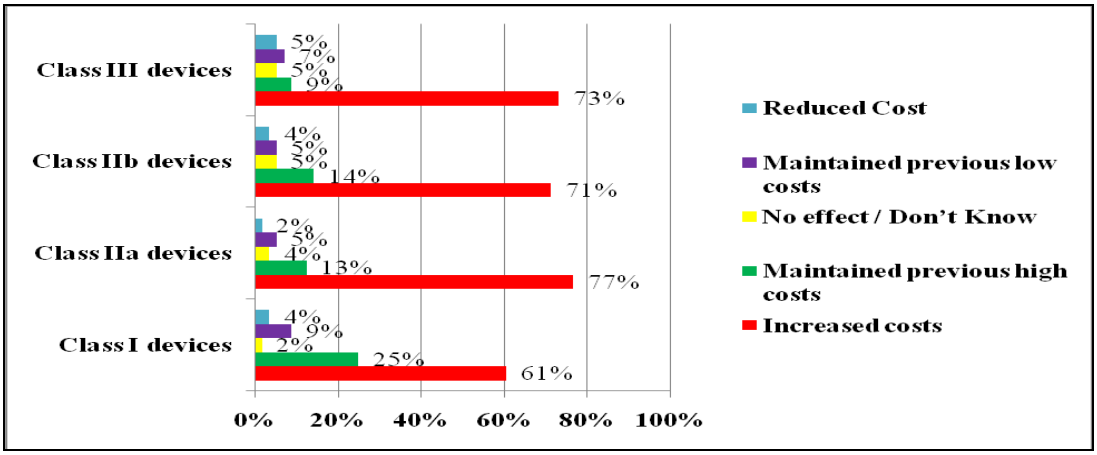

Figure 6. Cost impact after the implementation of Directive 93/42/EEC.

The study involved investigating the average time it takes for software devices to receive approval before their release to the market. Forty-five percent of the respondents noted that it takes more than 180 days, which is a long time. Additionally, 36% of the respondents observed that it takes 90 to 180 days. Sixteen percent stated it takes 45 to 90 days, and 4% stated it took less than 45 days. Figure 7 contains these findings.

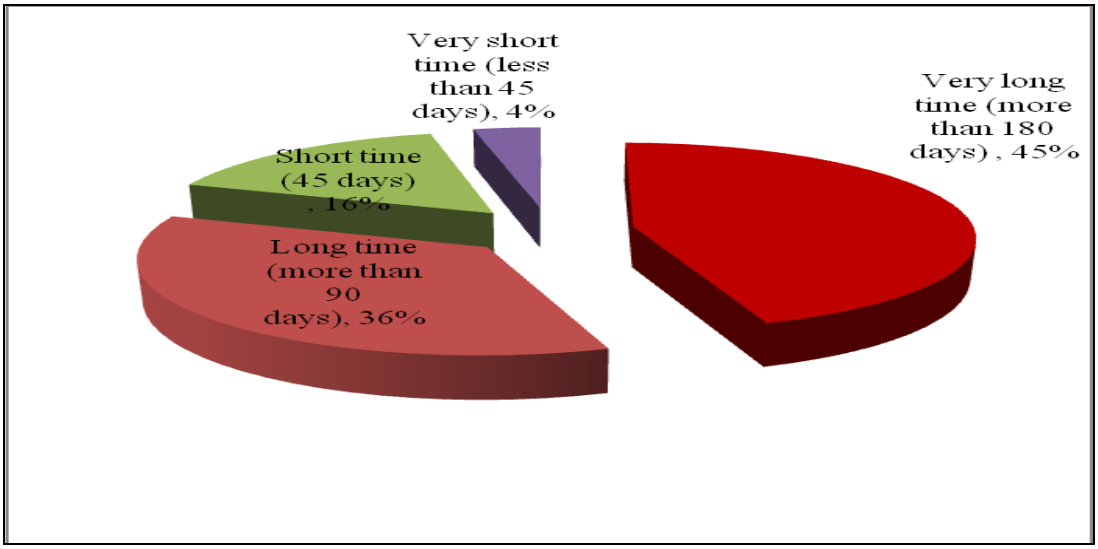

Figure 7. Duration for approval of software after the implementation of Directive 93/42/EEC.

The market surveillance involved evaluating the number of product recalls after June 30, 2004, and after June 30, 2010. The greatest improvement in terms of reduced recalls is with device input failures at 71.4%, while the least is others at 20%. These findings indicated that the medical software industry still has at least 20% product recalls, even after the implementation of Directive 93/42/EEC. The total number of recalls from among the sampled respondents dropped from 78 after June 30, 2004, to 35 after March 21, 2010. Nevertheless, even if there was a reduction in recall incidence, software malfunctions still had the highest frequencies among the other types of failures cited in the survey. Table 6 and Figure 8 contain data on the reduction of product recalls before and after the implementation of the Amendment M5 (2007/47/EC).

Table 6

Medical Device Malfunction and Failure Tabulations After June 30, 2004, and After March 21, 2010

Type of malfunction/failure	Number of recalls after June 30, 2004	Number of recalls after March 21, 2010	% reduction
No recall	78	35	38.1
Software malfunction	13	8	23.8
Behavior failure	3	2	20.0
Failure of output	5	3	25.0
Service failure	4	2	33.3
Display failure	9	2	63.6
Input failure	6	1	71.4
Response failure	7	3	40.0
Failure due to data	5	1	66.7
User instruction failure	4	3	14.3
Timing failure	5	1	66.7
System failure	6	2	50.0
Quality failure	5	3	25.0
Other	6	4	20.0

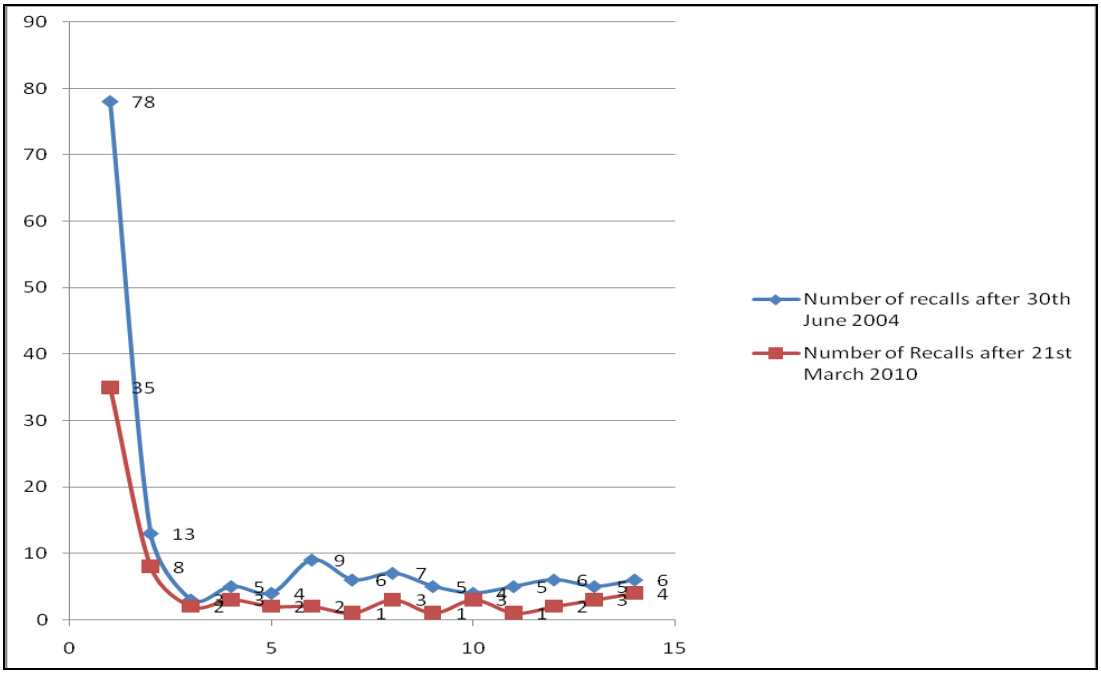

Figure 8. Medical device malfunction and failure trends after June 30, 2004, and after March 21, 2010.

Finally, the study involved surveying the impact of Directive 93/42/EEC on various firms' market values and the number of employees. First, Figure 9 contains the outcomes of market values for medical device organizations that range in size. Second, on the changes I established a fluctuating trend, as shown in Figure 10, where the percentages represent the company's share of the European market changed since March 24, 2011, and the number of employees changed since March 24, 2011.

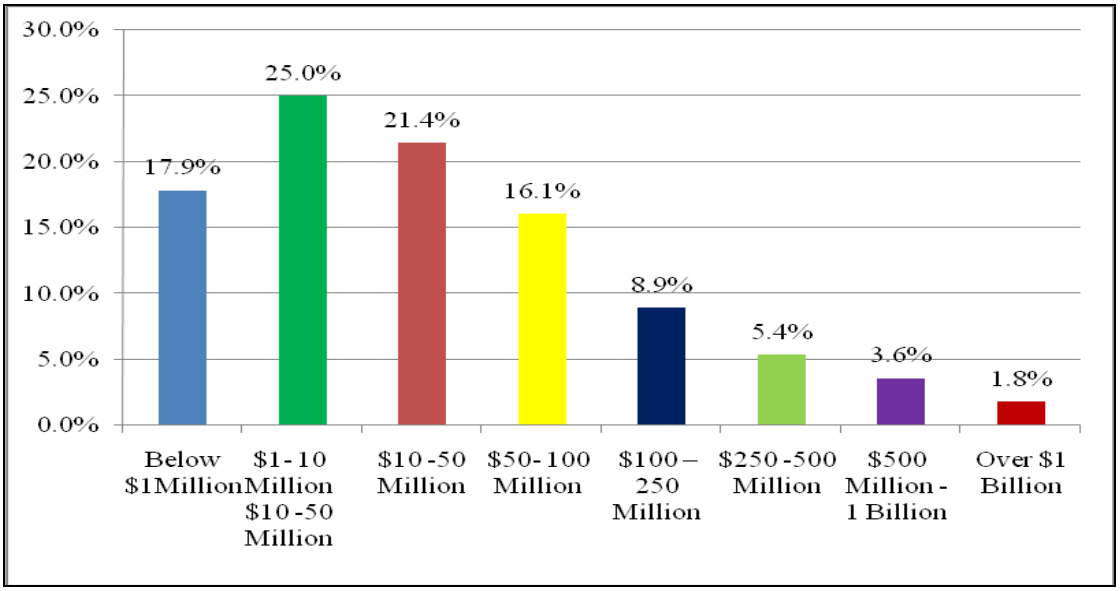

Figure 9. Value of respondents affiliated company.

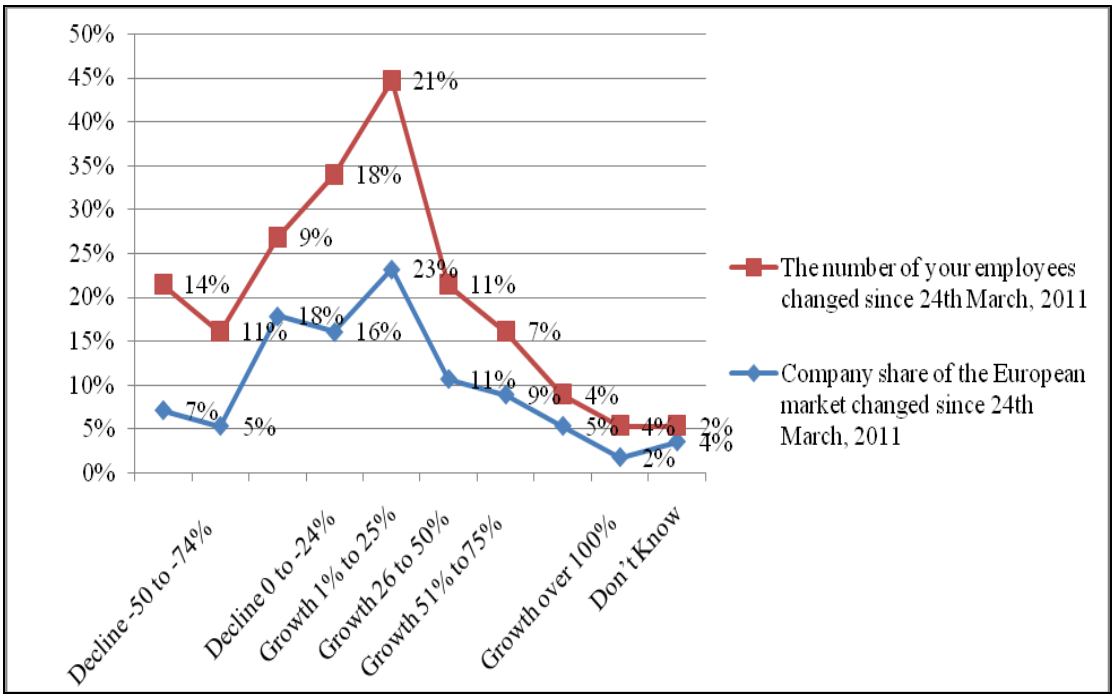

Figure 10. Changes in company market share versus number of employees.

Participants responded to a variety of open-ended questions regarding how enable better conformity assessment. I asked the respondents how to improve process conformity assessment. The responses indicated that regular updates and communications are necessary to reach the industry players to ensure all read from the same script. Moreover, I established that the leaders of each firm strengthen their internal assessment frequency and quality to conform to new medical device regulations. Adhering to third-party audits to ascertain conformity to Directive 93/42/EEC was a common view held by the respondents.

The study involved investigating what need to be done to improve the designation and monitoring of notified bodies. I found that the notified bodies require close supervision to ensure achievement of their mandates within Directive 93/42/EEC. Additionally, I found that stipulation and strict follow-up on monitoring schedules, supported by some random checks, is a common approach considered by MDD bodies. Overall, I established that the monitoring bodies must speed up their approval stages to reduce the number of product recalls.

I evaluated what I can do to make clinical requirements clearer, and I found that the stakeholders in the implementation differ on the interpretation of some articles of Directive 93/42/EEC. However, when language or communication barriers lead to issues, there are common online platforms to seek clarity within a short time. Additionally, there are routine meetings and workshops where leaders of the member countries and

industries converge to discuss and clear any sticky points on the clinical implementation of Directive 93/42/EEC.

An investigation of how to improve the process of post market surveillance revealed that most firms tend to rely on surveys and feedback from hospitals and end users on the performance of their devices. Most firms have additional internal checks and balances to verify the quality of the medical devices just before and after operations on patients. A lot of work will be necessary to strengthen post market surveillance, including clustering supervisions in different medical device classes and enforcing sanctions for any contraventions.

Within the inquiry of whether the process of approving medical devices is transparent, a majority of the respondents concurred and there were few dissenting views. Dissenting views arose regarding delays in approving medical devices. Moreover, some respondents cited additional standard requirements that go beyond the stipulations in Directive 93/42/EEC as potential causes for concern about the transparency of the entire approval process.

An investigation into how to improve the transparency of the entire approval process revealed that most respondents would like the time frame allocated for approving various medical device classes adhered to strictly to inspire confidence among the medical device industry players. The respondents indicated they want adequate time to comply whenever there are new amendments in the articles of Directive 93/42/EEC because some changes have serious implications on the firms' mass production strategies

and operations. Transparency can greatly improve when all the approval standards are properly communicate, interpret, and translate for international purposes.

I evaluated the respondents' view on the impact of Directive 93/42/EEC on market competition and established a level playing ground had taken shape. Some respondents noted that the impact was negative because the cost of compliance reflected on the firms' bottom line. Other respondents were uncertain of the impact because the leaders of their firms had yet to release vital reports and findings following the implementation of Directive 93/42/EEC.

Analysis of Data and Hypotheses Discussion

This study had four main questions and hypotheses addressed by a detailed literature review, interviews, and a case study of five companies purposively selected from the category of medical device manufacturers with product exported to European markets, among other destinations. This section contains a discussion on each research question in light of the qualitative findings of the above sources using ANOVA tests of the hypotheses. In testing $H1_a$ using ANOVA, at a 95% confidence level and gathering data from 56 respondents, the mean was 4.0, which indicated they agreed with the statement, "Changes to the EU MDD have led to a significant increase in the net income of medical device software firms in the US" Additionally, the *SD* of 0.89 indicated that the responses were closely clustered in support of $H1_a$, as shown in Table 7. When testing $H2_a$, the mean was 1.61, which fell in the range of *disagree to neutral*, and the *SD* was 0.91. The $H3_a$ tests had a mean of 1.45, which was also in the range of *disagree to*

neutral, with an *SD* of 0.60. Finally, the $H4_a$ tests had a mean of 3.98, which fell within the range of *neutral to agree*, with an *SD* of 1.07. Table 7 contains these findings.

Table 7

Descriptive $H1_a$-$H4_a$ Alternative Hypotheses

					95% CI			
Variable	*n*	*M*	*SD*	SE	LL	UL	Min	Max
$H1_a$								
Male	40	3.83	0.90	0.14	3.54	4.11	2.00	5.00
Female	16	4.44	0.73	0.18	4.05	4.83	3.00	5.00
Total	56	4.00	0.89	0.12	3.76	4.24	2.00	5.00
$H2_a$								
Male	40	1.60	0.84	0.13	1.33	1.87	1.00	4.00
Female	16	1.63	1.09	0.27	1.05	2.20	1.00	5.00
Total	56	1.61	0.91	0.12	1.36	1.85	1.00	5.00
$H3_a$								
Male	40	1.45	0.60	0.09	1.26	1.64	1.00	3.00
Female	16	1.44	0.63	0.16	1.10	1.77	1.00	3.00
Total	56	1.45	0.60	0.08	1.29	1.61	1.00	3.00
$H4_a$								
Male	40	3.93	1.14	0.18	3.56	4.29	1.00	5.00
Female	16	4.13	0.89	0.22	3.65	4.60	2.00	5.00
Total	56	3.98	1.07	0.14	3.70	4.27	1.00	5.00

Table 8 contains the results of the ANOVA tests of the hypotheses, at a 95% confidence level and gathering data from 56 respondents. The following sections provide

a discussion on each research question in light of the qualitative findings using ANOVA tests of the hypotheses.

Table 8

ANOVA $H1_a$-$H4_a$ Alternative Hypotheses

Variation	SS	*df*	MS	*F*	Sig.
$H1_a$					
Between groups	4.287	1	4.287	5.830	.019
Within groups	39.713	54	.735		
Total	44.000	55			
$H2_a$					
Between groups	.007	1	.007	.009	.927
Within groups	45.350	54	.840		
Total	45.357	55			
$H3_a$					
Between groups	.002	1	.002	.005	.945
Within groups	19.838	54	.367		
Total	19.839	55			
$H4_a$					
Between groups	.457	1	.457	.395	.532
Within groups	62.525	54	1.158		
Total	62.982	55			

MDD and Net Income for Company

Research Question 1: What is the impact of changes to the MDD to the net income of medical device software firms in the United States?

$H1_0$: There has not been a decrease in the net income of medical device software firms in the United States due to changes to the MDD.

$H1_a$: Changes to the MDD have led to a significant decrease in the net income of medical device software firms in the United States.

The first competitiveness factor ranked among the five medical device manufacturing companies was net income in millions of dollars. According to the literature reviewed, projected U.S. firm sales of medical devices were $102.4 in 2009, $107.1 in 2010, $112.1 in 2011, $117.4 in 2012, and $122.8 in 2013. By meeting the MDD essential requirements, U.S. firms were able to compete and sell more products to the EU markets. Compliance to the MDD promotes the innovation and the competitiveness of this sector by meeting the essential requirements: before firm leaders can market a medical device in the EU, the product must meet the essential requirements in Annex 1 of the MDD, as well as the standards related to the device class (U.S. Department of Commerce, 2008). From the case studies, ArtVenture Medical had the lowest mean income growth per annum ($-1.3779 million), while Varian had the highest mean growth ($374.974 million), as indicated Table 9 and Figure 11.

Table 9

Last Five Years Net Income for the Five Companies ($ Million)

Year	ArtVentive Medical Group	Varian Medical	Mindray Medical	Abiomed	CryoLife
2009	-0.0287	329.0000	139.1800	-28.4530	8.6790
2010	-1.0733	378.1300	155.4700	-10.9580	3.9440
2011	-2.6076	392.6800	166.6300	-2.8440	7.3710
2012	-0.8579	432.0900	180.2200	13.8390	7.9460
2013[a]	-2.3221	342.9700	149.5300	3.0780	7.1460
Mean	-1.3779	374.9740	158.2060	-5.0676	7.0172

[a]As of September 2013.

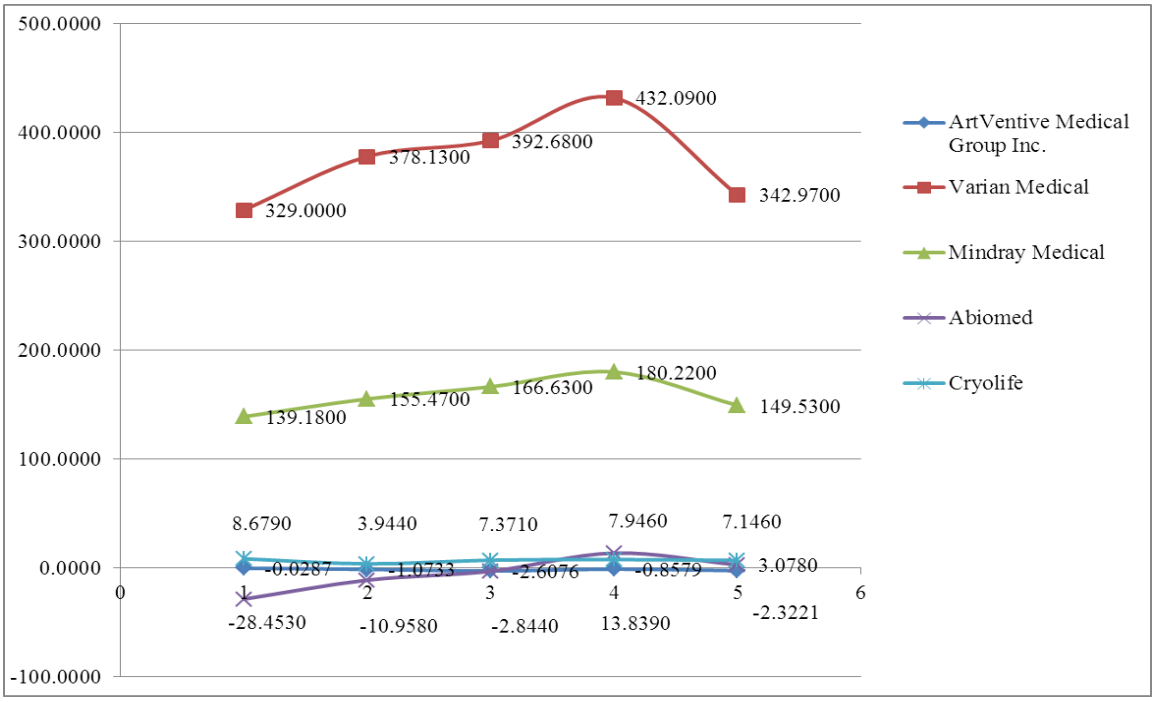

Figure 11. Net income trends for the five companies.

The second competitiveness factor ranked among the five medical device manufacturing companies was the diluted stock price figures in millions of dollars by the respective companies. After the presentation of the brief case studies of the five companies, I compared their diluted stocks prices over the same 5-year period. The SEC data showed that Varian Medical was the best performing, with a low of $0.63, a high of $1.0790, and mean of 0.8318. Additionally, the SEC data showed that ArtVentive was the lowest performing, with low of $-0.0002, a high of $0.02, and a mean of 0.0083 over the 5-year period. Overall, the income from stock share sales showed an upward trend, as demonstrated by the case study of the five companies shown in Table 10.

Table 10

Closing Diluted Stock Price Figures per Year

Year	ArtVentive Medical Group	Varian Medical	Mindray Medical	Abiomed	CryoLife
2009	-0.0002	0.6300	0.3279	-0.1200	0.0831
2010	-0.0030	0.8000	0.3475	-0.0200	0.0755
2011	-0.0116	0.7900	0.3945	0.0700	0.0673
2012	-0.0068	0.8600	0.4633	0.0700	0.0753
2013[a]	-0.0200	1.0790	0.2500	0.0300	0.1100
Mean	-0.0083	0.8318	0.3566	0.0060	0.0822

[a] As of September 2013.

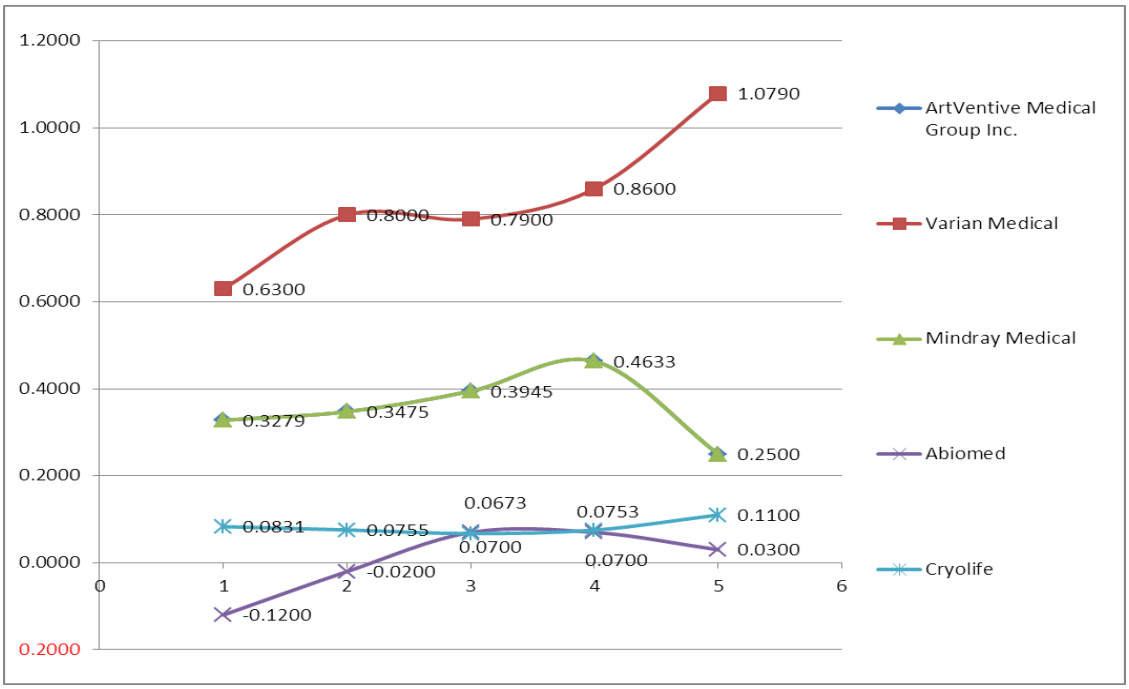

Figure 12. Stock movement from 2009 to 2013.

In a further demonstration of the impact of the MDD 93/42/EEC on income streams and sustainability, the literature reviewed showed that medical devices that can aid in the diagnosis of diseases or the administration of certain hospital procedures have

existed in the early 19th century (Zaykoski, 2011). However, the emphasis was on software-embedded devices and the performance increase from the last decade with the introduction of the MDD 93/42/EEC. Some of the medical procedures where the software-embedded devices have become competitive and made a strong impact are neurosurgery of brain tissues for persons with Parkinson's disease, cardiovascular implants for persons with heart valve complications, and general data collaboration with related diagnostic needs and recommendations (Lewin Group, 2008).

Other areas where medical device software has evolved are tumor localization, therapy, and treatment procedures with early detection being possible, hence increasing survival rates. Some medical device software is capable of guiding doctors to administer medicine to specific organs. However, developing the device software does not occur in isolation, because R&D firms are finding new uses and integration with biological tissue makers, robots, tissue implants, fluid and superficial dressings, or monitoring the ingestion of drugs (Lewin Group, 2008).

The most common type of medical device software is the noninvasive type, where surgeons are able to observe the body organs and tissues using an endoscopic procedure. This technology combines the diagnosis and surgery together or may require a patient to swallow some tablets embedded with tiny tracking devices (Higgins et al., 2003). As the tablet moves down the digestive system, the doctor can make conclusive observations and diagnose the problem. Other medical device software has been successful in aiding

diagnosis of internal tumors, abnormal growths, and Crohn's disease (Lewin Group, 2008).

Despite all the technology-driven advances in medical devices, the finding from this study indicated that Directive 93/42/EEC has turned around the medical device software export-trading environment in many ways. First, many U.S. medical device manufacturing companies have been exporting their product around the world. However, the implementation of Directive 93/42/EEC to the European markets will result in the leaders of these companies realigning their product to conform to certain safety and efficacy standards (Panesar-Walawege et al., 2010). Directive 93/42/EEC has enhanced the technology of medical device software to improve their performance and to reduce failure rates and recall incidences (Higgins et al., 2003). In return, the EU market promises high-value financial returns to the U.S. medical device manufacturers. Data analysis revealed that medical device exports to the EU in 2008, just after the introduction of Directive 93/42/EEC, were $13.8 billion. The key EU markets for medical devices with software are Germany, Italy, France, and the United Kingdom (Episcom, 2008).

After surveying the 56 participants, I evaluated their data to test $H1_a$. I found that most of the responses were distributed toward the right side of the figure, which is a preliminary indication of support for the test statement. Figure 13 contains the distribution of responses during the survey.

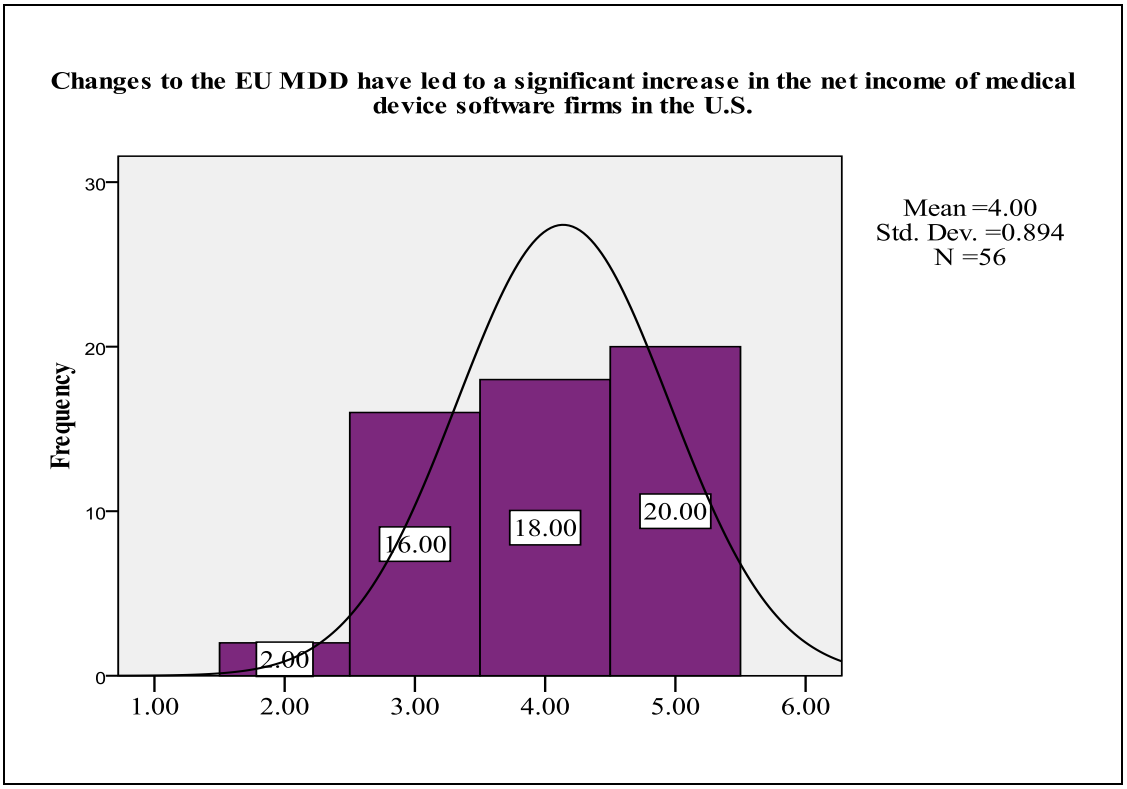

Figure 13. Alternative hypothesis $H1_a$.

As shown in Table 8, the mean sum of squares within gender groups was 39.713, while between gender groups it was 4.287. Because the mean between gender groups was above the $p = .05$ level of determination of significance, it was not possible to support $H1_0$; therefore, it was possible to uphold $H1_a$. Thus, the data indicated support for $H1_a$ (Changes to the MDD have led to a significant decrease in the net income of medical device software firms in the United States) but not for $H1_0$ (There has not been a decrease in the net income of medical device software firms in the United States due to changes to the MDD).

MDD and Training Needs

Research Question 2: What is the impact of changes to the MDD on the training costs for each EN/IEC/62304 -compliant software year of medical device software firms in the United States?

$H2_0$: Changes to the MDD have not significantly reduced the training costs for each EN/IEC/62304 -compliant software year of medical device software firms in the United States.

$H2_a$: Changes to the MDD have significantly reduced the training costs for each EN/IEC/62304 -compliant software year of medical device software firms in the United States.

Every year, leaders of medical device firms take their staff to various trainings. Respondents MOX and DOZ indicated that their companies spent approximately $100,000 per year on training of small teams. Research also showed that 73% of all the medical device firms in the United States had less than 20 workers each (U.S. Bureau of the Census, 2007) who required training. Another 15% of the firms had more than 100 workers who required training. In the United States, the locations of medical device manufacturers are throughout the nation. However, the most high-technology-oriented medical device firms, including software technology applicants, are in California, Florida, New York, Pennsylvania, Michigan, Massachusetts, Illinois, Minnesota, and Georgia (U.S. Bureau of the Census, 2007). Each of these high-technology firms requires matching trainings among the staff to deliver according to key performance indicators.

A review of the literature revealed that just before the MDD 93/42/EEC enforcement, the U.S. medical device exports data from NAICS was valued at $98 billion following an annual growth rate of 6% (Lewin Group, 2008). The wage rewards of most of the well-trained employees in the medical device manufacturers were 15% higher than the other nonmedical manufacturing sectors (Lewin Group, 2008). Additionally, the industry had over 365,000 workers in 2007 in the United States, with a mean yearly income of $60,000. The growth of the medical device industry in the United States is due to various technological and training advances in related sectors such as biotechnology, software development, microelectronics, instrumentation, and communication (U.S. Bureau of the Census, 2007). The export value indicated that these companies could afford to invest significant resources into staff training to meet the MDD 93/42/EEC standards.

The adoption of the MDD 93/42/EEC by U.S. medical device manufacturing companies has dual competitiveness at domestic and international levels that requires adequate staff training. At the domestic level, the leaders of medical companies have opportunities to improve the quality and innovativeness of their device software beyond the FDA and ISO certification benchmarks by training their employee (Lewin Group, 2008). Furthermore, the MDD 93/42/EEC creates competitiveness among U.S. companies as the staff members receive training to keep abreast of emerging technology standards regulating raw materials, software design processes, and technological scalability. The medical devices market is global, and firms with skilled and trained

employees can meet MDD 93/42/EEC requirements and compete more effectively in the EU market (U.S. Department of Commerce, 2008).

I evaluated the data from the survey of the 56 participants to test the $H2_a$ hypothesis statement. I found that the distribution of most of the responses was toward the left side of the curve, which is a preliminary indication of a lack of support for the test statement. Figure 14 contains the distribution of responses during the survey testing the hypothesis statement.

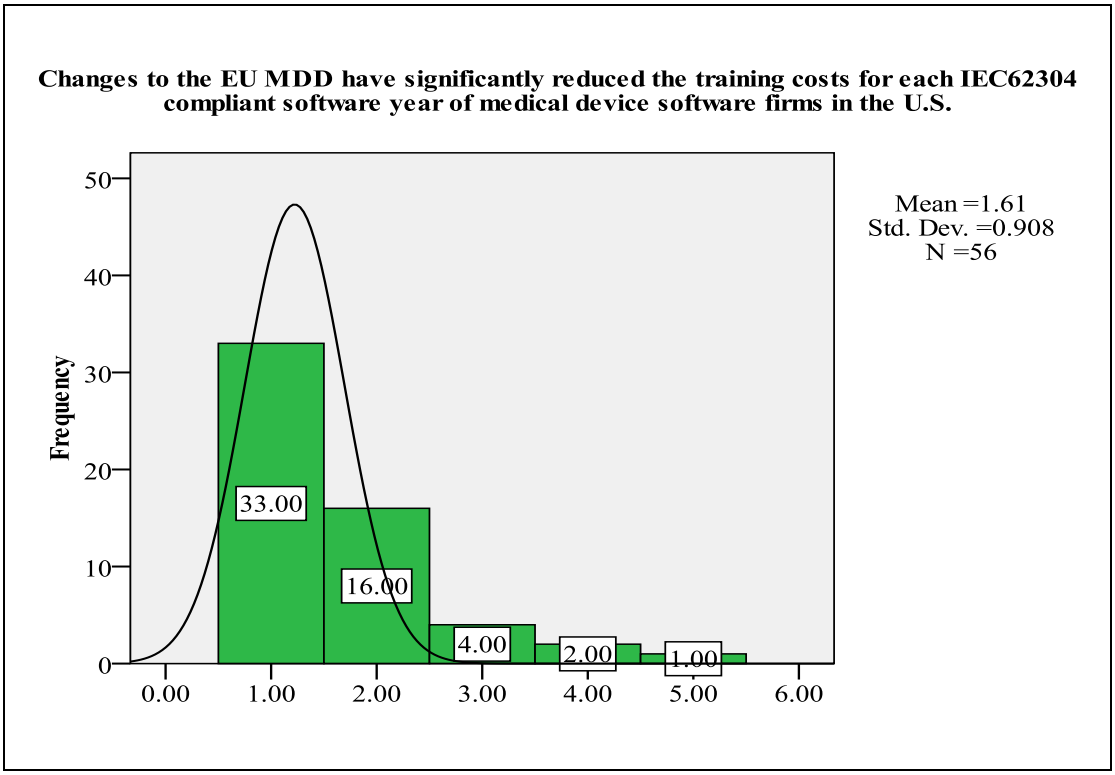

Figure 14. $H2_a$ alternative hypothesis.

As shown in Table 8, the mean sum of squares within gender groups was 45.350, while between gender groups it was 0.007. Because the mean between gender groups is below the $p = .05$ level of determination of significance, there was no evidence to support

the alternate hypothesis $H2_a$, and instead the data upheld the null $H2_0$. Therefore, $H2_0$ (Changes to the MDD have not significantly reduced the training costs for each EN/IEC/62304 -compliant software year of medical device software firms in the United States) received support, and findings supported the rejection of $H2_a$ (Changes to the MDD have significantly reduced the training costs for each EN/IEC/62304 -compliant software year of medical device software firms in the United States).

MDD and Project Cost of Medical Device

Research Question 3: What is the impact of changes to the MDD on the project costs of medical device software firms in the United States?

$H3_0$: There has not been a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States due to changes to the MDD.

$H3_a$: Changes to the MDD have led to a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States.

The MDD 93/42/EEC guides the leaders of U.S. companies to increase their investment in R&D. Medical device manufacturers may spend twice as much investment on R&D compared to other sectors (Lewin Group, 2008). Leaders in the U.S. medical device industry strive to deliver best quality products from their range of innovations and technologies (Denger et al., 2007). The case studies further established that leaders of most medical device manufacturing companies invest substantial resources in research

and development to standardize their products. There were approximately 5,300 manufacturers of medical devices in the United States in 2007, most classified as SMEs (ITA, n.d.).

Directive 93/42/EEC has opened new software market opportunities to companies that invest heavily in R&D because the safety (Panesar-Walawege et al., 2010) and efficacy standards outlined in the EN/IEC 62304 have emerged as a global standard for the software development life cycle and have achieved global harmony (Damian & Moitra, 2006). Device software companies that conform can receive reimbursement of tariffs, while noncompliant manufacturers pay higher tariffs or cannot enter the EU market.

Directive 93/42/EEC has improved the competitiveness of project costs of medical device software by making the requirements more transparent for firms selling in the EU. This applies where there are at least two different manufacturers of a medical software device with the same function in a volatile medical industry (Denger et al., 2007). Previous reports on dumping low-priced medical devices at the behest of safety and efficacy have reduced significantly with the introduction of Directive 93/42/EEC to all medical device manufacturers.

Directive 93/42/EEC has improved the harmonization of project costs with foreign regulations such as the FDA because past competition resulted in conflicting standards. Summary discrimination of a product without probing its quality and safety standards as envisaged in the EN/IEC 62304 and as a global standard for the software

development life cycle is catastrophic to medical device manufacturers (Panesar-Walawege et al., 2010). In the worst case scenario, such unfair competition can escalate project costs and lead to businesses winding up operations, while others could struggle with financial debts due to a lack of attractive partnerships, as was evident in some of the case studies (Damian & Moitra, 2006). The comparison of expenditures by each case study company for EN/IEC/62304 compliance per year indicated that ArtVentive had the lowest mean at $0.8101 million, and Varian had the highest mean at $166.3660 million, as illustrated in Table 11 and Figure 15.

Table 11

Expenditure for Each EN/IEC/62304 Compliant Software Year in R&D ($ Million)

Year	ArtVentive Medical Group	Varian Medical	Mindray Medical	Abiomed	CryoLife
2009	0.0000	148.7900	58.3800	26.2970	5.2470
2010	0.7043	156.8600	74.6400	26.6220	5.9230
2011	1.6307	175.9900	82.0200	26.7660	6.8990
2012	0.3982	189.1000	104.3100	26.0610	7.2570
2013[a]	1.3172	161.0900	86.4700	21.8300	5.9760
Mean	0.8101	166.3660	81.1640	25.5152	6.2604

[a] As of September 2013.

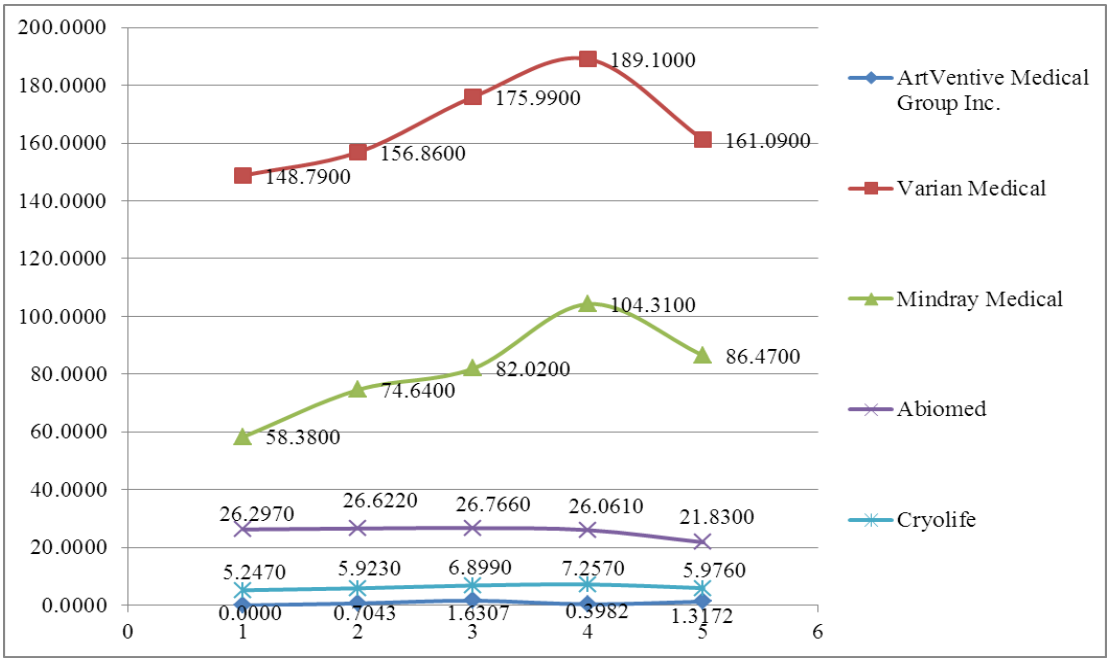

Figure 15. EN/IEC/62304 software compliance expenditure trends.

From the survey of the 56 participants, I evaluated their data to test the $H3_a$ hypothesis statement. Most of the responses were distributed toward the left side of the curve, which is a preliminary indication of a lack of support for the test statement. Figure 16 represents the distribution of responses during the survey testing the hypothesis statement.

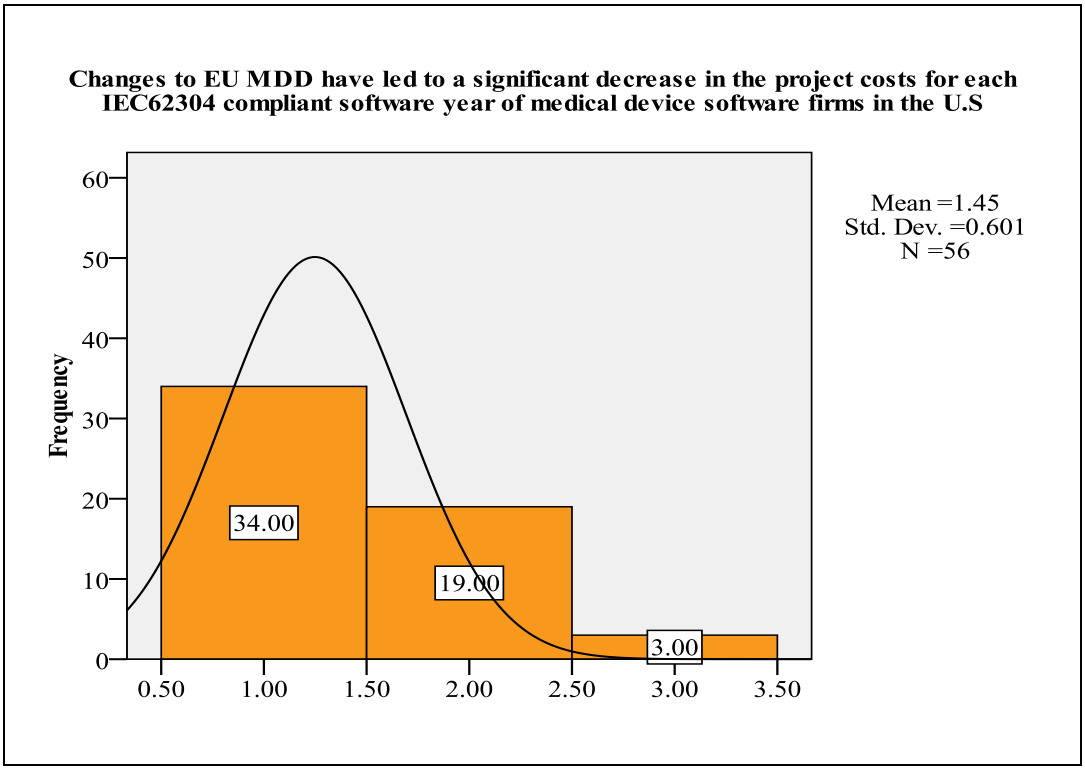

Figure 16. $H3_a$ alternative hypothesis.

As shown in Table 8, the mean sum of squares within gender groups was 19.838, and it was 0.002 between gender groups. Because the mean between gender groups is below the $p = .05$ level of determination of significance, the data did not support alternate hypothesis $H3_a$ and instead upheld the null $H3_0$. The findings revealed support for $H3_0$ (There has not been a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States due to changes to the MDD) but rejected $H3_a$ (Changes to the MDD have led to a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States).

MDD Impact on Medical Device Recall Rate

Research Question 4: What is the impact of changes to the MDD on the recall rate of medical device software firms in the United States?

$H4_0$: There has not been a significant decrease in the recall rate of medical device software manufactured by firms in the United States due to changes to the MDD.

$H4_a$: Changes to the MDD have led to a significant increase in the recall rate of medical device software manufactured by firms in the United States.

During the interviews, I highlighted FDA data that between 2002 and 2010, recalls occurred for approximately 1.5 million software-based medical devices. I also indicated that the 8-year period had more than double the number of software device recalls compared to the previous 8-year period. Directive 93/42/EEC repositioned medical device software in a more transparent manner not envisioned earlier because manufacturing standards, procedures, tests, validation, and accountability have all improved (Lee et al., 2006) to reduce the device recall statistics. Additionally, the recent amendment to Directive 93/42/EEC by the introduction of M5 (2007/47/EC) tightened the medical device software specifications by requiring medical device manufacturers to provide additional documentation to prove compliance with further safety and efficacy standards. This amendment further empowered oversight authorities to take firm action against nonconforming companies and their products (European Council, 2007).

The review of literature revealed that Directive 93/42/EEC has enlightened the medical device industry on procedures for conforming to international regulations to

reduce incidences of device recall. Therefore, new entrants into the medical device manufacturing sector targeting the EU markets have competitive standards to aid their business missions and visions. Directive 93/42/EEC applies equally among the device manufacturers targeting the EU markets, which indicates that disputes will resolve amicably and the sanctions for violation of applicable rules and regulations will not prejudice some companies more than is necessary.

Reviewed literature showed that Directive 93/42/EEC has helped SMEs in the medical device manufacturing to catch up with larger organizations because the same quality standards apply. Therefore, the entrants can compete for commercial market share from a qualitative accreditation and recognition, which translates to quantitative metrics such as revenue growth after acquiring strategic capital partners (McCaffery, Taylor, & Coleman, 2007) and a decrease in device recall among the SME firms.

I evaluated the data from the surveys of the 56 participants to test $H4_a$. The distribution of most of the responses was more toward the right side of the chart, which was a preliminary indication of support for the test statement. Figure 17 contains the distribution of responses during the survey testing of the hypothesis statement.

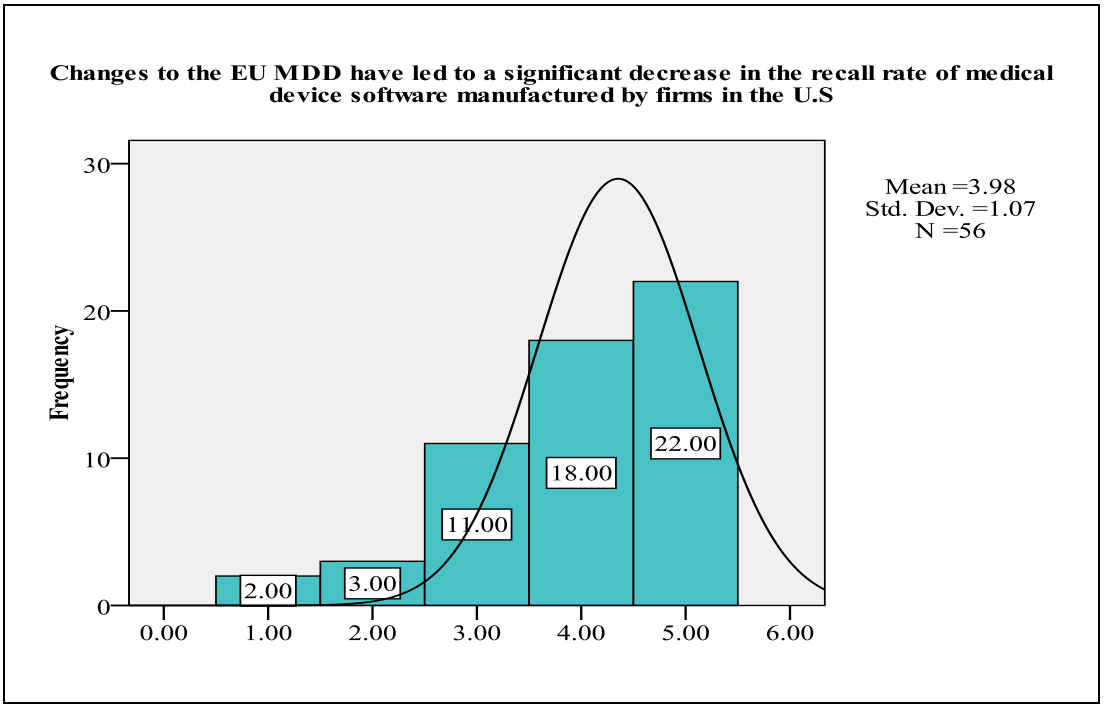

Figure 17. $H4_a$ alternative hypothesis.

As shown in Table 8, the mean sum of squares within gender groups was 62.525, and it was 0.457 between gender groups. Because the mean between gender groups was above the $p = .05$ level of determination of significance, the data did not support the null hypothesis $H4_0$ and instead upheld $H4_a$. Therefore, the findings indicated support for $H4_a$ (Changes to the MDD have led to a significant increase in the recall rate of medical device software manufactured by firms in the United States) but rejected $H4_0$ (There has not been a significant decrease in the recall rate of medical device software manufactured by firms in the United States due to changes to the MDD).

Proposed MDD Revisions and the Impact on Medical Device Manufacturers on Safety, Reliability, Quality, and Cost

Major revisions to the MDD 93/42/EEC from the original draft that served the medical industry for 2 decades are likely. The European Commission published the points for review in safety, reliability, quality, and cost on September 26, 2012. The first focus of the review is better "communication on safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals" (Andersson, 2012, the second focus is proposed rules for the medical devices, and the third focus is new regulations for in vitro diagnostic devices (Andersson, 2012).

Further, the reviews on the medical device regulations will cover active implantable MDD (under 90/385/EEC) and the MDD 93/42/ECC. The most important proposal is for medical device manufacturers to enforce regulations more than the MDD 93/42/EEC, as applicable within the EU. A concern is the entrenchment of directives in each country in the national laws, which normally occurs in nonuniform timelines from one country to the next. Therefore, the European Commission will address the statements by medical device manufacturers whose country of origin is lagging behind on the entrenchment of respective regulations as an excuse to be able to export products to Europe at lax standards. Previously, the flexibilities on the medical device transportation directives from different nations into Europe were able to circumvent the regulations,

which exposed the product users to additional safety and reliability concerns (Andersson, 2012).

On the aspects of device safety, the proposed changes seek to widen the regulatory boundaries outside the EU borders as follows:

- Medical devices embedded with software and designed with nonviable human tissues or their products after various alterations, including those applicable for therapeutic care, must undergo additional safety checks.
- Specific implantable devices that are not targeting medical operations but pose similar risks to the category of medical devices, even if for noncorrective procedures, must undergo additional safety checks and approval.
- All medical devices previously manufactured for single use but having a potential of reuse after the medic conducts certain clinical procedures must have adequate indications, and hospital leaders will take organizational responsibility during such reprocessing occasions.
- Medical devices whose part replacement is likely to compromise their original manufacturer's operational designs shall still be accredited under the CE making process, with all obligations of safety therein to the original manufacturers (Andersson, 2012).

On the aspects of reliability, the MDD 93/42/EEC revisions will target procedural matters where the Medical Device Coordination Group (MDCG) will be an oversight body with members and leadership drawn from the EU nations. The most striking

mandate for the group is the evaluation of risks for innovative medical devices to adhere to certain standards after series of scrutiny. The MDCG must inform the MDD 93/42/EEC commission whenever a company innovates a Class III device and declare all the details, even if doing so infringes on the intellectual property rights of the company. Failing to make this declaration could lead to no certification, yet the product details will still have leaked to public via the procedural scrutiny. This process of notification takes 28 days before the MDCG reports back in 60 days, in which the first half these days may have calls for more clarity on the product details. Indeed, this revision is likely to heighten bureaucracy likened to the MDD 93/42/EEC procedures (Andersson, 2012).

Under the quality issues targeted in the latest MDD 93/42/EEC reviews, Article 13 contained a proposal that at least one qualified person must be available in each company to lead compliance with the regulations. Article 13 further indicated that the qualified person must have specified academic achievement and not less than five years of experience in the medical device industry. Furthermore, the qualified person must ensure the positive release of products conforming to the batch standards. The qualified person is responsible for all the technical data entries and due diligence for presentation in current and future audits of the documents. The qualified person keeps abreast of the medical device technical and industry developments and ensures the MDD 93/42/EECs are implemented to the fullest. The qualified person is responsible for carrying out all investigations during recalls and other device incidences that fall within the MDD 93/42/EEC Point 4.1 Annex XIV (Andersson, 2012).

Under the cost aspects, the MDD 93/42/EEC revisions indicate pharmaceutical firms will follow guidelines of common technical specifications to price products as the Directive assumes they conform to standard safety and reliability requirements intended by the manufacturers. Therefore, the cost of a noncomplying device is not likely to be lower than market rates to move inventory even when their quality and performance are in doubt. Nevertheless, the revisions are somewhat uncertain about the fundamental cost issues of the medical devices because the wordings are ambiguous (Andersson, 2012).

Evidence of Trustworthiness

Member checking

Creswell and Miller (2000) describe member checking, reflexivity, triangulation, and audit trails as some of the most often used procedures to increase trustworthiness in qualitative inquiry. Trustworthiness of interpretations was enhanced through triangulation of quantitative financial data on the performance of the five medical device companies, in depth interviews with two experience managers in regulatory affairs and quality assurance. After initial interviews with the managers, I conducted a follow-up meeting to give them the opportunity to verify the transcripts. The meetings permit each manager to read the transcripts from the interview to ensure the accuracy and credibility. Keeping careful documentation of all components of the study and maintaining audiotapes for five years is also part of constructing an audit trail. When considering trustworthiness, the purpose of member checking was not to generalize findings, instead the goal was accuracy and credibility.

Reflectivity

On the issue of reflectivity, Creswell (1998) believes that all researchers have personal biases that can influence their interpretation of data. I believe that my professional experience provides firsthand knowledge, and sensitivity to the topic examined in this study. My extensive experience with software medical device manufacturing, preconceived belief or assumptions may have had a significant influence on the development of the research and the engagement of the participants. Although I made every effort to ensure objectivity, personal bias may have influenced my interpretation of the data collected. The interview participants were purposefully selected because of their unique expertise in their respective fields. I conducted the study using combination of questionnaires and structured interviewing techniques; asking the participants open-ended questions about their unique expertise with the research topic.

Triangulation

Triangulation refers to the simultaneous use of different methods and data in order to obtain different perspectives on a particular issue (Olsen, 2004). These perspectives include credibility, transferability, dependability, conformability and inter or intra coder reliability. In this study, triangulation involved the use of systematic literature reviews, interviews and case study of ArtVentive Medical Group Inc., Varian Medical, Mindray Medical, Abiomed and CryoLife. Triangulation also involved collection of quantitative financial data on the performance of the five medical device companies mentioned in the

sampling section and this was compared to the secondary sources of data obtained using the interviews and strategic literature reviews (SLR).

The influence of transcribing.

I opted for a complete transcription to ensure nothing of importance was overlooked. The transcription occurred after the completion of the interviews. The process involved listening to audio records and writing transcript. I listened the tape recording multiple times to verify the accuracy of transcription. Member checking was included as a validity strategy to allow the interviewees to review the transcripts to ensure an accurate transcription of their beliefs. Participants found no inaccuracies in the transcripts during the follow-up interview.

Transferability

Transferability is often a challenge in qualitative research. It refers to the degree to which a qualitative researcher can generalize or transfer the results of the research to other settings. I assumed that the findings from the case studies and the views expressed by the interviewees would provide a generalization of the medical device industry status. Therefore, the challenges and successes of the companies complying with the changes in MDD 93/42/EEC are shared and replicable with a fair degree of confidence.

Dependability

The idea of dependability highlights how the researcher's observations are tied to the context or setting of the study. In addressing the issue of dependability, my

dissertation provides a detail report of the research design and study results. This should allow future researchers to repeat the study, and to develop a thorough understanding of the methods and to gain or similar the same results.

Confirmability

Confirmability refers to the degree to which others could corroborate the findings of a study. The findings of this study are the result of the experiences and opinions of the participants. I used triangulation to address the issue of confirmability and to reduce the effect of investigator bias. In this study, triangulation involved the use of systematic literature reviews, interviews and case study of five medical device companies.

Threats to Reliability

Zikmund (2010) defines reliability as a measure of the degree to which the results that have been obtained are consistent and devoid of flaws. Hence, for the quantitative data, the Cronbach Alpha of 0.7 was used to determine the data validity. There are three main aspects of reliability and these are consistency, ability to be replicated, and accuracy (Golafshani, 2003). In this study, methods to ensure validity and reliability included minimization of bias, and triangulation to achieve convergence validity (Sekaran & Roger, 2010). The qualitative data were evaluated for content and construct validity, whereby, repetitive themes from the interviews and case study were sought (Kirk & Miller, 1986).

Minimization of Bias

Questionnaire bias was reduced by administering the questionnaires only to the right people, standardization of the questionnaire, and avoidance of jargon. The questions were also kept short and clear with no redundancies and appropriate formatting was used. Learner bias was avoided by randomizing the order of questions asked. Due to the sensitivity of the content of the survey, the data collection occurred in total confidentiality. Thus, respondents were not actively concerned about their information being disclosed. I reduced the threats to credibility by obtaining consent from the participants. I reduce the researcher bias by administrating the survey anonymously using SurveyMonkey.com. The data that were obtained were therefore abstracted. This enabled an evaluation of the research homogeneity and enhanced both the repeatability and validity of the study.

Chapter Summary

This chapter has contained findings from literature, interviews, and a brief survey before analyzing and discussing each along the provided research questions and hypotheses as follows.

The findings indicated support for $H1_a$ (Changes to the MDD have led to a significant decrease in the net income of medical device software firms in the United States) but rejected $H1_0$. The case study of the five companies and the literature review established firms' income increased after complying with the MDD. Even though the

income growth is not uniform across the sampled medical device manufacturing firms, there is a trend of general statistical growth.

The findings indicated support for $H2_0$ (Changes to the MDD have not significantly reduced the training costs for each EN/IEC/62304 -compliant software year of medical device software firms in the United States) but rejected $H2_a$. The literature sources and interview findings indicated that the training cost have significantly increased as leaders of firms seek compliance with the EN/IEC/62304. The study established that the training needs are at the quality and operational levels.

The findings indicated support for $H3_0$ (There has not been a significant decrease in the project costs for each EN/IEC/62304 compliant software year of medical device software firms in the United States due to changes to the MDD) but rejected $H3_a$. The graphical plots of the year-on-year expenditures in R&D showed a steady increase in the project costs. Moreover, these costs were likely to increase further with the implementation of the latest proposal to the MDD for 2012-2013.

The findings indicated support for $H4_a$ (Changes to the MDD have led to a significant increase in the recall rate of medical device software manufactured by firms in the United States) while rejecting $H4_0$. The MDD has increased the surveillance and internal audits of the medical device manufacturing systems to minimize device recalls and failure incidences that put the lives of the users in danger. Additionally, compliance to the MDD has created widespread commitment among the medical device manufacturers to improve device quality and communication among the stakeholders.

This chapter also included a review on the progress of the proposed MDD Revisions (2012-2013) and the impact on medical device manufacturers regarding safety, reliability, quality, and cost. The reviews are targeting improved communication between the commission and the respective medical device manufacturers, which have previously experienced some lapses, leading to the penetration of uncertified or unreliable devices in the markets. The aim of the reviews is to increase device software reliability by increasing the verification procedures under the supervision of MDCG. Another aim of the reviews is to improve the safety of medical devices embedded with software by proposing a raft of new measures to make the manufacturers more accountable. Under the review of Article 13, the proposal targeted better device quality by requiring every organization to have a senior qualified and experienced staff member to address all the issues from compliance, internal audits, and recall management. Article 13 requires that medical device manufacturers appoint at least one qualified person to lead compliance with the regulations. Finally, the review will serve to address the aspect of cost after the respective device manufacturers adhere to the common technical specifications. The next chapter contains the conclusions of the research questions and hypotheses, limitations, implications of social change, and recommendations for practices and future studies.

Chapter 5: Summary, Recommendations, and Conclusion

Introduction

The purpose of the study was to evaluate the impact of the changes in the MDD 93/42/EEC on the net income and share prices of compliant firms, the training cost for each EN/IEC/62304 compliant software year, project cost for each EN/IEC/62304, and the recall rate of devices manufactured by firms in the United States. This chapter, in consideration of the overall study limitations, contains a recapitulation each of the issues before a proceeding to discussion on the recommendations and the social change arising from EN/IEC/62304 compliance.

This study was conducted to fill a gap in the scholarly literature. The findings of this study represent the first time the impact of the changes in the MDD 93/42/EEC on medical device software and U.S. medical device companies' performances has been evaluated. The following main themes emerged from the study: (a) the Medical Devices Directive 93/42/EEC (MDD) with amendment M5 (2007/47/EC) have realigned device software manufacturing practices and incorporated other safety standards and (b) U.S. medical device companies have gained both domestic and global competitiveness in improving product safety, increasing sales revenue, and achieving stable stock performance. The conclusion of this chapter contains a recommendation to the EU Commission Services on how to update their best practices for enforcing conformance.

Interpretation of Findings

The first purpose of the study was to evaluate the impact of MDD 93/42/EEC on the device manufacturers' competitiveness benchmarked on the net income and share prices. The results of the research indicated overwhelming competitive advantages for the complying device manufacturers, including special certification and quality marks on the products preferred by hospitals and clinics. Additionally, medical devices that comply with the MDD 93/42/EEC have fewer product recalls, which often cause immense income losses to the device manufacturers, aside from the requirement of extra software checks and surveillance (Rakitin, 2006).

The findings from this study also indicated that manufactures of medical software devices have positive income returns that improved after they complied with the MDD 93/42/EEC. The same competitive advantages reflect on stable stock performances. Device recall cases highlighted in the press create public sentiments that can reflect in the stock market (Rakitin, 2006). However, the findings did not reveal any correlation between the increased revenues of U.S. firms in the EU and their compliance with the MDD 93/42/EEC.

The need to reduce operational costs arises because compliance to the MDD 93/42/EEC amendment targeting software safety and efficacy is a costly venture before a firm receives certification or accreditation to export to European markets (Panesar-Walawege et al., 2010). The cost factor is mostly in the due diligence and massive

documentation procedures. Thus, as medical device manufacturing companies' automated operations increased, the numbers of manual laborers decreased accordingly.

The second purpose was to evaluate the impact of changes of the MDD 93/42/EEC on the training cost for each EN/IEC/62304 compliant software year. The findings indicated the changes of the MDD 93/42/EEC have led to redefining the training needs for innovations, prototyping, design, testing, validation, and release processes (Lee et al., 2006; McCaffery et al., 2010). The extensive literature reviews revealed the process of MDD 93/42/EEC has retraced the staff training process to ensure better efficacy and accountability from the respective manufacturers (McCaffery & Dorling, 2009).

The literature review and interviews established that Amendment M5 (2007/47/EC) had created new needs for retraining medical device manufacturers and practitioners to improve the success rates of the respective software-embedded devices (European Council, 2007). The interview responses included the extended training costs that the respective medical device manufacturers factor in their R&D going forward. The findings further indicated the need to train medical device manufacturers and users on FDA regulations and ISO 62304 requirements. This globally recognized standard is the benchmark for software development and testing (Damian & Moitra, 2006); hence, exporters to the EU region who conform are progressing toward Directive 2007/47/EC.

The other impact of introducing the MDD 93/42/EEC is demand for skilled or specialized employees. The MDD 93/42/EEC amendment calls for recruiting staff

members who can provide the company with skills and productivity that will propel profitability (Sobelman, 2008). This case study revealed that some firms had struggles with internal organization, especially after acquisitions or mergers where staff members come in with different performance cultures. The synergy of skills such as software design and development is crucial for medical device manufacturers to nurture for research sustainability and better returns on investments (McCaughey et al., 2010).

The third purpose of the study was to examine the impact of the MDD 93/42/EEC changes on the project cost for each EN/IEC/62304 . There was evidence that fixed costs of compliance with the MDD 93/42/EEC run into millions of dollars every year across the medical device industry. On the variable costs, this study involved examining the impact of the MDD 93/42/EEC on the employee recruitment trends with evidence collated from the interviewees. In many medical device manufacturing firms, the MDD 93/42/EEC has led company leaders to restructure reorganization.

According to the extensive literature sources and interviews, the introduction of the MDD 93/42/EEC has had mixed consequences for recruiting employees because leaders seek those with top skills, and their compensation has cost implications on the project for each EN/IEC/62304 compliance software release. Leaders lay off many workers as they pursue efficiency and cost-cutting goals (McCaffery, 2010). However, some of the people who lost their job will often find new positions in related medical device companies.

Finally, this study involved evaluating the impact of changes in the MDD 93/42/EEC on the recall rate of devices manufactured by firms in the United States. The number of device recall before 2010 was approximately 1.5 million. However, the MDD 93/42/EEC is according the manufacturing firms competitive edge over their other segment players apart from elimination of unreliable or unsafe products in the market that often trigger recall, which indicates that the MDD 93/42/EEC has provided extra surveillance needs and operations in the medical industry. The fact that certain medical devices with software embedded have the mark of quality assurance provides the manufacturers with advantages of better pricing and higher revenue returns because the MDD 93/42/EEC requires extra research and documentation to the specific proportion of redesigned device software. For example, if internal audits of a medical device company reveal 20% of the software requires a redesign, the leaders will test and recertify only that portion of the software, which indicates that the R&D will be rational and modest, and the device products will continue to be priced competitively in the markets (Sobelman, 2008).

Limitations of the Study

A description of the limitations of the study is described in chapter 1. This includes the difficulty in making generalizations from the research methodology, the small sample size, the validity and reliability of the quantitative instrument. Qualitative research was suitable for this study; however, the results obtained from qualitative studies are not generalizable to entire populations (Maylor & Blackmon, 2005). When

considering the study findings, a primary limitation of this study was the potential limitation of purposive sampling. The potential disadvantage was the possibility to focus. The study included stringent inclusion and exclusion criteria to select the respondents, which has led to a limited sample size. Another limitation of this study was the potential for selection bias and response bias. Chapter 1 also outlined a strategy to address these limitations. The quantitative research included descriptive statistics, correlation, and data coding for analysis of variance, which was not only useful in testing the four hypotheses, but also to mitigate against the generalization limitation. The survey administration was anonymous to help reduce such a bias.

When considering trustworthiness, I used Guba's four criteria: credibility, transferability, dependability and confirmability. The basis of the responses collected from the survey was the opinions of the interviewees. These opinions constituted a threat to the overall credibility of the study. I used triangulation to address the issue of confirmability and to increase the validity and the reliability of the study results.

Based upon the results of this study, I may have failed to reject or confirm some hypotheses. A plausible explanation for the lack of significant results lies in the small sample size. Any deviation will probably be due to the small sample size and resulting low statistical power of the study. Because of the lack of existing research in this area, the sample size further limited this study. The small sample size resulted from the inability to recruit additional participants, following the study modification detailed in Chapter 3, from already limited participant firms.

Recommendations

This study provided a basis for future research studying the impact of the European Medical Device Directives on medical device manufacturers. I conducted this study to fill a gap in the scholarly literature. Based upon the findings of this study and considering the limitations and scope of the study, suggestions for future research are as follows.

First, future researchers should investigate how medical device manufactures complying with the MDD 93/42/EEC can improve their market time deliveries, shorten the R&D life cycle, increase the device software revenue, and streamline the manufacturing predictability timelines. This is a call to improve future competitiveness. The compliance criteria were slowing down many operations among the medical device manufacturers who pursue industry innovations at the same time. Additionally, some medical device manufacturers tend to view the MDD 93/42/EEC as a bureaucratic system that imposes additional cost on their vision for lean operational management.

Secondly, future researchers should indicate how medical device manufacturers could assess their current business operations to increase compliance with the MDD 93/42/EEC while maintaining pace with medical industry innovations. New medical device software designs that pursue business and compliance goals tend to emphasize one aspect while the other suffers from lack of flexible adaptations to standards. Researchers should address the MDD 93/42/EEC standards and software designs rigidities that cloud management's judgment on the best way forward. Since the MDD 93/42/EEC came into

effect, the leaders of many companies have been struggling to implement of efficiency practices such as timesavings and addressing market feedback on time. Moreover, even though the MDD 93/42/EEC amendment calls for companies to focus on testing the revised designs toward a relaunch process after a recall, future studies need to guide the scale of validation to save operational time and resources.

Thirdly, future researchers should show how medical device manufacturers could be consistent in organizational governance. In the past, as the medical device manufacturers went through their usual business in compliance with the MDD 93/42/EEC has seen blur of role such as who to review software, what bugs to eliminate , when to relaunch, and how to communicate safety and reliability changes to the medical industry is appropriate. Even though the MDD 93/42/EEC represents an attempt to formalize staffing and operational procedures, the findings in this study revealed that the diversity of medical device software creates unique challenges for each company. Therefore, software design projects that appear to be in regulatory compliance with the MDD 93/42/EEC can actually be struggling with business contingency measures.

Fourth, future researchers should investigate how medical device manufacturers can take advantage of the open software design platforms to speed up their strategic plans. Even though many originators patent their software, the medical industry continues to establish collaborations that benefit from prior MDD 93/42/EEC compliance to shorten life cycles for other up-and-coming companies, especially the SMEs. Future researchers

should establish how the rest of the medical industry device manufacturers could increase collaboration in project, portfolio, documentation, and quality management.

Finally, future researchers should come up with a universal methodology of complying to the MDD 93/42/EEC, where medical device manufacturers can refine aspects of product improvement and operational sequencing with the new product development, management, team responsibility, organizational systems, and software designs. These researchers should also address objectives such as goal-setting strategies. Future researchers should further explore a framework within which medical device manufacturers anywhere in the world could comply, to support marketing of compliant products, scheduling new product dates, efficiency, and improving life-cycle durations.

Implications of Social Change From MDD 93/42/EEC Compliance

This study has implications for positive social change. The findings of this study indicated that the changes in the MDD 93/42/EEC have a positive impact on the safety and reliability of software embedded medical devices. I sought to generate knowledge to contribute to a direct understanding of the phenomenon. As software embedded medical devices have been diversifying, the need to regulate their safety during applications became urgent owing to the increasing number of hazards and recalls (Rakitin, 2006). Members of the Council on medical devices of the European Commission believe that a consistent and coherent implementation of the MDD 93/42/EEC with Amendment M5 (2007/47/EC) is necessary to ensure the protection of human health (European Council, 2007). As a result, EN/IEC 62304 emerged as a global standard for the software

development life cycle. Medical device manufacturers failing to abide by the stipulated standards could lose their ability to access the respective markets, especially in the EU where the medical devices directive applies (Damian & Moitra, 2006). The implication for social change is to inform medical device manufacturers of the consequences of failure to comply with the standard. I indicated that most medical device manufacturers that comply or are in the process toward complying with the MDD 93/42/EEC amendments have less internal autonomy regarding how the operations run because the standard contains details of process flows to minimize risks and hazards on the products (Sobelman, 2008).

From a social change perspective, the MDD 93/42/EEC has made medical device manufacturers more consistent in practices of software material designs and made them repeat the high-quality production of equipment that meets high-performance expectations. The MDD 93/42/EEC has led medical device manufacturers to improve their product maturity time-to-market lags because of established standard operational procedures. The MDD 93/42/EEC has increased the frequency of audits that medical device manufacturers must accomplish to ensure compliance. Compliance with the MDD 93/42/EEC has improved the business results of many companies with products recalled following hazardous events. Moreover, any medical device manufacturer wishing to export to the EU has improved the software product quality under a consistent process. The outcome is resilient business performance in European markets, even when the economic environment is facing tough times (Sobelman, 2008).

The implication for social change included the evaluation of the changes in the MDD 93/42/EEC designed to make medical device safe and effective. MDD 93/42/EEC compliance has created high-performing device software manufacturers who have embraced a methodological standard as an organizational culture. Therefore, the medical device manufacturers have fortified their internal management policies to synchronize with industry innovations classes and times. The MDD 93/42/EEC has realigned the social technological links and methodology for medical device manufacturers because they share experiences and inventions to drive the industry forward. Moreover, the MDD 93/42/EEC compliance has reshaped the social accountability of medical device manufacturers to show more care for human health and maintain high standards over time. The evidence of social accountability manifests in the increasing sales and net revenue of the respective medical device manufacturers. Research shows more social change in the area of quality management, whereby the industry has been able to police and report entry of counterfeit medical devices that have potential health risks, which indicates that the European market has a self-audit and social reporting framework and methods to protect the health and safety of the medical device users.

Recommendations for Practice

Recommendations for Practice on MDD 93/42/EEC Source Code

The first recommendation is to make source code for all medical devices open and auditable. According to Sandler et al. (2010), this would enhance the safety and reliability

of these devices. Through this study, I established that the security of medical devices could vastly improve by making device software reliable (McCaffery, 2010).

Recommendations for Practice on the EN/IEC/62304 Standard

The second recommendation is that leaders of U.S. companies manufacturing medical software devices adopt this amended standard for all their product life cycles because it entails risk quality and risk management. This standard is important as it includes operationalization of the ISO 14971, which takes care of any additional hazards not captured by the EN/IEC/62304.

Recommendation for Practice on Adoption and Use of Comprehensive Model-Based Approaches

To eliminate less obvious errors and covert bugs during the project management advice (PMA) stage, medical device software manufacturers should have to adopt a model-based approach during the design of medical device software (McCaffery et al., 2010). This will enable the use of detailed white-box testing and other recognized model-checking methods to root out the errors and bugs before they enter the market, which will reduce the incidences of injuries, deaths, and recalls arising from defective software. The final recommendation is that the development of comprehensive use models such as illustrated in EN/IEC/62304 be a requirement for all manufacturers (McCaughey & Dorling, 2009). This will help to enhance the effectiveness of the regulation process and hence ensure safer and more effective medical device software that can also protect user privacy more effectively.

Conclusion

The study involved evaluating the amendments of the MDD 93/42/EEC and the implications on medical device software. Via the interviews, I established that various procedures of medical device software coding have changed due to the introduction of the MDD 93/42/EEC, to which all manufacturers targeting the EU markets must conform. I examined past studies on the problem area through a systematic review of the literature from journals, articles, and other research databases such as the SEC and Yahoo Finance that cover the MDD and the performances of the involved companies. The literature review covered the impact of Directive 2007/47/EC, followed by the amendment to resolve issues surrounding software quality and efficacy. The literature review also included the competitiveness of medical devices in term of sales and revenue and the backdrop that certain software malfunctions have led to costly recalls for the manufacturing companies (European Council, 2007).

The case study of the five companies and the literature review established firms' income increased after complying with the MDD. The findings indicated that the training cost have significantly increased as leaders of firms seek compliance with the EN/IEC/62304. The graphical plots of the year-on-year expenditures in R&D showed a steady increase in the project costs. Finally, the study findings indicated that compliance to the MDD has created widespread commitment among the medical device manufacturers to improve device quality, thus resulting in lower device recalls and failure incidences that cause harm to the users, the medical device operators or service

personnel. Overall, the findings were useful in closing literature gap, as the various medical device manufacturers enhance the safety and performance of the embedded software. I will share or publish the findings of the study with the EU Commission Services to update their best practices for enforcing conformance with the EN/IEC/62304:2007. Furthermore, the outcomes of the study are applicable to various medical device manufacturers targeted by the MDD 93/42/EEC (Panesar-Walawege et al., 2010).

The overall goal of the qualitative case study was to establish the impact of the MDD 93/42/EEC to the safety and reliability of the software system. The conclusion of this study was that the MDD 93/42/EEC has reorganized the medical industry and especially the software customization and design standards to ensure high success rates and low malfunctions that can pose material and health risks to patients or during hospital administration. The literature review and interviews revealed that a significant proportion of medical device recalls occurs after actual damage or hazards (Rakitin, 2006). The goal of the MDD 93/42/EEC and specifically Amendment M5 (2007/47/EC) is to create a proactive framework of a concept of proof that device software will function according to specifications and limit the risk to human health (European Council, 2007). Medical device manufacturers outside the EU initially viewed the introduction and amendment of the MDD 93/42/EEC as a social bureaucracy and as providing preferential treatment to the European medical industry, but the findings in this study indicated that the measures are defensible for the benefit of all stakeholders (Sobelman, 2008).

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Appendix A: Questionnaire

Purpose:

The purpose of this study is to determine the effect of the EU Medical Device Directive on medical device software, on the project costs of medical device software firms in the U.S.

The information obtained from this questionnaire will primarily be used for my dissertation research.

Completing this Questionnaire:

Please read each question carefully and do not skip an item unless you deem it not applicable to you. This questionnaire should take about 30-45 minutes to complete.

Data Confidentiality

I want to assure you that your individual responses will be kept completely confidential, by me, and your participation in this study is absolutely voluntary.

My dissertation committee will be given an overview of my research findings and suggestions. No one at the University will see your responses.

SECTION I: Background Information

Objective:

The information collected in this section will not be used in any manner to identify you. The objective of collecting this information is to be able to find any patterns in demography that may have an influence on management practices.

1. Could you please tell me briefly about yourself and your area of responsibility?

2. Size of the company:

3. Type of company:

4. Current Job Title:_____

5. Department:_____

6. Gender
    a) Male
    b) Female

7. In what age group are you?

    a) 25 and under b). 26 to 35 c). 36 to 45
    d). 46 to 55 e). 55 and older

8. Number of years with current employer:

    a). Less than 5 years b) Less than 10 years
    c). Less than 15 years d) over 20 years
    e). More than 30 years

SECTION II: Effectiveness of Directive MDD 93/42/EEC on the Safety of Medical Devices

1. Based on your experience, how effective has the MDD 93/42/EEC been in enhancing the efficacy of medical devices? Please tick the appropriate boxes for each device type.

Device type	Very effective	Effective	Not certain	Not effective	Not effective at all
Class I devices					
Class IIa devices					
Class IIb devices					
Class III devices					

2. How effective has the MDD 93/42/EEC been in enhancing the safety of medical devices? Please tick the appropriate boxes for each class of device.

Device type	Very effective	Effective	Not certain	Not effective	Not effective at all
Class I devices					
Class IIa devices					
Class IIb devices					
Class III devices					

SECTION III:Impact of the MDD 93/42/EEC on the Costs of Medical Devices

1. How costly is the approval process for medical devices? Please tick the appropriate boxes for each class of device

Device type	Very costly	costly	Not costly	Very cheap	I do not know
Class I devices					
Class IIa devices					
Class IIb devices					
Class III devices					

2. What effect have the Amendments had on the cost of approval?
    a. Increased the cost
    b. Reduced the cost
    c. No effect
    d. I don’t know
3. How long does the approval process for medical devices take?
    a. Very long time (more than 180 days)
    b. Long time (more than 90 days)

c. Short time (90 days)

d. Very short time (less than 90 days)

SECTION IV: Better Conformity assessment

1. What can be done to improve the process of conformity assessment?

---

2. What can be done to improve the designation and monitoring of notified bodies?

---

3. What can be done to make the clinical evaluation requirements clearer?

---

4. What can be done to improve the process of post market surveillance?

---

5. Is the process used to approve medical devices transparent? Please circle one

    a. Yes

    b. No (Please explain)

    _____

    c. I don't know

6. What can be done to improve the transparency of the approval process?

---

7. Have the amendments had a significant impact on competition?

    a. Yes

    b. No

    c. I don't know

SECTION V: Market Surveillance - Medical Devices Recalls

1. Have you had any recalls of your devices after 30th June, 2004?

a. Yes

b. No

2. If the answer to the previous question is yes, what was the number of recalls what factors led to these recalls? Please fill the table below appropriately

Type of malfunction/ failure	Number of recalls
Software malfunction	
Behavior failure	
Failure of output	
Service failure	
Display failure	
Input failure	
Response failure	
Failure due to data	
User instruction failure	
Timing failure	
System failure	

Quality failure	
Other	

3. Have you had any recalls of your devices after 21st March, 2010?

    a. Yes

    b. No

4. If the answer to 3 above is yes, what was the number of recalls and what factors led to the recalls? Please fill the table below appropriately.

Type of malfunction/ failure	Number of recalls
Software malfunction	
Behavior failure	
Failure of output	
Service failure	
Display failure	
Input failure	
Response failure	

Failure due to data	
User instruction failure	
Timing failure	
System failure	
Quality failure	
Other	

SECTION VI: Impact of the MDD 93/42/EEC on the Firm's Revenues

1. What was the value of your company's exports to Europe between 24th March 2011 and 24th March 2012?

---

2. How has your share of the European market changed since 24th March, 2011?

    a. Has increased by_____%

    b. Has not changed

    c. Has reduced by _____%

    d. I don't know

3. How has the number of your employees changed since 24th March, 2011?

    a. Has increased by _____%

    b. Has not changed

    c. Has reduced by _____%

    d. I don't know

Appendix B: Interview Questions

Objective: To assess the impact of EN/IEC/62304 on your organization.

Comment: EN/IEC 62304 standard has been embraced as a global benchmark for management of the software development lifecycle.

Lead Question 1: Is EN/IEC/62304 implemented in your firm?

Comment: According to a FDA's analysis conducted between 2002 and 2010, about 1.5 million software-based medical devices were recalled. During these eight years, the number of recalls of software-based medical devices has more than doubled.

Lead Question 2: What in your opinion is attributable to this high percentage?

Probing Question: What factors explain the emergence of these defects after the initial software release? You can give specific examples.

Comment: EN/IEC/62304 provides a framework of software development lifecycle processes, by defining the majority of the software development and verification activities.

Lead Question 3: Are best-practice (sound software development practices for medical devices from planning, requirement analysis, implementation and verification, integration, and software release) currently underway at your organization?

Lead Question 4: How do you demonstrate compliance to the standard?

Probing Question: Does your organization have a specific work instruction or SOP for EN/IEC/62304?

Comment: The FDA and the European Union have observed an increase use of off-the-shelf software (SOUP) in automated medical devices prior to the introduction of EN/IEC/62304.

Lead Question 5: What concerns do you have with the usage of SOUP in medical devices?

Probing Question: Do you believe that EN/IEC/62304 fully addresses these concerns?

Comment: According to the FDA, software validation is a requirement to software used as components in medical devices, to software that is itself a medical device, and to software used in production of the device or in implementation of the device manufacturer's quality system.

Lead Question 6: Do you believe that the introduction of EN/IEC/62304 has made medical device software validation safer?

Comment: Medical devices must be validated to ensure accuracy, reliability, consistent intended performance.

Lead Question 7: Do you believe that EN/IEC/62304 has been effective in enhancing the safety of medical devices?

Probing Question: In which way are medical devices produced under IEC 62034 safer?

Comment: The U.S. medical device industry is expected to remain highly competitive globally, due in part to the introduction of innovative products to market.

Lead Question 8: Do you believe that medical device software produced under the guidance of EN/IEC/62304 provides firms with a competitive advantage?

Probing Question: How precisely does EN/IEC/62304 offers consumers greater value?

Comment: Although EN/IEC 62304 standard has been embraced as a global benchmark for management of the software development lifecycle, implementation of the standard has been slow (Ken, 2010).

Lead Question 9: What justifies the slow adoption of the standard by medical device manufacturers?

Probing Question: In your opinion what must be done to improve the implementation of EN/IEC/62304?

Comment: The ultimate objective of EN/IEC/62304 is to ensure that medical device software is not only effective but safe.

Lead Question 10: Are you aware of any unintended consequences associated with the implementation of EN/IEC/62304?

Probing Question: Are you aware of any effects of the implementation of EN/IEC/62304 on software costs and employees training?

Probing Question: Any further comments?

Thank you for your participation.

Appendix C: Acronym Table

Acronym	Term
510(k)	Premarket Notification
AARA	American Recovery and Reinvestment Act
AERs	Adverse event reports
AHWP	Asian Harmonization Working Party
ANSI	American National Standards Institute
BPA	Bisphenol A
CAD	Computer-aided design
CAM	Computer-aided manufacturing
CDRH	Center for Devices and Radiological Health
CE marking	Conformité Européenne; meaning "European Conformity"
CEN	Comité Européen de Normalisation
CENELEC	Comité Européen de Normalisation Électrotechnique; English: European Committee for Electrotechnical Standardization
CFC	Chlorofluorocarbon
CMS	Center for Medical and Medicaid Services
COC	Cyclic olefin copolymers
COP	Cyclic olefin polymers
DBS	Deep brain stimulators
DHEP	di(2-ethylhexyl) phthalate
DOS	Denial of service
EEA	European Economic Area
EEC	European Economic Community
EN	European Norm
ETSI	European Telecommunication Standards Institute
EU	European Union

Acronym	Term
FDA	Food and Drug Administration
GAO	Government Accountability Office
GHTF	Global Harmonization Task Force
GMP	Good manufacturing practices
GPOs	Group purchasing organizations
HCMDSS	High Confidence Medical Device Software and Systems
HHS	Health and Human Services
HMOs	Health management organizations
ICD	Implantable cardiac defibrillators
ID	Identification
IEC	International Electrotechnical Commission
IMD	Implantable medical devices
IP	Intellectual property
IRB	Institutional Review Board
ISO	International Organization for Standardization
LAHWP	Latin American Harmonization Working Party
MAC	Media access control
MAUDE	Manufacturer and User Facility Device Experience
MCRs	Minimum medical cost ratios
MDD	Medical Devices Directive
MEMS	Micro-electro-mechanical systems
MHRA	Medicines and Healthcare products Regulatory Agency
MoH	Ministry of Health
NAFTA	North American Free Trade Association
NAIC	North American Industry Classification
NAICS	North American Industry Classification System

Acronym	Term
NCMS	New Cooperative Medical Scheme
NCVA	National Venture Capital Association
onc	Office of the National Coordinator for Health IT
PMA	Pre-market approval
PVC	Polyvinyl chloride
QA	Quality Assurance
QS	Quality System
R&D	Research and development
RFID	Radio-frequency identification
SEC	U.S. Securities and Exchange Commission
SCC	Standards Council of Canada
SOP	Standard Operating Procedure
SOUP	Software of Unknown Pedigree or Provenance
U.K	United Kingdom
U.S	*United States* of America
UDI	Unique Device Identifier
UEBMI	Urban Employee Basic Medical Insurance
URBMI	Urban Resident Basic Medical Insurance
VOS	Value of shipment
WHO	World Health Organization

Appendix D: List of International Standards

Name	Subject
21 CFR part 820	Code of Federal Regulations Title 21- PART 820: QUALITY SYSTEM REGULATION.
Directive 76/64/EEC	Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community.
Directive 84/539/EEC	COUNCIL DIRECTIVE of 17 September 1984 on the approximation of the laws of the Member States relating to electro-medical equipment used in human or veterinary medicine (84/539/EEC).
Directive 90/385/EEC	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.
Directive 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
Directive 98/79/EC	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical device.
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003).
EN/IEC 62304	Medical device software -- Software life cycle processes.
IEC 60601-1-11:2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

Name	Subject
ISO 13488	Quality systems -- Medical devices -- Particular requirements for the application of ISO 9002.
ISO 14971	Medical devices -- Application of risk management to medical devices.
ISO/IEC 90003	Software engineering -- Guidelines for the application of ISO 9001:2000 to computer software.
MDD 2007/47/EC	Directive 2007/47/EC of the European parliament and of the council of 5 September 2007 amending MDD 93/42/EEC.
MDD 76/764/EEC	Medical Directive (repealed as from 1 January 1995).

Appendix E: Walden University IRB approval

Original E-mail
Subject: Notification of Approval to Conduct Research-Guy Didier Foe Owono
Date: Tue, Nov 26, 2013 03:22 PM CST
From: IRB IRB@waldenu.edu
To Guy Didier Foe Owono <guydidier.foeowono@waldenu.edu>
CC: "irmak.renda-tanali@waldenu.edu" <irmak.renda-tanali@waldenu.edu>, Walden University Research <research@waldenu.edu>

Dear Mr. Foe Owono,

This e-mail serves to inform you that your request for a change in procedures, submitted on 11/22/13 has been approved. Your interpretation of the steps associated with data collection is correct. You may implement the requested changes effective immediately. The approval number for this study will remain the same.

This email also confirms receipt of the letters of cooperation for Spiracur Inc, and Robert Bosch Healthcare, Inc. and also serves as your notification that Walden University has approved BOTH your dissertation proposal and your application to the Institutional Review Board. As such, you are approved by Walden University to conduct research.

Please contact the Office of Student Research Administration at research@waldenu.edu if you have any questions.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:

http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZegKlmdiQ_3d_3d

Sincerely,

Jenny Sherer, M.Ed., CIP
Associate Director
Office of Research Ethics and Compliance
Email: irb@waldenu.edu
Fax: 626-605-0472

Office address for Walden University:
100 Washington Avenue South
Suite 900

Minneapolis, MN 55401

Information about the Walden University Institutional Review Board, including instructions for application, may be found at this link: http://researchcenter.waldenu.edu/Office-of-Research-Ethics-and-Compliance-IRB.htm

Appendix F: Walden University conditional IRB approval

Original E-mail
Subject: Conditional IRB Approval-Guy Didier Foe Owono
Date: Fri, Sep 20, 2013 03:29 PM CDT
From: IRB IRB@waldenu.edu
To Guy Didier Foe Owono <guydidier.foeowono@waldenu.edu>
CC: "irmak.renda-tanali@waldenu.edu" <irmak.renda-tanali@waldenu.edu>, Walden University Research <research@waldenu.edu>

Dear Mr. Foe Owono,

This email is to notify you that the Institutional Review Board (IRB) has approved your application for the study entitled, "Impact of EU Medical Device Directive on Medical Device Software." conditional upon the approval of the community research partners, as documented in signed letters of cooperation. Walden's IRB approval only goes into effect once the Walden IRB confirms receipt of those letters of cooperation.

Your approval # is 09-20-13-0109393. You will need to reference this number in your doctoral study and in any future funding or publication submissions. Also attached to this e-mail are the IRB approved consent forms. Please note, if these are already in an on-line format, you will need to update those consent documents to include the IRB approval number and expiration date.

Your IRB approval expires on September 19, 2014. One month before this expiration date, you will be sent a Continuing Review Form, which must be submitted if you wish to collect data beyond the approval expiration date.

Please note that this letter indicates that the IRB has approved your research. You may NOT begin the research phase of your doctoral study, however, until you have received the **Notification of Approval to Conduct Research** e-mail. Once you have received this notification by email, you may begin your data collection. Your IRB approval is contingent upon your adherence to the exact procedures described in the final version of the IRB application materials that have been submitted as of this date. This includes maintaining your current status with the university. Your IRB approval is only valid while you are an actively enrolled student at Walden University. If you need to take a leave of absence or are otherwise unable to remain actively enrolled, your IRB approval is suspended. Absolutely NO participant recruitment or data collection may occur while a student is not actively enrolled.

Your IRB approval is contingent upon your adherence to the exact procedures described in the final version of the IRB application materials that have been submitted as of this

date. If you need to make any changes to your research staff or procedures, you must obtain IRB approval by submitting the IRB Request for Change in Procedures Form. You will receive confirmation with a status update of the request within 1 week of submitting the change request form and are not permitted to implement changes prior to receiving approval. Please note that Walden University does not accept responsibility or liability for research activities conducted without the IRB's approval, and the University will not accept or grant credit for student work that fails to comply with the policies and procedures related to ethical standards in research.

When you submitted your IRB application, you a made commitment to communicate both discrete adverse events and general problems to the IRB within 1 week of their occurrence/realization. Failure to do so may result in invalidation of data, loss of academic credit, and/or loss of legal protections otherwise available to the researcher.

Both the Adverse Event Reporting form and Request for Change in Procedures form can be obtained at the IRB section of the Walden web site or by emailing irb@waldenu.edu: http://inside.waldenu.edu/c/Student_Faculty/StudentFaculty_4274.htm

Researchers are expected to keep detailed records of their research activities (i.e., participant log sheets, completed consent forms, etc.) for the same period of time they retain the original data. If, in the future, you require copies of the originally submitted IRB materials, you may request them from Institutional Review Board.

Both students and faculty are invited to provide feedback on this IRB experience at the link below:

http://www.surveymonkey.com/s.aspx?sm=qHBJzkJMUx43pZegKlmdiQ_3d_3d

Sincerely,
Jenny Sherer, M.Ed., CIP
Associate Director
Office of Research Ethics and Compliance
irb@waldenu.edu
Phone: 612-312-1341
Fax: 626-605-0472
Office address for Walden University:
100 Washington Avenue South
Suite 900
Minneapolis, MN 55401

Appendix G: Invitation to Participate in Research

This form represents the original that was sent out to the participants in the organization under study requesting their participation in the research study.

Guy D. Foe Owono
3283 Mirage Way
San Jose, CA 95135
Tel: 1 408 667 9487

October 28, 2013

Attn: Kaleem Mohammed
Manager QA & RA
Robert Bosch Healthcare, Inc
2400 Geng Rd Palo Alto, CA 94303

Dear Kaleem,

I am currently pursuing a PhD in Applied Management and Decision Sciences at Walden University's College of Management and Technology, in the U.S. My dissertation will examine changes in the EU MDD, the impact on medical device software, and the impact to firm competitiveness.
The medical device industry is a key component of healthcare systems. As more medical products have become dependent on embedded software, safety regulations for those devices have shifted to the reliability of software systems. The European Union believes that a consistent and coherent implementation of the Medical Devices Directive 93/42/EEC (MDD) with amendment M5 (2007/47/EC) is necessary to ensure human health protection.

The aim of the research, as stated in the previous section, is to examine changes in the EU MDD and the impact on medical device software.
I plan on conducting an interview and administering a survey to about 2 employees. The SurveyMonkey.com website will be used to administer and store the survey. However, I will conduct the interviews personally in order to obtain the specific information that could support the intended study. Participants will complete a survey and subsequently be interviewed.

I have estimated the burden for this collection of information at 90 to 120 minutes, including the time for reading the question, completing the questionnaire, and participating in the interview.

In addition, I welcome the opportunity to review any available data on company's financial performance, in order to assess the impact of the EU MDD to firm competitiveness.
In the event of a positive answer to my request, I plan on administrating the survey by early November 2013, and anticipate completing the process within few hours. I will appreciate if you could provide the names of two employees who are willing to participate in the study, so I can coordinate the exact times of data collection with them in order to minimize disruption to their activities.

Once the data is collected, consolidated, and analyzed, I shall provide a copy to your office to ensure the integrity of the information. This information will then be incorporated into a doctoral research paper.
Since this study will involve employees under your supervision, I hereby formerly request your approval to engage them in the study. I have attached herewith a "Recruitment letter", and a consent form that will be emailed to the participants for your reading and review.
I welcome the opportunity to discuss the planned data collection with you, and I am available to answer any questions you might have relating to this matter.

I can be reached either by email at **guydidier.foeowono@waldenu.edu**or via phone at +1 408 667-9487.

Thanks in advance for your cooperation.

Sincerely

Guy Foe Owono
PhD Candidate
Walden University, College of Management and Technology

Appendix H: Consent Form

This form represents the original that was sent out to the participants in the organization under study informing them of their right to voluntary participation and confidentiality.

You are invited to take part in a research study of **Impact of EU Medical Device Directive on Medical Device Software.**

You were chosen for the study because:

1. you have been working in the medical devices software field for a period not less than 5 years
2. the company you are working for has released a EN/IEC/62304 compliant software since the publication of the standard in 2007
3. you are at least 18 years old to participate in this reseach
4. and you are able to speak and write in English

This form is part of a process called "informed consent" to allow you to understand this study before deciding whether to take part. Please read this form and ask any questions you have before agreeing to be part of the study.

This study is being conducted by a researcher named Guy Didier Foe Owono, who is a doctoral student at Walden University.

Background Information:

The purpose of this study is to study the impact of changes to the EU MDD on medical device software.

Procedures:

If you agree to be in this study, you will be asked to:

- Read and sign this consent form agreeing or declining to participate in the study,

- Participate in a survey questionnaire administered in SurveyMonkey. The researcher has estimated the burden for this collection of information at 45 to 60 minutes, including the time for reading the question and completing the questionnaire.
- Participate in an interview to be conducted by the researcher. The researcher has estimated the burden for this collection of information at 60 minutes. The interview will be audio-recorded and transcribed to text.

Here are some sample questions:

1. What is the impact of changes to the EU MDD on medical device software?
2. What is the impact of the EU MDD on Europeans medical device manufacturer's competitiveness?
3. How effective has the MDD 93/42/EEC been in enhancing the safety of medical devices?
4. Have you had any recalls of your devices after 21st March, 2010?

Voluntary Nature of the Study:

Your participation in this research project is completely voluntary. You have the right to say no, and may withdraw at any time should you change your mind. You may choose not to answer specific questions or stop participating at any time. You may skip any questions that you feel are too personal.

Whether you choose to participate or not will have no affect on your employment.

Risks and Benefits of Being in the Study:

The researcher has deemed the psychological stress associated with the participation in the study no greater than what one would experience in daily life. The only anticipated risk to the participants could result from the nature of the questions posed in the interviews or surveys.

The study could result in direct contribution to social change.
The researcher hopes to provide the EU Commission Services input to improve the implementation of IEC 62304.

Payment:
The researcher does not plan on providing any compensation to the participants for their research participation.

Privacy:
Any information you provide as well as the records of this study will be kept confidential .The researcher will not use your personal information for any purposes outside of this research project. Also, the researcher will not include your name or anything else that could identify you in the study reports. The documents and recordings will be stored in a nonpublic location and will be kept for a period of at least 5 years, as required by the university.

Contacts and Questions:
The researcher's name is **Guy D. Foe Owono**. The researcher's faculty advisor is **Dr. Irmak Renda-Tanali**. You may ask any questions you have now. Or if you have questions later, you may contact the researcher via phone at **+1 408 667-9487** or email at **guydidier.foeowono@waldenu.edu** or the advisor by phone at **+1 240 684-2435** or email at **irmak.renda-tanali@waldenu.edu.**
If you want to talk privately about your rights as a participant, you can call Dr. Leilani Endicott. She is the Director of the Research Center at Walden University. Her phone number is 1-800-925-3368, extension ***3121210.***
Please retain a copy of this form for your records.
Statement of Consent:

I have read the above information and I feel I understand the study well enough to make a decision about my involvement.

By replying to this email with the words, "I consent" , I understand that I am agreeing to the terms described above.

Please include in the email the telephone number at which you can be reached for the phone interview.

Walden University policy on electronic signatures: An electronic signature is just as valid as a written signature as long as both parties have agreed to conduct the transaction electronically.
Electronic signatures are regulated by the Uniform Electronic Transactions Act. Electronic signatures are only valid when the signer is either (a) the sender of the email, or (b) copied on the email containing the signed document.
Legally an "electronic signature" can be the person's typed name, their email address, or any other identifying marker. Walden University staff verify any electronic signatures that do not originate from a password-protected source (i.e., an email address officially on file with Walden).

Appendix I: Transcribed Interviews Responses

Objective: To assess the impact of EN/IEC/62304 on your organization.

Time: 8:00 A.M. PST

Date: December 13, 2013

Place: Milpitas, CA

Interviewee: Mr. MOX

Position of Interviewee: Manager

Brief introduction by Interviewer.

Interviewer: Thank you very much MOX. for accepting to be part of this research study. As you know the purpose of this study is to determine the impact of the MDD to medical firm.

Interviewee: I am very excited that you are completing your PhD, this is significant achievement.

Interviewer comment: EN/IEC 62304 standard has been embraced as a global benchmark for management of the software development lifecycle.

Question 1: Is EN/IEC/62304 implemented in your firm?

Responder 1: yes, 62304 was implemented in our organization at the beginning of this year. You have brought an outside consulting group. Our entire software group got trained on 62304.

Interviewer comment: According to a FDA's analysis conducted between 2002 and 2010, about 1.5 million software-based medical devices were recalled. During these eight years, the number of recalls of software-based medical devices has more than doubled.

Question 2: What in your opinion is attributable to this high percentage?

Interviewee: it all attributed to risk analysis. The initial risk analysis during the initial development phase and risk analysis during verification and Validation (V&V). Risk analysis should be a complete life cycle activity. It should start during the initial design phase. It should cover, supply chain, manufacturing, design transfer, how embedded software is transfer to manufacturing. Learning from post market surveillance activities.

Probing Question: What factors explain the emergence of these defects after the initial software release? You can give specific examples.

Interviewer comment: EN/IEC/62304 provides a framework of software development lifecycle processes, by defining the majority of the software development and verification activities.

Question 3: Are best-practice (sound software development practices for medical devices from planning, requirement analysis, implementation and verification, integration, and software release) currently underway at your organization?

Interviewee: We have implemented 62304 fully, we are practicing fully. All our procedures have been revised, and people have been trained. We have spent $100,000 (100k) on training. We have about 265 associates globally.

Question 4: How do you demonstrate compliance to the standard?

Interviewee: Again right now, everybody is going through a learning curve. It is an excellent process well structured.

Probing Question: Does your organization have a specific work instruction or SOP for IEC 62304?

Interviewee: We have a procedure for software development life cycle, and we revised it last year to comply with 62304.

Interviewer comment: The FDA and the European Union have observed an increase use of off-the-shelf software (SOUP) in automated medical devices prior to the introduction of IEC 62304.

Question 5: What concerns do you have with the usage of SOUP in medical devices?

Interviewee: Yes it is a big concern, basically managing SOUP. We do not have a procedure on how to manage SOUP. That is one area where regulatory angencies will look into.

Probing Question: Do you believe that EN/IEC/62304 fully addresses these concerns?

Interviewee: To me it a concern. We need to have a documented procedure on how to manage SOUP. There should be a documented process; it should be part of our design process, and during all design activities. The Software design document, SDDs, must clearly document what off the shelf, commercial software we are using. A completely defining a maintenance plan.

Interviewer comment: According to the FDA, software validation is a requirement to software used as components in medical devices, to software that is itself a medical device, and to software used in production of the device or in implementation of the device manufacturer's quality system.

Question 6: Do you believe that the introduction of EN/IEC/62304 has made medical device software validation safer?

Interviewee: definitely, because it requires certain documentation, which aligns with the level of concern, and based on the classification of the software whether A, B &C the required documentation is clearly identified, which documentation you should have in place. But one thing I see that people may flag, is low level classification of product, they may not document. But I will recommend that the process should be applied the same to all classes, so that you have a standard practice, otherwise people may slip.

Interviewer comment: Medical devices must be validated to ensure accuracy, reliability, consistent intended performance.

Question 7: Do you believe that EN/IEC/62304 has been effective in enhancing the safety of medical devices?

Interviewee: When you are classifying your software, it is based on what you call the defect, the adverse effects that you may see in the software. You have to define the classification based on the failure you may be seeing. If you do not do it meticulously,

then any auditor may found out that you skip it: that you overlook it. They will ask you to do it again.

Probing Question: In which way are medical devices produced under IEC 62034 safer?

Interviewee: Basically, the complete software design development documentation, the software architecture, the risk analysis, the V&V (verification and validation).

Interviewer comment: The U.S. medical device industry is expected to remain highly competitive globally, due in part to the introduction of innovative products to market.

Question 8: Do you believe that medical device software produced under the guidance of EN/IEC/62304 provides firms with a competitive advantage?

Interviewee: Definitely, it will provide competitive advantage, because it is a harmonized standard. That mean the scientific community is behind it.

Probing Question: How precisely does EN/IEC/62304 offers consumers greater value?

Interviewee: again from the point of safety and efficacy of the product.

Interviewer comment: Although EN/EN/IEC/62304 standard has been embraced as a global benchmark for management of the software development lifecycle, implementation of the standard has been slow (Ken, 2010).

Question 9: What justifies the slow adoption of the standard by medical device manufacturers?

Interviewee: It is the understanding of the requirements, and also people do not have templates. For example, what should go in the design and development software document, what should go in software architecture documents? People are not clear on this. I am answering based on our own experience. We are struggling. What we are doing to do, we are going to buy some temples that are being used in the industry, which are develop by some experts. So we are going to buy them and use them. This is where people have struggled implementing that.

Probing Question: In your opinion what must be done to improve the implementation of IEC 62304?

Interviewee: Training: our firm invested $100,000 on training.

Interviewer comment: The ultimate objective of EN/IEC/62304 is to ensure that medical device software is not only effective but safe.

Question 10: Are you aware of any unintended consequences associated with the implementation of IEC 62304?

Interviewee: So far, we have not seen any adverse even report business.

Probing Question: Are you aware of any effects of the implementation of EN/IEC/62304 on software costs and employees training?

Interviewee: the cost is the cost of compliance. If you are selling a product to the EU, you are required to comply with 62304; otherwise, you might not be able to sell the product.

Probing Question: Any further comments?

Interviewee: I will say that, 62304 is a good standard. The only thing is that we need guidance and more for example, sample templates. If the standard is requiring software architecture document: they should be guidance at the minimum what the content of the software architecture should be. That should help the industry.

Thank you for you participation.

Curriculum Vitae

GUY FOE OWONO
3283 MIRAGE WAY SAN JOSE, CA 95135
EMAIL: GUYOWONO@YAHOO.COM

SUMMARY OF QUALIFICATIONS

Results oriented manager with extensive cross-functional experience in Engineering, Development, Operations, Quality, Risk Management, Six Sigma and Reliability Testing of complex products. International Management Experience. Proven success in building and leading teams involved in hardware, and software. Extensive hands-on and conceptual expertise and experience in all phases of product development process and implementation from concept through product start-up and support. This includes product requirements definition, design and phase reviews, verification and validation, and engineering for new product introduction (NPI) to manufacturing.

Led V&V activities of major medical software releases including 5 Nuclear Medical Gamma camera releases, and a Proton Therapy device over the last ten years.

PROFESSIONAL EXPERIENCE

02/2010 – PRESENT VARIAN MEDICAL SYSTEMS PT, MILPITAS, CA/ COLOGNE, GERMANY

Sr. Engineering QA Manager, and Safety Officer

Reporting to the Director of R&D, direct and control the activities of the Quality, the Risk and Safety Management Teams to ensure compliance to products requirements during development and commercialization phases.

- Act as Safety Officer pursuant to § 30 Medical Devices Act (MPG) in Germany
- Convey and chair meetings of the Change Review Board (CRB)
- Convey and co-chair meetings of the Change Control Board (CCB)
- Co-chair meetings of the Safety Review Board (SRB)
- Develop quality standards for company products
- Participate in technical design reviews and conduct phase gate reviews
- Define and monitor Engineering Key Performance Indicators (KPIs), and present the results of Quality Metrics at the Quarterly Management Review meetings
- Track KPIs CAPA for closure.
- Provide Regulatory and Process training for all employees.

SELECTED ACCOMPLISHMENTS

- Drafted the strategy for the 510 (k) submission of the Proton Therapy Device.
- Developed the companywide employees training matrix to comply with - 21 CFR: PART 820 -QUALITY SYSTEM REGULATION

- Established and conducted all phase gates reviews and managed all aspects of testing and QA for the release of a 100 million Euro project (Proton Therapy Device).
- Established release criteria for the Proton Therapy Device and effectively managed it release.
- Co-directed a task force that oversaw the activities required to obtain CE certification from TÜV (notified body) for the Proton Therapy Device.
- Developed the company Product Development Life Cycle (PLC) and assured compliance to IEC 62304: Medical device software – Software life cycle processes.
- Established the Safety Review Board, the Change Control Board (CCB), and the Change Review Board (CRB); convey and chair these meetings.
- Developed and established both the Engineering Change Order (ECO) and Engineering Change Review (ECR) Processes and trained employees on the ECO and ECR processes.
- Co-directed a task force that established and oversee the CAPA process, the nonconformance (NCR) process and the Complaint Handling process.

07/2008 – 07/2010 – ACCEL INSTRUMENTS GMBH, A VARIAN MEDICAL SYSTEMS COMPANY/ BERGISCH GLADBACH, GERMANY

Head of Engineering QA

Reporting to the Head of R&D, with a dotted line to the Executive Vice President and GM of Varian Proton Therapy Worldwide, directed and controlled the activities of seven departments consisting of up to 30 professionals: Quality Team, Product Configuration Management Team, Risk and Safety Management Team, Compliance Management Team, Technical Publication Team and System Operation Team.

- Built a non-existing Quality Assurance organization and transformed it into a cohesive, aligned Engineering QA organization with improved morale.
- Participated with other senior managers to establish strategic plans and objectives.
- Developed quality standards for company products.
- Developed work instructions for conducting and documenting design reviews
- Participated in technical design reviews and conduct phase gate reviews
- Designed the requirements and oversaw the implementation of Rational ClearQuest as a defect and change tracking tool, and DOORS for requirements management.
- Interacted with executive level and provided vision and leadership in identification, design and implementation of New Product Development.
- Provided Regulatory and Process trainings for all employees including senior managers and executive level as required.
- Directed weekly bug scrubs using ClearQuest

03/2008 – 07/ 2008 PHILIPS MEDICAL SYSTEMS, NUCLEAR SYSTEMS INTEGRATION, MILPITAS, CA

Sr. Quality Manager/SPECT

Reporting to the Director of Engineering Systems, directed the activities of the Quality group and Reliability team involved in 24/7 operation.

- Organized and provided daily briefing to the General Manager of Philips NucMed and the executive staff on progress made during V&V and reliability testing, problems encountered, proposed changes, required actions and potential impacts.
- Co-lead projects from concept through delivery, ensuring compliance in project lifecycle and quality and reliability processes.

12/2007 – 03/2008 PHILIPS MEDICAL SYSTEMS, NUCLEAR SYSTEMS INTEGRATION, MILPITAS, CA

Sr. V&V Lead & Reliability Program Manager IV

Reporting to the Director of Engineering Systems, designed and implemented methods and procedures for inspecting, testing and evaluating the quality and reliability of Single-photon emission computed tomography (SPECT)/ PET/CT products and maintain Six Sigma principles.

- Managed all QA activities of Single-photon emission computed tomography Cameras
- Managed quality resources consisting of up to 15 professionals involved in 24/7 operation.
- Provided daily briefing to the GM of Philips NucMed and the executive staff on testing progress, and on metrics to ensure continuous improvement.
- Directed overall product testing, reliability testing and process quality continuous improvement initiatives realizing 25% increase in department efficiency and achieving ultimate objective of ONE defect call per month.
- Directed weekly bug scrubs using ClearQuest.

7/2000 - 12/2007 PHILIPS MEDICAL SYSTEMS, NUCLEAR SYSTEMS INTEGRATION, MILPITAS, CA

Sr. Verification & Validation Lead

Reporting to the Director of Quality Assurance, organized and managed V&V Testing activities.

- Prepared and participated in two successful FDA audits and inspections in the last five years
- Directed as a project team member weekly bug scrubs using ClearQuest.

7/1999 – 7/2000 ADAC LABORATORIES, MILPITAS, CA

Senior Systems Design Engineer

- Managed all QA testing activities under my supervision
- Participated as a project team member in cross-functional project team activities.
- Generated, maintained and implemented Verification Validation documents for all products under my supervision.
- Performed periodic bug scrub and communicated feedback to R&D staff regarding test findings.

11/1998 – 7/1999 STANFORD UNIVERSITY- CLINIC OF NUCLEAR MEDICINE, PALO ALTO, CA

Graduate Research Assistant

- Participated in the development of a finger detector (Personal Dosimetry).

11/96-10/98 UNIVERSITY HOSPITAL, DEPARTMENT OF NUCLEAR MEDICINE, DRESDEN UNIVERSITY OF TECHNOLOGY, DRESDEN, GERMANY

Graduate Research Assistant

- Conducted research on scattering problems in Nuclear Medicine and evaluated the use of a 3D fuzzy-segmentation method for volume quantification in Nuclear Medicine (SPECT, PET, MCD)
- Evaluated the use of Transmission-Emission Computed Tomography for improved volume quantification using both dual and triple detector SPECT systems in SPECT
- Provided trainings to Physician staffs on the effectiveness of various scatter & attenuation correction methods and image segmentation methods in Nuclear Medicine.

03/97-07/97 CENTRAL HOSPITAL-ST. JUERGEN-STRASSE, BREMEN, GERMANY DEPARTMENT OF BIOMEDICAL ENGINEERING

Summer Associate

- Provided assistance to professional staff in planning investment costs for medical equipment and service contracts with dealers.

08/95-10/95 GLEITMODYLAEN, INC., MUNICH, GERMANY

Engineer Associate

- Received detailed training and experience in ISO 9001
- Ensured that performance and quality of products conformed to establish standards.

PROFESSIONAL DEVELOPMENT

- 12/2007 Philips Six Sigma Green Belt Certification
- 02/2002 Certificate in Risk Management Philosophy of the Medical Devices Directive(s)
- 10/2000 Certificate in Medical Device Software Testing
- 04/2000 Certificate in CQM "Team Problem Solving"
- 03/2000 Certificate in UNIX, C & C++ Programs:
- 02/2000 Certificate in Project Management
- 07/1999 Certificate in Customer Service

EDUCATION

WALDEN UNIVERSITY, SCHOOL OF MANAGEMENT, MINNEAPOLIS, MN 55401

2006 PhD Candidate in Engineering Management & Decision Sciences

DRESDEN UNIVERSITY OF TECHNOLOGY, SCHOOL OF ELECTRICAL ENGINEERING, GERMANY

1998 Master in Electrical Engineering: Biomedical Engineering

1995 B.S. degree Electrical Engineering: Biomedical Engineering

PUBLICATIONS

Author: Foe Owono G.D.*, Schmitt T. *, Oehme L.°, Andreeff M.°, Franke W.-G.°, Freyer R.*: Analysis of the impact of attenuation and scattering methods of the volume quantification in ECT, presented and published on the 32nd Annual Conference of the German Society of Biomedical Engineering (GSBE) in Dresden, Sept. 8-12, 98.

*** Dept. of Biomedical Engineering, °University Hospital, Dept. of Nuclear Medicine, Dresden University of Technology.**

Co-Author: Schmitt T., Foe Owono G.D., Oehme L., Andreeff M., Franke W.-G., Freyer R.: A new Fuzzy-Segmentation approach for volume quantification in ECT, poster-presentation on the 32nd Annual Conference of the GSBE in Dresden, Sept. 8-12, 98.

*** Dept. of Biomedical Engineering, °University Hospital, Dept. of Nuclear Medicine, Dresden University of Technology.**

SPECIAL SKILLS

- Excellent knowledge and understanding of the requirements of ISO 9001, ISO 13485, FDA 21 CFR 820 (QSR), PART 11 – CFR, EN ISO 14971, IEC 62304, IEC 62366, IEC 60601 3rd Edition
- Excellent knowledge of common industry practices like DFM/DFT, FMEA, Design for 6-sigma. ISO/IEC 12207 Systems and software engineering — Software life cycle processes,
- Familiar with MIL-STD-498, on software development and documentation and MIL-STD-499, on Engineering Management (System Engineering)
- Cross-cultural and international experiences in the USA and abroad. International travel.

Foreign language proficiency: Proficient in French and German, basic knowledge of Spanish

Affiliation: Member of the American Society for Quality

Special interests: Aviation/aeronautics, traveling, black belt in Tae Kwon Do, and table tennis.