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# Feasibility of Human Factors Research in Medical Device Development

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## Abstract

Patient safety is strictly at the forefront during the inception and development stages of medical devices production. Protecting medical device users is a key concern when global medical device companies are seeking to bring a new product to the U.S. market. The Food & Drug Administration (FDA) has set forth clear expectations regarding necessary documentation that must be submitted along with the premarket submission for medical devices. One of such essential documentations includes a valid Human Factors Summary Report. Identifying important elements that define and govern human factors consulting firms that create such reports is the main focus of this project.

Examining the reliability, integrity, functionality, and influence that such reports carry is not only looked into closer, but its findings are also conceptualized in the form of a booklet, which advertises human factors consulting services to potential clients. The objective is to clearly define what constitutes a successful report, how are such services beneficial to their client and ultimately patients, and the processes that encompass human factors research. The booklet serves as a visualization tool that serves not only as an informational source, but also as a summary of all key elements.

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## Glossary

**Ergonomics.** Application of scientific information to improve human work environments.

**Human Factors Engineering.** Study of improving device design, usability and safety.

**Pre-market Approval.** Process to gain FDA approval for high-risk medical devices.

**Pre-market Notification.** Process to gain FDA approval for modified devices with a predicate.

**User interface.** Interaction between user and device or software.

## Abbreviations

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| CDRH | *Center for Devices and Radiological Health* |
| COI | *Conflict of Interest* |
| FDA | *Food & Drug Administration* |
| HFE | *Human Factors Engineer* |
| ICF | *Informed Consent Form* |
| IRB | *Institutional Review Board* |
| IVT | *Institute of Validation Technology* |
| PMA | *Pre-market Approval* |
| PMN | *Pre-market Notification* |
| RFP | *Request for Proposal* |

# Chapter 1.

# INTRODUCTION

## 1.1. Background

In order to successfully navigate the United States Food and Drug Administration's (FDA) pre-market approval (PMA) process, it is paramount for medical device manufacturers to be fully aware of existing regulatory requirements. The FDA's PMA process serves as a way to apply scientific and regulatory methods to improve the evaluation process of both the safety, as well as effectiveness of Class III medical devices.[1] Class III medical devices are considered to be high risk and are especially scrutinized by the FDA, due to the level of impact they can have on the human health. Devices such as implantable pacemakers and ventilators are considered to be Class III devices, the FDA states that only 10% of marketed medical devices are part of this risk classification.[2]

It is important to note that the PMA process is rigorous and requires extensive clinical evidence. According to Dr. Gail Van Norman, a scholar and bioethicist, if a Class III device has a predicate and only minor modifications are being implemented, manufacturers typically have the ability to undergo the pre-market notification (PMN) regulatory path. Dr. Van Norman states that the PMN process is less rigid and does not emphasize the need for clinical evidence, as compared to the PMA regulatory path. Regulatory paths justifiably vary depending on the device's classification, Dr. Van Norman believes that the FDA's capability to protect patients by

[1] U.S. Food & Drug Administration. (2018b). *Premarket Approval*, https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/#when

[2] U.S. Food & Drug Administration. (2017). *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, https://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm

reinforcing its standards of safety and efficacy could be compromised if processes for drug and device approval became streamlined.[3]

Introducing potential life altering and health improving medical devices to the market is crucial and can help to sustain medical innovation globally, yet if the approval process is rushed or incomplete, the device could be more harmful, rather than beneficial to patients. Depending on a devices assigned regulatory Class (I-III), the regulatory control governing that class varies. Due to Class III devices having a more thorough approval process, the following inquiries are closely evaluated by the FDA: Does scientific evidence exist that the potential risks of the device are less than the positive aspects that can ultimately benefit patients, and will the device become advantageous to the health of the population it seeks to benefit?[4]

Navigating the FDA's approval process is best accomplished by including the expertise of a human factors consulting firm early on in the product development stages. It is in the manufacturer's best interest to seek guidance from a third party, such as a human factors consulting firm, due to the specialized knowledge consultants can provide, as well as the lack of potential conflict of interest (COI). Human factors consultants are typically not employees of the medical device manufacturing company nor have they directly participated in the design process of the device. They collect data by conducting research studies that examine the interface between participants and medical devices, they heavily rely on evidence-based guidelines and principles to create methods that will decrease potential harm to patients and increase the level of assurance in terms of safety and effectiveness of medical devices.[5] Human factors is similar to

[3] Gail A. Van Norman. (2016). *Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices*, JACC: Basic to Translational Science, Vol. 1, Issue 4, 277-287.
[4] U. S. Food & Drug Administration. (2018c). *Step 3: Pathway to Approval*, https://www.fda.gov/ForPatients/Approvals/Devices/ucm405381.htm.
[5] World Health Organization. (2009a). *WHO Patient Safety Curriculum Guide for Medical Schools*, World Health Organization, 100-107.

'Ergonomics', which aims to apply scientific information regarding humans and their relation to object design, systems and environment for human use.[6]

### 1.2. Statement of the Problem

Human factors consultants, also known as Human Factors Engineers (HFEs), seek to improve the device design. Their recommendations, which are based on findings through observation, interview assessments, risk analysis, and other data collection methods, are intended to improve usability and user interface, as well as ensure patient safety. Their reports provide guidance to medical device manufacturers and help to show that thorough evaluations were conducted. According to the United States Department of Health & Human Services, HFE's responsibilities are defined as,

> "Applying what is known about human capabilities and limitations to the design of products, processes, systems, and work environments. It can contribute to the design of any system with a human interface, including hardware and software". [7]

Analyzing the feasibility of the reports that are created as a direct result of device evaluations will help to establish further understanding on the topic and examine the positive impact the work of HFEs has had on patient safety over the years. The goal is to find how reliable and effective such reports are and to what extent they influence product design and development. The main focus during such studies is to identify potential risks to the patients that will be using the device, as well as weighing the strengths and weaknesses of the product, such an evaluation allows for the user interface to become efficient and most importantly safe. Manufacturers are often times not fully aware of potential user errors, until their product undergoes user interactions and HFs receives direct feedback from carefully recruited study participants.

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[6] World Health Organization. (2009b). *Human Factors in Patient Safety Review of Topics and Tools*, World Health Organization, 5-6.

[7] U.S Department of Health and Human Services. (n.d.). *Human Factors Engineering (HFE)*, https://www.usability.gov/what-and-why/glossary/h/index.html.

### 1.3. Project Question(s)

In search of answers to questions such as the significance of human factors research and how effective the reports of human factors consultants are, it is important to first understand the processes that are applied and the types of devices that are being investigated. Additionally, it is essential to take a closer look at the regulatory frameworks the FDA has set in place to further examine, if patient safety has increased over the years and if current measures are effective. Other questions also include the method by which human factors consulting firm gain clients, what services are provided to them, and what defines success reporting and how it is measured.

### 1.4. Project Objectives

The project seeks to provide further clarification regarding the feasibility of human factors research, especially during the development of medical devices that are considered to be high risk. The FDA has taken precautions in order to ensure that medical devices used by patients are both safe and effective. One of such precautions includes the need for a human factors reporting, which outlines the usability and safety of a device, by conducting research studies involving participants from the general population. This approach can best determine a device's usability and can detect any use errors that could potentially occur, prior to a device gaining market approval. The aim is to not only examine current human factors research processes in terms of medical device development, but also to understand the relationships and connection between human factors consulting firms, their clients, and the FDA.

### 1.5. Significance

Patient safety is a concern that affects individuals from nations across the globe. It is in society's best interest to ensure that current implemented regulatory frameworks and guidelines are appropriate and best suit the needs of the medical community. Medical devices are used by

both patients and doctors, ensuring that such devices are user friendly and do not pose a risk to the well-being of all parties involved is complex and requires particular expertise. Needed expertise can be gained and applied to a device by including the services of human factors consultants. Such consultants typically have an extensive background working with medical device manufacturers and pharmaceutical companies.

According to a book written by the Institute of Medicine in 1999, health care in the US has plenty of room for improvement. The book states that approximately 44,000 to 98,000 patients die per year, due to medical errors that could have been prevented, besides errors in performing operations and procedures, the book also lists equipment and system failure as a factor that play key roles.[8] The FDA's responsibility is to protect individuals from preventable errors, by necessitating medical devices to undergo human factors testing. The federal agency is taking pro-active steps in hopes of decreasing hazardous devices from gaining market access and to ultimately increase patient safety.

### 1.6. Exclusions and Limitations

Due to the small pool of human factors consultants that specialize in medical device development, more specifically device design, gathered information is not intended to set a standard or create generalizable knowledge, but rather to provide a look into some of the key elements that govern such consulting firms. This project primarily provides an overview of research processes and highlights key elements. Previously created questions to gain more knowledge about the topic were followed, an exploratory approach that examined the project objectives. The focus was on human factors research in the field of medical device development.

[8] Institute of Medicine. (2000). *To Err Is Human: Building a Safer Health System*. Washington, DC: The National Academies Press.

# CHAPTER 2.

# PROJECT DESCRIPTION AND NEED ASSESSMENT

## 2.1. Discussion of Project Elements

Due to the influence HFE have on medical device development, especially during the design and evaluation stages, it is important to take a closer look as to what research processes human factors consultancy firms utilize to create such significant reports. The project focuses on the analyzation of support services consultants provide, in order to assist medical device manufacturers by turning their research into a successful, operational, and marketable product. The FDA's Office of Device Evaluation strongly believes that minimizing use-related hazards and risks by applying human factors/usability engineering processes.[9] The objective is to evaluate the validity of hiring a third party to conduct human factors research on behalf of the manufacturer. Additionally, to ascertain more knowledge in terms of important elements that constitute a successful human factors consulting firm geared towards medical device development. Such elements include research processes, acquisition and maintenance of client funding, and accurate reporting methods.

This capstone project consists of collected research and data that aims to bring a better understanding to the profession of an HFE, justify why such services are indispensable to the research community, and provide a comprehensive report by creating a booklet geared towards attracting potential clients seeking to bring a medical device to market. The comprehensive report will encompass the need and effectiveness of human factors research reporting and how it

[9] U.S. Food & Drug Administration. (2018a). *Human Factors and Medical Devices*, https://www.fda.gov/medical devices/deviceregulationandguidance/humanfactors/default.htm.

increases patient safety, the booklet on the other hand, will serve as a visual tool to highlight the most important and relevant elements of human factors research from the perspective of potential medical device manufacturer clientele.

**2.2. Need(s) Assessment**

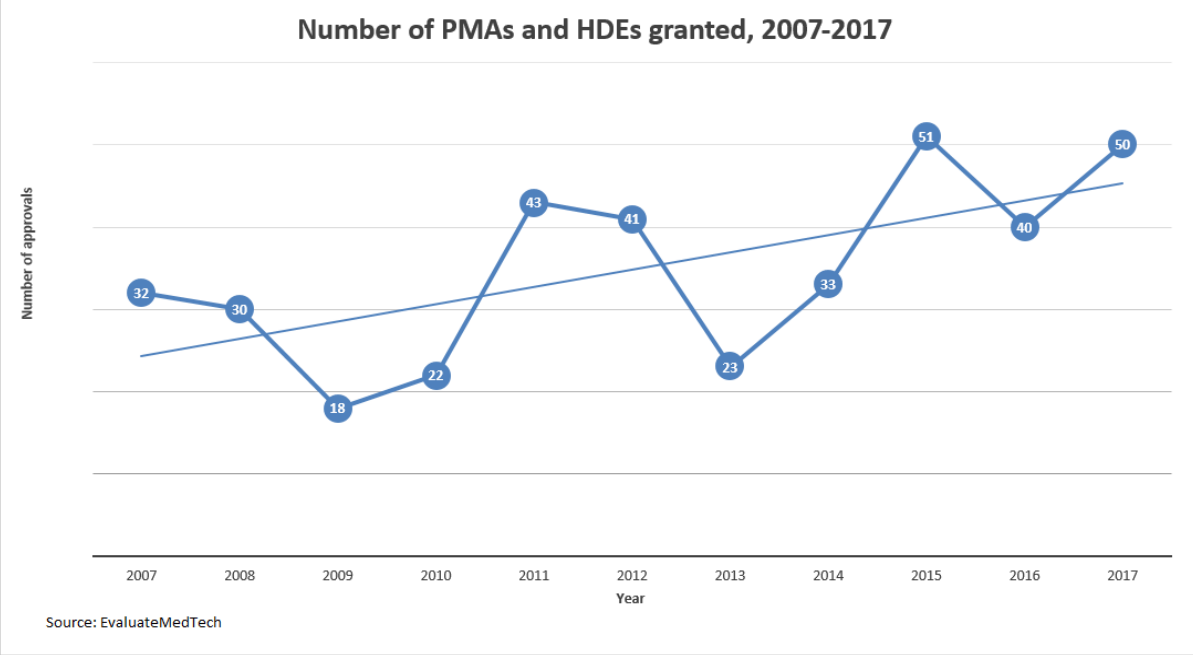
An article published by **t**he Harvard Business Review entitled, *Why Organizations Forget What They Learn from Failures*, examines why errors occur and tend to reoccur over time. The author Francisco Polidoro Jr., explains that product recall due to safety concerns triggers a 'learning cycle', during which organizations adamantly seek to improve existing errors, however, the issue is that initial motivating forces gradually cease and lead to "seeds of the next error".[10] With an increase of Class III devices being introduced to the market, patient safety remains a valid concern. Human factors consulting services are essential due to the research findings and recommendations they can provide, which in turn help to uphold the FDA's mission to protect patients from harm resulting from faulty device design or use error.

Elizabeth Cairns' article, *Twice as many in half the time: the FDA speeds up device approvals*, provides valuable insight into a complex issue. In her article she explains that there has been a significant increase of FDA approvals since 2007, yet the FDA still seems to have difficulty with finding a balance between introducing potentially life-saving medical devices to patients and rejecting devices that are considered to be too high risk or provide only few benefits to the population.[11] The image below depicts the noticeable increase in FDA device endorsements over a ten-year span.

[10] Francisco Polidoro Jr.. (2016). *Why Organizations Forget What They Learn from Failures*, https://hbr.org/2016/02/why-organizations-forget-what-they-learn-from-failures.

[11] Elizabeth Cairns. (2018). *Twice as many in half the time: the FDA speeds up device approvals.* http:// www.epvantage.com/Universal/View.aspx?type=Story&id=761422&isEPVantage=yes.

Table 1. Number of PMAs and HDEs granted, 2007-2017[12]



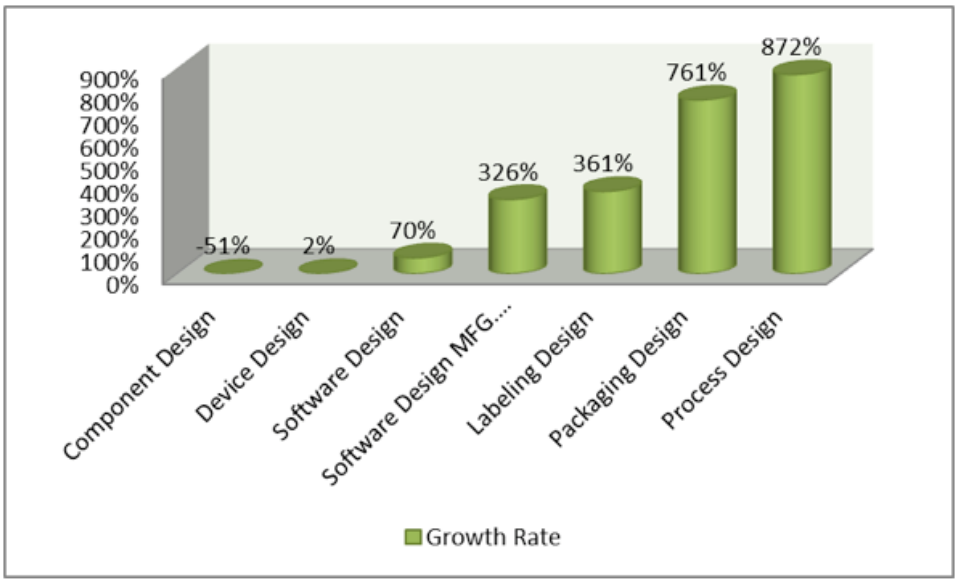

Source: EvaluateMedTech (2018), published by EP Vintage-powered by EvaluateMedTech

Another alarming fact that supports the need for accurate human factors research reporting is the number of medical device recalls between 2010-2015. The Institute of Validation Technology (IVT) published a report that raised awareness about the increase in medical device recalls between the years 2010-2015. The institute called it an epidemic whose root cause included issues such as flawed device and process design, device labeling, and software design.[13] The analysis of recall trends and identification of the different design components that brought about such a spike in recalls is based on CDRH's published data that includes recall repository data, as well as the FDA's yearly published reports on medical device recalls. The table below shows the growth year of each design component between the years of 2010-2014.

[12] ibid

[13] Institute of Validation Technology. (2016). *Recall Epidemic 2010-2015:Medical Devices*, http://www.ivtnetwork.com/article/recall-epidemic-2010-2015-medical-devices.

Table 2. Recall Growth Rate % 2010-2014[14]




Source: Created and published by the Institute of Validation Technology (2016)

Based on annually published reports by the FDA it has become evident that there is a consistent need for accountability and oversight of medical device manufacturers and the devices that they bring to market. In regard to the table shown above, The IVT provides the following conclusion,

> "In correlation with the upward trending of device design recalls, medical device manufacturers have failed consistently to mitigate hazards associated with component design, labeling design, packaging, design, process design, and software design. Each of these sub components of device design has seen a drastic upward trend in related recalls over the last five years, with only component (-51%) and (+70%) staying under a 100% growth rate average over the same five year span". [15]

The goal is to effectively address device issues that pertain to critical components such as the design, software, labeling, packaging as early as possible and not until after the device is already on the market. The recall growth rate is concerning and poses a risk to millions of patients, if appropriate measures are not taken by the FDA, a steady increase of recalls is likely to occur.

[14] ibid
[15] ibid

### 2.2.1. Establishing the Need

In order to determine the need, it is important to first analyze the issue and the major components that are leading to the continuation of the problem. This is best accomplished by taking a closer look at published reports that provide factual evidence, which helps to support the argument for the need. For this project, the need for human factors research in medical device development is made clear through the large number of recalls within the past decade and the gradually increasing amount of high risk medical devices that are being approved by the FDA. It is important to notice that the FDA seeks to create a balance between device need and patient safety. HFEs aim to assist not only medical device manufacturers, but also the medical community as a whole.

### 2.2.2. Metrics

Statistical based evidence depicted through graphs and diagrams serve as a visual aid to better understand the existing issues and needs. Evidence published by healthcare analysts and research institutions was utilized due to the factual data presented in their reports.

### 2.2.3. Sources

The primary sources for this project are government agencies such as the FDA and CDRH, as well as healthcare analysts and human factors experts that have written insightful articles and reports. Other sources include publications by the World Health Organization, which serve as guiding documents for healthcare and human factors professionals on a global scale.

# CHAPTER 3.

# LITERATURE REVIEW

## 3.1. Overview of Literature Review

The primary sources utilized for the examination and analysis of the topic are documents created under the supervision of the FDA and experts that have extensive experience in the field of human factors, as well as articles that have been published, highlighting the significant contributions of human factors engineering. The Center for Devices and Radiological Health (CDRH), which falls under the direction of the FDA, is a valuable resource for human factors consultants. The governmental agency's publications provide key non-binding guidance and recommendations on how to properly conduct research and ultimately protect device users. Prior to the 21st century, HFE was not a priority to most medical device manufacturers. However, since the early 2000s, the FDA have pushed for an increase in patient safety and devices that effectively could meet the needs of users.

Experts argue that the FDA was a motivating force by implementing FDA created regulations that slowly, yet steadily increased the agency's supervision and enforcement. According to the article entitled, *The Benefits of Applying Human Factors Engineering*, published by the Industrial Designers Society of America, the article argues that medical companies largely focus on human factors engineering from a regulatory standpoint versus addressing commercial imperatives.[16] They fear that such a shift in priorities could take away from collaborations with industrial designers, seeking to create devices that are not only in compliance with governing regulations, but are also user friendly and address the needs of

[16] Michael Wiklund, StephenWilcox. (2014). *The Benefits of Applying Human Factors Engineering*, Quarterly of the Industrial Designers Society of America, Vol. 33, No.2, 44-48.

patients.[17] Although there have been varying thoughts on the role HFEs should play in the product design stages, human factors research has become a significant method of evaluating the safety and usability of medical devices.

### 3.2. Details of Literature Review

In 1995, the National Research Council published a book entitled, *Emerging Needs and Opportunities for Human Factors Research*. The council explains that human factors research is intended to minimize the possibility of human error from occurring by challenging existing medical device designs, as well as health care practices.[18] Human factors research primarily consists of two separate, yet equally important types of methods of evaluation, which are formative studies and validation testing. The method with which consultants apply research processes is dependent on the needs of the client. Research methods can be individualized to best address the clients known concerns and device safety concerns that were not apparent at first, but surfaced during the research study with study participants.

An example of safety concerns that arose during human factors studies involved epinephrine auto-injectors. These devices are used during food allergy emergencies and have been proven to be life-saving, if used correctly within a short period of time, after an allergic reaction occurs. According to an article written by Laura Gosbee, a human factors consultant, human factors research studies have shown that both patients and doctors have had difficulty using the epinephrine auto-injector exactly the way that the medical device manufacturer intended. Additionally, portability of the device was identified as an issue, its size made it

[17] ibid
[18] National Research Council. (1995). *Emerging Needs and Opportunities for Human Factors Research,* The National Academies Press, Washington, DC, 3-5.

inconvenient to carry on one's person.[19]An advantageous component when seeking to gain FDA market approval is to collect solid evidence in terms of usability and safety of products by allowing a product to undergo human factors evaluation processes.

The CDRH clearly defines the meaning of human factors formative evaluations and validation testing. Formative evaluations are conducted during one or more stages during the device development process and help to identify user interface's strengths and weaknesses, as well as seeks to identify potential use errors that could arise. Contrary to the formative evaluations, validation testing is conducted at the end of the device development process, assesses the effectiveness of risk management measures, but similarly focuses on assessing potential harm that may arise due to user error.[20] The CDRH has mentioned in its publication of the human factors engineering guide, which is targeted towards industry and FDA staff, that it views human factors testing as an imperative component of product development for medical devices.[21] It highly recommends for medical device manufacturers to utilize human factors testing as a component of their design control subsystem. While the goal is to avoid serious harm from occurring to patients, the CDRH also cautions that conducting human factors testing in an incorrect manner or completely leaving out such a valuable component, could lead to an increased risk of harm to users.[22]

In addition to formative evaluations and validation testing, human factors consulting services can also include medical device labeling readability testing. Readability testing regarding medical device labels evaluates a patient's ability to comprehend the printed

[19] Laura Lin Gosbee. (2004). *Nuts! I Can't Figure Out How to Use My Life-Saving Epinephrine Auto-Injector!*, Joint Commission Journal on Quality and Safety, Vol. 30, No. 4, 220-223.
[20] U.S. Department of Health & Human Services. (2016). *Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff*, https://www.fda.gov/downloads/MedicalDevices%20%20/.../UCM259760.pdf., 1-3.
[21] ibid
[22] ibid

information and comprehend, as well as follow set instructions. Proper labeling of devices is important and can protect patients from potential use errors, being exposed to risks, and helps to assure safe and effective use.[23] Due to changing regulations governing product development, it is essential for human factors engineers to remain abreast of such changes and to ensure that quality consulting services are consistently provided to clients.

The British Standards Institution (BSI) focuses on best practices, it is the world's first National Standards Body. BSI seeks to assist organizations by improving their internal performance, as well as reduce risk while sustaining growth.[24] An article written by Bob North, which was published by the BSI group, highlights the key responsibilities involving human factors services and how relevant and essential such services have become over the years. In the article entitled, *The growing role of human factors and usability engineering for medical devices*, the author states the following,

> "Usability has a major impact on healthcare, particularly with regard to the overall effectiveness of medical devices. Simply put, if usability is lacking, the completion of user tasks may be slower and more error-prone. Therefore, delivery of therapy will suffer and patient safety may be compromised. Moreover, it is well known that easy-to-use products are more popular, resulting in market discrimination and a competitive advantage. Therefore, usability can be a positive attribute from a business and sales perspective as well as controlling risk".[25]

### 3.3. Applicability of the Literature Review

The primary focus when reviewing relevant literature was to identify sources that provided expert knowledge, as well as data from previous studies involving human factors research processes that have been conducted. This focus helps to provide a clear overview of the

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[23] U.S. Food and Drug Administration. (2001). *Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers*, https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationand Guidance/GuidanceDocuments/ucm070801.pdf 5-6.
[24] British Standards Institution, *About BSI*, https://www.bsigroup.com/en-GB/about-bsi/
[25] Bob North, (n.d.). *The growing role of human factors and usability engineering for medical devices*, https://www.bsigroup.com/LocalFiles/es-ES/Medical%20devices/Papel_ingenieria_ usabilidad_dispositivos _medicos_BSI.pdf, 2-3.

topic being explored and provides further insight. The presented literature informs the reader of set guidelines that human factors must abide by while performing consulting services. The importance of the work human factors consultants do is outlined within guiding documents created by government agencies and significant contributions are highlighted by experts in the field. It is important to draw a connection between the expectations of the FDA and the support human factors research provides, in terms of increasing patient safety by evaluating medical device design and usability.

# CHAPTER 4.

# PROJECT METHODOLOGY

## 4.1. Methodology Overview

Data collection was primarily obtained through observational and interview methods, interviews were conducted face-to-face. The collected data was then analyzed and compared to published literature and various consulting firms that specialize in medical human factors. This approach provided an opportunity to fully understand human factors research processes and applications, the needs and expectations of medical device manufacturers, as well as the safety precautions set in place for human subjects, which choose to voluntarily participate in human factors research studies. Lastly, reports resulting from research studies are discussed to further understand how findings are made and communicated to the client, in order to ensure that patient safety is ultimately achieved.

Collected data is presented in the form of a booklet. The booklet details services provided by human factors consulting firms. It is a booklet that can serve as a useful resource to potential clients and those that are interested in the field. The booklet contains a list of services that established consulting firms provide, an overview of research processes and methods, human factors research reporting success rates and how success is measured, a step-by-step explanation of human factors research approach and execution, and further explanation as to why human factors research services should be acquired by medical device manufacturers. The objective is to clearly define what constitutes a successful report, how are such services beneficial to their client and ultimately patients, and the processes that encompass human factors research. The booklet functions as a visualization tool that serves not only as an informational source, but also as a

summary of all key elements. Visual and textual components help to create a booklet that functions as a potential marketing tool and source of information.

**4.2 Project Design and Discussion**

The project is comprised of various elements, such as the collection of data through observation and direct input from experienced human factors consultants, as well as the review of published literature that has been written by experts in the field of human factors. The project's lay out consists of the collection and verification of data, which in turn is conceptualized through the creation of a booklet (see Appendix 2). The booklet serves as a tool for readers to review the key components that govern a successful human factors consulting firm, from the perspective of a potential client, medical device manufacturer, or an individual that simply seeks to gain more information. Significant knowledge that can be gained by reviewing the booklet include a detailed outline of the services consulting firms provide, why their services are indispensable when it comes to ensuring patient safety, and how accurate reports are created that ultimately serve as a guide for their clients to improve device design and meet regulatory requirements.

Prior to collecting data through observational and interview methods, it is essential to properly review existing medical device guidelines and market approval processes established by the FDA. The FDA has the power to approve or reject a medical device that is attempting to reach the market, if the agency deems that there are remaining patient safety concerns or if the device fails to be proven as effective. By fully understanding the expectations of the FDA, a solid foundation is built to then better comprehend why the work of human factors consultants is vital to their clients. After the review of relevant publications created by the government agency and various human factors experts, the process of observing and interviewing human factors

consultants helps to provide clarity from a realistic and applicable perspective. This process enables one to see the field of human factors and the responsibilities that consultants carry in a more in-depth manner. Lastly, the booklet is created as a marketing tool, it provides a summary of the topic and highlights key components. The booklet consists of relevant images, figures, and written text.

### 4.3 Discussion of Interview Processes

The interview process allowed for relevant knowledge about human factors research to be more closely examined. The process consisted of specific questions that were posed to three professionals that work actively in the field and have varying levels of consulting expertise (see Appendix 1). Listed questions do not ask for private information that could harm research participants or violate their privacy, as well as their clients. Due to the type of support that consultants provide to their clients, it is important to treat gained information in a sensitive manner. Comparing and contrasting actual human research processes with the guidelines provided by the FDA, enabled the verification and validation of existing practices. Qualitative data was collected by interacting with consultants and conducting interviews on an individual basis in an informal setting.

The collected data was written down and provided responses were then compared to one another. Additionally, research was conducted to verify the validity of the qualitative data by paralleling the responses to published literature. The type of questions posed to the interviewees were not too specific, which could have caused confidentiality concerns. The aim was to receive honest feedback regarding their view on how the work that they do as consultants benefits both medical device manufacturers, as well as increases patient safety. Interviewees had the opportunity to speak from a professional stand point and discuss their work experiences, while

operating within the field. Remarkably, all three participants strongly believe in the positive impact that their consulting work has regarding patient safety. It is important to note that published literature by the FDA was often times referenced, when explaining why human factors consulting services are essential to medical device development. This shows the depth of influence and guidance that the FDA has within this profession.

Responses to questions regarding the procurement of future funding were clarified by explaining the process by which all human factors consulting firms secure clients. Medical device manufacturers select the consulting firm(s) that they wish to work with and release a confidential Request for Proposal (RFP). Afterwards, both parties negotiate pricing and the contract terms. A concrete response to the question on how success is measured could not be provided in an open manner, due to the lack of specified quantitative data. For a consulting firm, success is measured by the projects that they receive from clients. The standard of success is not measured by the devices that are approved by the FDA or the number of patients that benefit from the medical device.

Answers in terms of patient safety and upholding the integrity of collected data were straightforward and in accordance with current laws and regulations. Interviewees were fully aware of the ramifications that come along with non-compliance and discussed the importance of including IRB approval on research studies that posed potential harm to study participants. This proactive approach helps to mitigate potential risk and ensures the physical and legal protection of all parties involved. Furthermore, non-compliance can lead to a tarnished reputation and the loss of data integrity, which is especially detrimental to the consulting firm’s client.

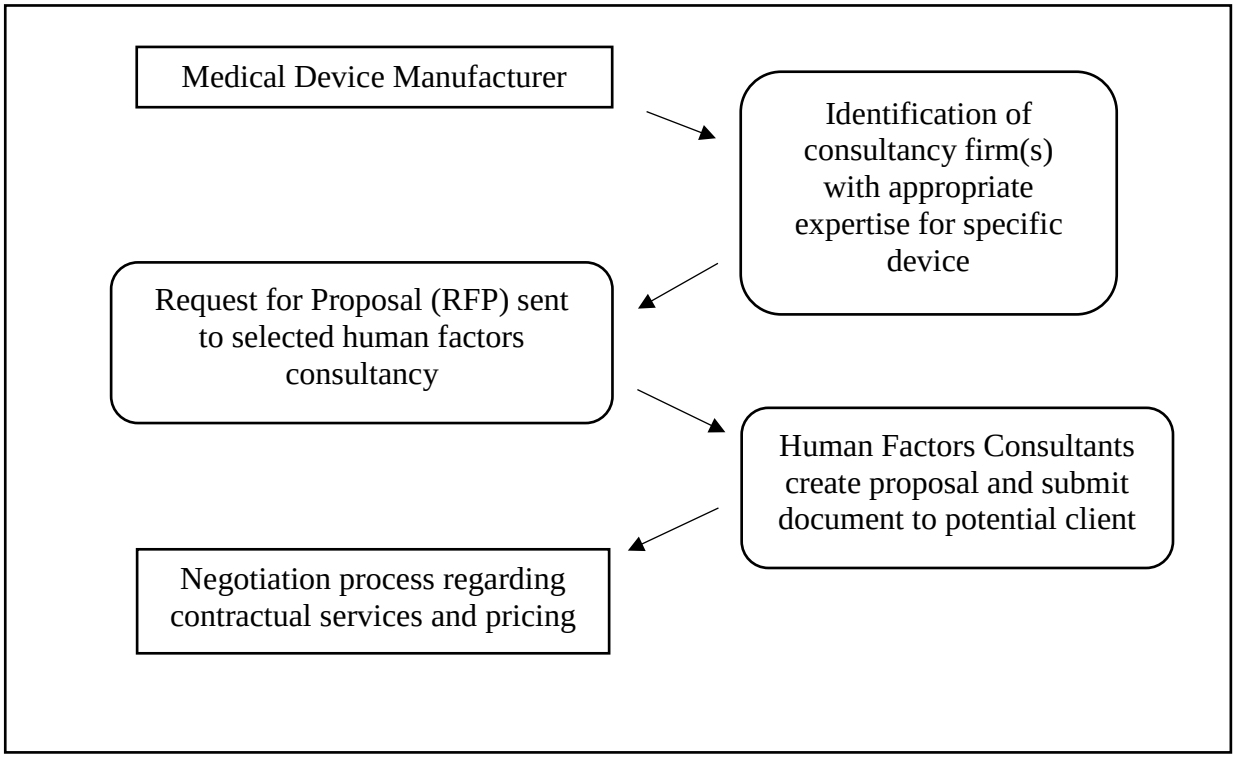
# CHAPTER 5.

# PROJECT RESULTS AND DISCUSSION

## 5.1 Project Result 1

The purpose of the project is to develop a better understanding of human factors research in regard to increasing patient safety by providing expert knowledge on how to improve medical device design, prior to medical device manufacturers seeking market approval from the FDA. By understanding the various research processes that are applied to human factors studies, it becomes more evident as to how impactful the work of human factors consultants truly is. Below is a chart that depicts the manner in which initial communication between clients and consultants is established. Consultancy service providers are selected by the medical device manufacturer.

Figure 1. Initial Communication with Consultants and Client



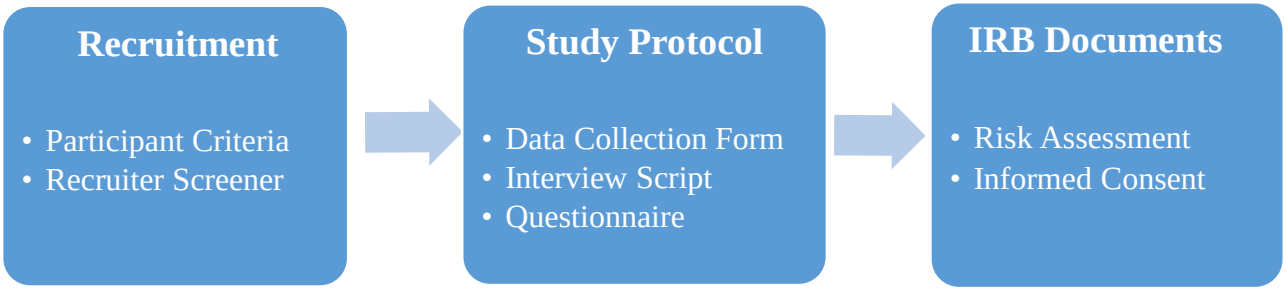

Source: Gloria Mainz

Due to the highly confidential nature of the medical device products that manufacturers are seeking to bring to market, RFPs are not made public and are only intended to be received and reviewed by select human factors consultants. In the field of human factors, confidentiality plays a key role and becomes the foundation of each consultancy-client relationship. Therefore, if selected to provide services, consultants are made aware of the level of commitment and responsibility that is expected from them by the client. It is important to note that consultants receive funding on a project basis, rather than being contracted to the same client over a span of years. This helps to alleviate any bias when conducting research studies and creating reports regarding the safety and efficacy of the device. Additionally, COI does not become an issue that can potentially impede progress or invalidate the final report submitted to the FDA.

Once a contractual agreement has been made between both parties, the consultancy team develops a strategy to best address the client's needs. This can range from creating a use risk assessment of the device to conducting either a formative evaluation study or validation testing. The method with which the device is analyzed and evaluated strongly depends on the device's development stage and the needs of the client. Ultimately, clients identify and express their desired services in the RFP, however, it is under the consultant's discretion to discuss other potential concerns that may arise and how to mitigate them. For example, a client may be requesting that validation testing be conducted in order to prove that the device is safe and ready to be introduced to the market at its current stage. If a consultant identifies risks that need to be addressed, the consultant should inform the client of the safety concerns and recommend that additional services be provided, such as a use risk assessment or that a readability test regarding the device's labeling be conducted.

Similar to clinical research studies, human factors research involves the creation of study documents, requires IRB approval (if applicable), and recruitment of study participants. The figure below shows the essential actions that need to be taken in order to conduct studies that are ethical, compliant with regulatory and legal guidelines, and most importantly result in relevant and helpful data.

Figure 2. Study Documents Preparation




Source: Gloria Mainz

Study participant recruitment is usually conducted by acquiring services from an outside recruitment company that specializes in finding human subjects that meet the criteria. The selection criteria is provided to the recruitment company by the consulting firm shortly after the negotiation process with the client has concluded, in order to ensure that sufficient time is afforded to successfully screen and recruit participants, as well as schedule and reserve a suitable research facility. Utilizing a third party is efficient due to the time constraints and limited resources consultants face. Their services typically do not include participant recruitment and making facility reservations. The recruitment process is time consuming, often times consultants have a strict timeline that they must follow, in order to deliver the requested services to the client according to a pre-negotiated schedule.

Prior to the study begin, clients are presented with the individualized study documents, which include the documents listed above in Figure 2. This helps to ensure that their needs have been fully understood and that the study framework meets their expectations. Additionally,

clients are asked to provide feedback and confirm accuracy of the device information mentioned in the study protocol. This approach helps to ensure that final reports submitted to the FDA are accurate and that collected data involving the medical device is directly applicable to the device design.

### 5.2 Project Result 2

Through the application of interview/observational methods and further literature review, insight regarding the process by which human factors consulting firms gain clients, what services are provided to their clients, what defines success reporting, and how is success measures. Data collected through interviews shows that success could not be discussed in depth using quantitative data. As mentioned previously, success is measured by the projects that they receive from clients. From the perspective of a consulting firm, the standard of success is not measured by the devices that are approved by the FDA or the increase of safe devices that are being used by patients. A concrete number of successful projects per year could not be attained due to such records being of confidential nature.

According to interviewed human factors consultants, human factors summary reports are created on behalf of the client to submit to the FDA, as part of the market approval process. A successful report encompasses key elements such as detailed explanation of the need for the device and its purpose/target population, risk analysis of the product and how it compares to similar devices that are on the market, any design changes that have been made to the device as a result of potential safety concerns, and the results of applied human factors research methods. Formative studies and validation testing are two main components of human factors research that seek to detect obvious and less evident device design issues that can lead to use errors. The first goal, prior to beginning the research study, is to create a study protocol that includes primary and

exploratory objectives. This is typically established by the client. Essentially, it is the consultant's responsibility to create a research plan that will address all of the client's concerns, as well as identify potential errors or concerns that the FDA may have in regard to the device. Consultants must be able to mitigate present and anticipated safety concerns, in order to create a comprehensive report. The second goal is to execute studies in a compliant manner.

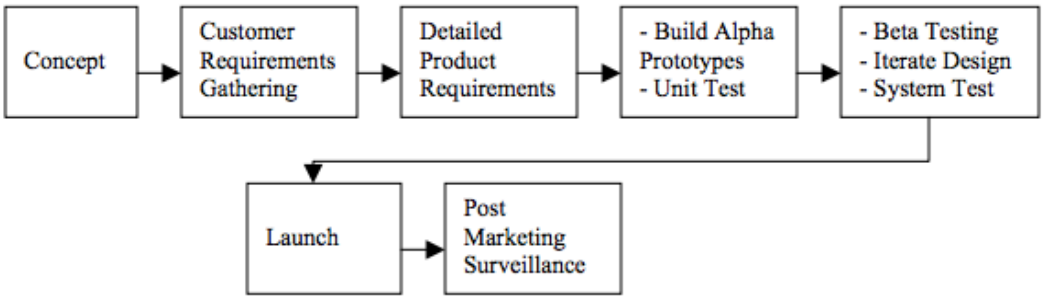
Based interview responses and observation, the safety of study participants is taken very seriously. Informed consent forms and IRB approval (if applicable) are another key component to successfully executing human factors research. Consultants ensure that participants remain safe by informing them of potential risks prior to the start of their session, as well as implement preventative measures. For example, if a participant acts in a manner that could lead to self-harm, after he or she has already been informed of potential risks, study staff will intervene and discontinue the session immediately. The collection of data does not take precedent over the safety of those participating in the study.

Depending on the work that a consulting firms finalizes on behalf of a client, the reputation grows and either helps to gain potential clients or decreases the number of projects that the firm receives. Medical device manufactures reach out to carefully selected consulting firms, this makes accurate and comprehensive human factors reporting imperative. Within the healthcare sector, consulting firms are recommended depending on their effective customer service, application of relevant expertise, and reporting skills. According to an article entitled, *Challenges in HCI Development for Medical Devices: A Human Factor's Perspective*, the authors explain that there is a need for regulatory approval and design controls that include a comprehensive risk analysis, as well as evaluation and mitigation.[26] The figure below shows the

[26] E.W. Isrealski, W.H. Muto. (n.d.). http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.455.2678 &rep=rep1&type=pdf, 1-3.

medical device development process from the perspective of a client, consultants are needed typically during the alpha prototype building and beta testing stages.

Figure 3. Typical Product Development Cycle[27]




Source: E.W. Isrealski, W.H. Muto, Abbott Laboratories

Based on research findings, the following key components were incorporated into the booklet: Emphasis on customer service skills and consultant expertise, types of research methods applied to address needs, list of services provided to clients and previously types of projects that have been completed, and the firm's contact information (see Appendix 2). The booklet does not represent a specific human factors consulting firm, but merely serves as a tool to visually review elements discussed in the capstone project. HF Consulting is a fictional firm that was created to create a sample booklet that a consulting firm could use for marketing purposes. The document is designed to attract potential clients and individuals that seek to gain further insight. The reason why this approach was taken is to provide a clear overview of the capstone project. Furthermore, the booklet highlights important components that govern human factors consulting firms that specialize in the field of medical device development.

[27] ibid

# CHAPTER 6.

# RECOMMENDATIONS AND DISCUSSION

## 6.1 Introduction

After careful examination of collected data via interview and observational methods, it became evident that research processes and other services provided by human factors consultants must be conducted in a well-structured and professional manner. The reputation of consulting firms requires them to uphold a high standard of professionalism, because their future funding depends on their ability to attract clients, the quality of their work, and the ability to enforce patient safety during studies. Therefore, accurate reporting and excellent customer service skills are a necessity. After concluding the interviews with three human factors consultants, significant gaps or errors in research processes or business practices could not be found.

## 6.2 Recommendations

Medical device manufacturers continuously acquire human factors consulting services in order to improve device design and decrease risk of harm for patients. Established consulting firms employ consultants with expertise in navigating the FDA approval process, which serves as a benefit to their clients. Besides the need for experts that have gained experience with the requirements set forth by federal agencies, consultants also require interpersonal skill development. Interpersonal skills help to create and maintain relationships with clients, as well as communicate with study participants in a professional and personable manner. Based on observation of business practices by reviewing created study documents, the need for continuous internal training was noted. Internal training includes structured courses on topics such as applicable regulatory and legal frameworks, communication skills, and quality standards in terms of human factors reporting. Similar to most businesses, fostering growth and providing

professional development opportunities needs to remain a priority, in order to develop a well-rounded staff. Currently, set standards on how to determine whether consultants have the necessary training on how to effectively communicate with study participants is not a common practice. Particularly, when studies are conducted on a global scale that involves participants from various cultural backgrounds and with limited language skills.

### 6.2.1 Recommendation 1

The primary recommendation that was identified by the author, after the evaluation of collected data through observational methods was the need for feedback from study participants, regarding their experience working with consultants (study staff). In short, the study staff performs their duties from a perspective of a consultant, however, after a study has concluded, there is no direct feedback provided to them from the standpoint of the study participant. The data that is collected for the client can only be as relevant and valuable as the consultant's ability to effectively communicate and interact with the study participant. Honest and concrete feedback can be provided from study participants by concluding studies with a survey that collects qualitative data, as well as written feedback. Gathering feedback from study participants can be attained by providing a participation survey. Their input should be voluntarily and remain anonymous. This approach can help to improve business practices and help consultants to develop their interpersonal skills, as well as advance the method with which their research processes are executed. An example of a study participation survey is shown below in Table 3 and Table 4.

Table 3. HF Research Participation Survey

**Human Factors Research – Participant Survey**

*Thank you for participating in our Human Factors research session, which is designed to improve the quality and usability of Medical Device X, which is being developed by Company Y. We greatly appreciate your feedback, your input can help us improve our research process and communication with future participants. Your opinions matter to us and the medical community. This survey is anonymous and your name will not be disclosed. Thank you for your participation and honesty.*

| Please rate the following questions : | Always | | Occasionally | | Never | |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | N/A |
| *The Human Factors research staff was helpful and receptive.* | | | | | | |
| *I was fully informed of the tasks that I would be completing, prior to the session start.* | | | | | | |
| *I was confident utilizing the medical device based on the instructions I was given.* | | | | | | |
| *Sufficient time was provided in order for me to successfully complete each task.* | | | | | | |
| *Questions that arose during the session were answered in a timely and accurate manner.* | | | | | | |
| *Obstacles that arose during the session were handled in a professional and discreet manner by research staff.* | | | | | | |
| *Based on this experience, I would participate in Human Factors research again.* | | | | | | |
| Reminder – You will remain anonymous and your feedback will only be used for quality improvement purposes. | | | | | | |

Source: Gloria Mainz

Table 4. HF Research Written Feedback

| ***What did you like and/or dislike about the research session?*** |
|---|
| |

| ***What can we do to improve our research practices and/or interactions with participants?*** |
|---|
| |

*If you agree for us to contact you regarding your feedback, please provide your email below. Thank You!*
Email:

Source: Gloria Mainz

# CHAPTER 7.

# CONCLUSION

Human factors services have increasingly become necessary and beneficial to both medical device manufacturers, as well as regulatory bodies, such as the FDA. The main objective is to ensure that patient safety remains at the forefront and that risks involving patient-device interactions do need led to serious harm. With each current and upcoming medical device there will always remain a certain level of risk, however, many risks can be mitigated prior to a device being approved by the FDA, by challenging the device design and having it undergo extensive evaluations by human factors consultants. The capstone project could not determine a definite success rate. This is primarily due to the reason that a client is not required to follow guidance provided by consultants. When submitting documentation to the FDA for market approval, it is not possible to separate the human factors report from other documentation, which means that the exact degree of impact cannot be measured.

Based on publications released by the FDA and experts within the field, the need for human factors research is apparent. As shown in Appendix 2, the most successful way to attract potential clients is to highlight the expertise provided by consultants, previously completed projects that have resulted in comprehensive and accurate reports or assessments, and flexibility regarding pricing and scheduling. Clients seek to acquire consulting services to bring their device to market, which makes integrity very important amongst consultants. It is crucial to remember that services provided to a client are to remain in line with regulatory and legal requirements. COI or untruthfulness when creating reports is not tolerated by the FDA and can ultimately tarnish the reputation of the human factors consulting firm.

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# APPENDICES

## Appendix 1. Interview Questions

**Johns Hopkins University**

**Capstone Project**

The following interview questions will help to provide a deeper understanding of human factors consulting research practices, as well as reporting. Your professional insight is greatly appreciated and will help to provide further clarification regarding the feasibility of human factors research in medical device development. Your name will remain anonymous and your responses will only be used for research purposes. Thank you for your feedback.

1. How has human factors validation testing benefitted patient safety over the years?
2. How is success measured at human factors consulting firms? What is the success rate of research conducted on behalf of medical device companies?
3. What are potential obstacles that can risk the integrity of human factors testing?
4. How heavily does human factors testing weigh in terms of product development for medical devices?
5. What are current methods to acquire new clients and secure future funding?
6. How do you ensure that users provide honest and unbiased feedback during research testing?
7. Has patient safety increased from direct input of human factors research?
8. Does the FDA provide appropriate guidelines and make expectations clear, regarding the requirements of the findings submitted within the reports? Please explain your response.
9. What is considered to be “realistic and complete” human factors validation testing, as stated by the Center for Device and Radiological Health (CDRH)?
10. Explain the risk management strategies that are used to address use-related hazards.

**Appendix 2. Booklet**

## About us

We are a human factors consulting firm that is dedicated to our clients. Our team has a wealth of expertise that will address your consulting needs and will provide you with the necessary support. Our staff has professional experience in various fields, such as clinical research, regulatory affairs, human factors engineering, project management, and industrial design.

- HF Consulting has over 15+ years of experience in the field of medical device development and patient safety
- Our diverse team and expertise helps to ensure the best possible outcome. Your needs are our priority.

## Contact Us

Our team is looking forward to answering any questions you may have, please do not hesitate to contact us at:

5 Dover Plain
Huntington, NY 12476

Phone: 908-743-2654
Email: info@hfconsulting.com
Web: hfconsulting.com

Source: Jane Carthey

**HF Consulting**
5 Dover Plain
Huntington, NY 12476

# HF CONSULTING

**Medical Device Development**

# Table of Contents



# Our Expertise

## Research Studies

With extensive experience in creating necessary study documents and executing research studies that result in relevant and accurate data, we are the consulting firm that is outcome driven and will support your needs. Let us handle all aspects including patient recruitment and study reporting.

## Risk Management

Minimizing risk and increasing the usability and safety of medical devices is our motto. Identifying and mitigating risks associated with your device is of utmost importance. Our consultants can develop a detailed strategy to ensure a positive outcome.

## Regulatory Guidance

Difficulty understanding the market approval process? Do you require further insight on how to successfully navigate the FDA market approval process or have questions? Let us help you.

# Why work with us?

Our ability to successfully apply our expertise to various types of projects makes us a valuable consulting firm. Our team continuously benefits from professional development opportunities, which further enhances their current skill set and ultimately becomes an advantage to our customers. Our empathy for patients drives our desire to help you develop your product and assist in bringing to market.

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*Safety is our ultimate goal, hence, your needs as a medical device manufacturer are our priority.*

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## Addressing your needs

The first step is to contact us and establish communication. Tell us what your needs are and we will apply our knowledge and expertise to best address the requests you may have.

## Research methods

In accordance with federal laws and regulations, our team conducts formative evaluations and human factors validation testing. We analyze the device user interface, as well as the device use environment. During the development of medical devices, it is important to consider the device user and his/her needs as the patient, lay caregiver, or healthcare professional.

Our goal is to reduce errors that arise due to design related issues.



# Overview of our Values

## Integrity

It is essential for our work to be conducted in an honest and accurate manner, which is why we ensure that our services remain compliant with federal laws and regulations. We are dedicated to our clients, you can expect transparency and honest feedback!

## Professionalism

Whether you require in-person meetings or teleconference calls, our consultants will be there for you. Our resources and expertise will benefit you and find solutions to your consulting needs.

## Trust

We greatly value our clients and strongly believe in creating and maintaining consultant-client relationships that last. Our team has a customer service mindset and will prioritize your needs.

# About us

## Background

Founded in 2001, our consulting firm has been spearheaded by passionate and driven leadership. As the medical community evolves and patient safety remains at the forefront, medical human factors consultancy services that are both effective and relevant are imperative.

> *"...FDA is primarily concerned that devices are safe and effective for the intended users, uses, and use environments."*
> *— U.S. Food and Drug Administration*

## Our Services

Our consulting firm has experience in the following areas:

- Risk Management
- Research Study Support
- Regulatory Guidance



Our consultants have worked on projects involving devices classified as low, medium, and/or high risk. Medical devices have ranged from syringes and inhalers to auto-injectors, delivering life-saving medication. We understand the sensitive nature of your developed device and ensure that our work for you will remain confidential and secure. Our firm has implemented strict policies and guidelines that protect our clients and their privacy.

# Mission Statement

## Closer look at our mission statement

With a goal oriented mindset and empathy for patient safety, our firm seeks to help bridge the gap between medical device manufacturers and federal agencies, such as the FDA. Additionally, our mission is to increase patient safety by applying human factors engineering to improve device design.

By undergoing formative evaluations and validation testing, we are able to identify and mitigate potential use errors that can lead to harm to device users. We want to help you develop devices that can successfully gain market approval.

## Appendix 3. Biography

The author, Gloria Mainz, completed her undergraduate studies at Pace University, earning a Bachelor of Arts degree in Political Science. Her interest in the field of research led her to pursue a Master of Science degree in Research Administration from Johns Hopkins University. She has worked for Texas A&M University as a Program Assistant in the past and furthered her knowledge of clinical research practices, while working as a clinical research coordinator at the United States Military Academy. She hopes to remain in the field of research and is enthusiastic about future opportunities that will help her to enhance her current knowledge and skill set as a research professionals.