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The Design of Medical Devices

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ABSTRACT: This paper aims to review the design of medical devices and investigate its relationship among different factors that must be taken into consideration throughout the process. The theoretical foundation of this paper was formed by conducting a comprehensive literature review on medical device design. A new model is presented to illustrate the relationship between medical device design and four specific success factors. The model shows that product development, tissue modeling, training, and FDA regulations are the four primary success factors that are essential to medical device design. The proposed model clearly shows how device manufacturers must take into consideration many factors during the design process in order to have commercial success with their equipment. This paper demonstrates that medical device design is a unique and complicated process, which requires the utilization of a specialized cross-functional team to overcome the various obstacles along the way.

KEYWORDS: Medical Device Design, Product Development, Tissue Modeling, Training, FDA Regulations.

1 INTRODUCTION

There is growing literature on medical device design [1], [2], [3], [4], [5], [6]. The medical device industry is driven by the overall proficiency of the manufacturers with the design process and its various requirements. The design process incorporates the inherent connection of both science and design [1]. This process can be seen as a combination of methods from engineering disciplines, government regulatory agencies, and independent certification and compliance companies [2]. The clinical success of a design depends not only on its functionality but also its technical efficacy and reliability as well [1]. The daily tasks and workflow of healthcare practitioners are greatly influenced by the medical device design process [4]. This process can be detailed and structured in larger organizations or informal and facilitated in smaller companies [2].

Device efficacy primarily has been the most important element of medical device design, but now there is an increased understanding of human factors in designing and developing medical devices [6]. Human factors engineering (HFE)-based design provides optimum results such as increased safety, reduced errors, decreased training time, and improved task performance [3]. User centered design is more common during the product development phase of the medical device design process [6]. The feedback of the end user combined with intuitive design capabilities ensure the quality of the device, and it appears that this approach is really making an impact across the industry [4]. Also, another important element to this type of approach is the concept of applied ergonomics during the design process. Applied ergonomics allow designers and engineers to develop information about the wants and needs of the users instead of providing solutions to the wrong problems [6]. This can lead to faster time to market, simpler user manuals and learning tools, improved marketing, increased sales, reduced customer training, extended market life, clearer compliance with regulatory requirements, reduced exposure to liability claims, and increased user satisfaction [3].

The development of complex medical devices is more difficult because of the requirements from the regulatory environment it has to work in that need specific processes and testing to illustrate both the safety and efficacy of the device [7]. New product development can be improved by improving cross functional team communication, the use of quality

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metrics for product definition, and performance assessments during development [7]. The ultimate benchmark for new product development and innovation is the actual commercial success of the products [8]. The key to sustained product development success is innovation, integration, and the use of financial metrics [8].

There is a lack of research pertaining to the various factors that influence the medical device design process. This paper analyzes these important factors and how they affect the progression of the design process. The four main factors that are examined in this paper are product development, tissue modeling, training, and FDA regulations. These factors play integral roles in medical device design and must be taken into consideration throughout the duration of the process. Medical devices are important parts of improving patient outcomes and overall safety, so it is necessary to become familiar with how they are designed and developed.

2 RESEARCH METHOD

The research presented in this paper is focused on medical device design and four important factors that have effects on the process. These four factors and their relation to medical device design that were examined are product development, tissue modeling, training, and FDA regulations. The theoretical foundation of this paper was formed by reviewing prevalent literature presented at popular medical device industry conferences and publications. This review-centric research approach assisted in building a solid knowledge base from which it was possible to become familiar with this particular field of study. It is important to be aware of the work and opinions of other experts in a subject area in order to form a baseline for your own opinion. We must become familiar with the most current work that has been done in a field so that we know exactly what is considered the state of the art. It is from this type of approach that we are not only able to provide new insight into the field of study under investigation but also make a more significant contribution to it as well.

3 MEDICAL DEVICE DESIGN PROCESS

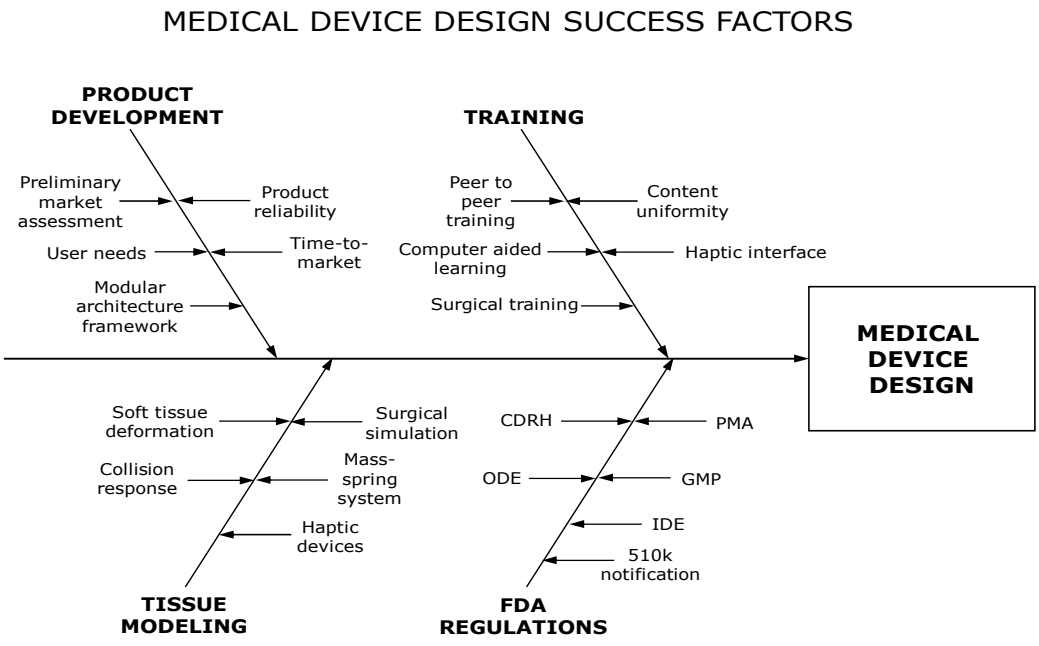

Figure 1. The Medical Device Design Process success factors.

3.1 ADDITIONAL FACTORS

In reviewing the literature, there were additional factors that were discussed along with the four primary success factors shown in Figure 1. These additional factors were divided into corresponding subfactors for each of the primary factors as illustrated in Table 1. Each of these additional factors is also presented in Figure 1 to show its role in the design process.

Table 1. Additional Factors

Product Development	Reference
Time-to-market	[9]
Preliminary market assessment	[8]
Modular architecture framework	[10]
User needs	[8]
Product reliability	[10]

Tissue Modeling	Reference
Soft tissue deformation	[11]
Surgical simulation	[12]
Mass-spring system	[13]
Collision response	[12]
Haptic devices	[14]

Training	Reference
Peer to peer training	[15]
Computer aided learning	[15]
Content uniformity	[16]
Surgical training	[17]
Haptic interface	[18]

FDA Regulations	Reference
Center for Devices and Radiological Health (CDRH)	[19]
Office of Device Evaluation (ODE)	[19], [20]
Premarket approval (PMA)	[20]
510k notification	[20]
Good Manufacturing Practice (GMP)	[21]
Investigational Device Exemption (IDE)	[22]

4 DISCUSSION

4.1 MEDICAL DEVICE DESIGN

There is much to discuss as far as the roles that these four specific factors play in regards to the medical device design process. The interdependence of device design as a whole makes it an extremely unique operation with several variables along the way. The definition of the word design is complex in nature and can be interpreted in various ways depending on how it is viewed. An engineer may view the definition of design as it relates to medical devices as the functionality components of the equipment. The research shows that medical device design requires the use of cross functional design teams to balance fundamental disciplinary tenets of function, appearance, and value [1], [2]. There has been research conducted comparing the medical device design process to the traditional scientific method. It is important to have a balance of both approaches because the scientific method accounts for quantitative and qualitative data analysis that is translated into actionable requirements for design [1], [2]. We must be able to trace all design decisions to a device requirement that is justifiable via scientific experimental exploration or explicit/implicit user communication, which may lead to pitfalls during regulatory review if this step is avoided [1], [2].

The user centered design (UCD) approach is one of the most prevalent in the medical device industry, and there has been plenty of research done supporting it as well. The research shows that this type of approach focuses on end user feedback mechanisms deployed in pre-market and post-market phases of the device lifecycle [3], [4], [6]. We know that medical device manufacturers can utilize these feedback mechanisms and apply a set of device-specific analysis algorithms to effectively flag design flaws and inform future design [3], [4], [6]. UCD techniques help to optimize design around the needs, wants, and limitations of device users, which allows developers to foresee how users are likely to operate the device and avoid assumptions that may not reflect the context of use [3], [4], [6]. The feedback from end users is one of the most important

components of medical device design efforts. Some effective methods for gathering this feedback include prototyping, cognitive walkthrough, interviews, and usability testing [3], [4], [6].

A similar design approach to UCD involves the integration of applied ergonomics in order to better understand the needs of the users. This type of approach allows us to identify problems that may not yet be known or named by patients, physicians, or other stakeholders because many important user issues are not part of conscious awareness [3], [4], [6]. It has been proven that we can produce results that decrease operational time, minimize unintended device effects, and make it easier for the healthcare practitioner to do the "right thing" and harder to do the "wrong thing" [3], [6]. One of the most effective ways to acquire user feedback is to conduct interviews with them in order to identify necessary design requirements. The experience that the user has with a device can determine the adoption of a device oriented clinical practice as a standard of care as well as customer/brand loyalty [3], [6]. These interviews will capture the environment of use, cultural background, education, training, and personal bias of the user experience that typically cannot be addressed by product design [3], [6]. The product design team can then recognize behaviors, opinions, and fundamental tenets to determine the priorities as determined by the users [3], [6]. The goal of this process is to inform the team of critical issues, align them with regard to the prioritization of device features and attributes from the viewpoint of the user, and inspire creative thoughtful solutions, with positive impact on the design of the device [3], [6].

Usability testing is a technique that is frequently used for design validation and also is a cornerstone of best practices for the design of medical devices [3], [6]. It involves the systematic approach of observing and recording users performing actual tasks with real products. The usability target values should be established with input from users through market research techniques such as surveys, interviews, and focus groups [3], [6]. The primary goal behind usability testing is to validate that product usability meets usability objectives, and alone it is definitely not enough for the overall product validation without other extensive laboratory and clinical testing [3], [6]. Also, it is important to perform an analysis of user needs up front in order to acquire a better understanding of the users, their tasks and goals, and the use environment. The research shows that the validity of the usability objectives is dependent upon this up front analysis [3], [6]. It has been proven that usability testing plans must be developed in collaboration with professionals with human factors expertise, and they are also needed in the interpretation and analysis of the results in order to produce reliable data [3], [6].

4.2 PRODUCT DEVELOPMENT

Product development is an important factor that has a significant influence on medical device design. The development of new products is an intricate process that requires both experience and versatility by the device manufacturers. The management of innovation and the related processes of new product development (NPD) will play a key role in the future success of the medical device industry [7], [8], [23]. The research shows that product success is related to understanding user needs, attention to marketing, efficiency in development, effective use of outside technology and management seniority and authority [7], [8], [23]. It also has been proven that product success was particularly influenced by the predevelopment activities including preliminary market assessment and technical analysis along with proficient NPD where customer integration was implemented during the early stages of development [7], [8], [23]. The research conveys that experience has a profound effect on the development process, and an experienced development team that is well versed in the design and manufacturing of medical devices can greatly enhance the success of a commercialization program by reducing development times [7], [8], [23].

The amount of time required for product development is definitely an important element to device manufacturers. This is where the concept of time-to-market becomes essential because it is the ultimate gauge for the commercial success of a new product. The research shows that it is highly desirable to reduce time-to-market as much as possible without incurring significant additional development costs, but this is not an easily attainable goal for all device manufacturers [8], [9], [23]. It has been proven that product introduction delays reduce profits by delaying revenue and reducing peak sales, which punishes companies with the late products because of the short amount of time it takes for high-technology products to become obsolete [8], [9], [23]. Some device manufacturers are able to reduce time-to-market as well as product development costs as a result of large payoffs in revenue from device commercial success [8], [9], [23]. However, rapid product development is not necessarily appropriate for all device manufacturers because of the trade-offs that may accompany it. Some of these trade-offs include a messy development process, more management attention required, the need for higher-caliber staff, higher organizational stress, and increased development costs [8], [9], [23]. There are a number of ways to control development speed such as defining the right product, assembling the right team, getting close to the customer, designing product architecture for speed, and managing market, technical, and regulatory approval risk [8], [9], [23].

Some device manufacturers utilize a modular architecture framework during product development to facilitate the process. The research conveys that this modular framework aims to incorporate design variables and criteria that are unique to the medical domain to facilitate reliable operation, easier maintenance, and faster product development time [10], [23]. This can be achieved by collaborating with users and manufacturers of medical equipment and literature search; to translate user inputs to specific design targets; to develop a preliminary modular design framework using multi criteria optimization methods; to test preliminary modular architecture using a simple medical device [10], [23]. It has been proven that poor architecture increases costs by forcing companies to pay for launch difficulties, late engineering modifications, difficult part fabrication, inefficient assembly, and excessive part proliferation [10], [23]. The research shows that modular design strategy allows us to efficiently manage and develop complex products and systems by decomposing them into simpler subsystems without compromising the system's integrity [10], [23]. This type of approach helps to improve the reliability and maintainability of the product due to standardized modules and the simple product architecture [10], [23].

4.3 TISSUE MODELING

Tissue modeling is another important factor that has a significant influence on medical device design. The modeling of soft tissue in regards to medical device design typically refers to soft tissue deformation. It is important to know how a device will interact with human tissue during the design process in order to maintain the safety of the patient. One of the most prevalent models used for human soft tissue is the mass-spring system (MSS). The main idea of MSS is to discretize the simulated object with masses between which composite linear elastic spring model is also adopted [13], [14]. The particle is constraint to both the elasticity from the spring and the damping force which is proportional with velocity [13], [14]. The research shows that MSS has the advantages of fast computing, simple implementation, low computational complexity, and better ability to adapt the changes of soft tissue topology when compared with the Finite Element Method (FEM) [13], [14]. Also, it has been proven that soft tissue is continuous, incompressible, homogeneous and isotropic solid and a nonlinear constitutive model based on the observation of its force-displacement behavior [11]. There has been research done using the quasi-linear viscoelasticity (QLV) model proposed by Fung in which the tissue behavior can be decoupled into both a linear viscoelastic stress-relaxation response and a time-independent elastic response [11]. There also has been research conducted to understand the localized soft-tissue deformation phase immediately preceding crack growth as observed during the cutting of soft tissue [24]. The observed behavior exhibited a characteristic pattern: repeating units formed by a segment of linear loading or deformation followed by a segment of sudden unloading or localized crack extension in the tissue [24]. It has been proven that during the deformation phase immediately preceding crack extension in the tissue, the deformation resistance of the soft tissue was characterized with the local effective modulus (LEM) [13], [14], [24].

The modeling of soft tissue is especially valuable for surgical simulation, which is another approach for medical device design. The types of devices that are used during surgical procedures must be put through some type of surgical simulation in order to ensure patient safety is maintained. There has been research conducted describing this simulation as two processes in which the first one is the collision detection part that detects occurrence of contacts between the virtual tools and the virtual organs, and the second one is the collision response that computes proper response of organs such as deformation fields and interaction forces [12], [13]. When any tool-tissue collisions occur, the tissue model computes the response of the tissues in terms of the deformation fields as well as the interaction forces [12], [13]. The research shows that the objective of collision detection in virtual environments can be summarized as finding the occurrence and location of collision points between the virtual organs and the tools [12], [13]. It has been proven surgical simulation requires soft tissues to react to the applied forces in a realistic fashion and in real time [14]. There has been research done where the modeling approach has been integrated into a virtual palpating surgery training system and the users could control the virtual tools and manipulate the virtual organs with haptic devices [14]. Surgical simulation is not an easy process to model, but it definitely is required when attempting to design safe medical devices used during surgery.

4.4 TRAINING

Training of the healthcare practitioners is another factor that must be taken into consideration during medical device design. These people will be the ones that use the devices most frequently, so they must be able to operate them fairly easily to provide effective patient care. It has been proven that peer to peer training has been found to be the most popular method of learning how to use medical equipment [15]. There has been research conducted that proposed computer aided learning is a viable solution, which can provide significantly superior facilities, both in presenting information, and also assessing and recording the performance of trainees [15]. Some factors that must be considered for training programs include accuracy and relevance of information, quality of presentation, ease of comprehension for the student, and accessibility and adaptability of material to a variety of skill levels [15]. There has also been research done on systematic

training that can minimize legal and medical risk in medical device operation through four requirements, which are reliability, accessibility, content uniformity, and standards uniformity [16].

Surgical training is essential for healthcare practitioners to be prepared for the challenges associated with actual surgical procedures. It is vital that they are comfortable and familiar with the devices and equipment used in these settings in order to have successful patient outcomes. The research shows that the integration of haptic interfaces into surgical training programs has become more prevalent because of the psychomotor experience of touch it provides [17], [18], [25], [26]. It has been proven that haptic feedback is an effective method in teaching the necessary motor skills required during surgical procedures [17], [18], [26]. There has been research conducted on suture training systems that can evaluate the performance of the trainees by analyzing three parameters, which are task efficiency, task safety, and task quality [17]. The research shows that a haptic interface is highly desired for medical training on needle insertion and tissue cutting in order to train the medical personnel in a virtual environment rather than on a real patient with more practice and less risks [18]. It has been proven that not only is a realistic visual representation of human anatomy and tissue deformation very important, but also the ability to command the graphic environment and interact with it through the feel of the forces and torques is also of paramount importance [26].

4.5 FDA REGULATIONS

The FDA regulations imposed on device manufacturers is another factor that must be considered in medical device design. The manufacturers must adhere to all of these regulations throughout the design process in order for the devices to be released on the market. The Center for Devices and Radiological Health (CDRH) is the organization of the FDA that is responsible for regulating medical devices. The Office of Device Evaluation (ODE) is part of the CDRH and has been placing increased emphasis on expediting its review of marketing applications, which has resulted from the increasing number of new technologies that have important public health benefits as well as lead to overall cost savings in the provision of health care [19], [20], [27]. Premarket approval (PMA) is one of the procedures to obtain marketing clearance, which is required for new technologies that are life-supporting, life-sustaining, or implanted in the body [19], [20], [27]. Also, the PMA must contain very detailed test data, usually including clinical data from studies in humans, demonstrating the product's safety and effectiveness [19], [20], [27]. A less complex marketing clearance procedure that is utilized is the 510(k) notification in which the device manufacturer provides information outlining the basic operating principles of the device, proposed labeling, and an explanation of how the device is equivalent to particular devices already being marketed [19], [20], [27]. There has been research conducted regarding the FDA regulations of medical device software, which falls under the Good Manufacturing Practice (GMP) requirements for medical devices [21]. There also has been research done on the FDA regulations of deep brain stimulation devices in which they are considered to be significant risk devices because of their intention as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject [22]. As a result of this, it is required to receive approval of an Investigational Device Exemption (IDE) application with the FDA prior to beginning the investigation as well as complying with regulations involving institutional review boards (IRBs) and informed consent [19], [22].

5 CONTRIBUTION AND NEW INSIGHT

There has been a significant amount of literature detailing various aspects of the medical device design process. However, there is a lack of research in regards to the many factors that must be taken into consideration during this process. The objective of this paper is to provide new insight into the design process by analyzing the effects that these factors have on it. By reviewing some of the literature available on the field, it was clearly evident that this process is both interdependent and complex as a result of these factors [9]. The objective behind the proposed models in this paper is to illustrate this concept of interdependence and how we must be aware of all the elements that have an influence on the phases of the design process.

The research conveys that device efficacy definitely plays an important role in determining the outcome of the design process with the manufacturers [6]. Also, the proposed models show how both product reliability and user needs have direct impacts on the product development phase of this process [8], [10]. Similarly, this has an influence on the time-to-market of the device by affecting the speed of the development process [9]. The development speed can be facilitated by completing a thorough preliminary market assessment in order to ensure the best opportunity for commercial success [8]. Another way to expedite development speed is to implement a modular architecture framework, which makes the process as efficient as possible [10].

One of best ways to simulate or test medical device efficacy is through the utilization of tissue modeling. This will ultimately ensure patient safety by simulating soft tissue deformation response that accompanies the device interaction with the body [11]. The design process is not complete without ultimately knowing how the body will respond to being exposed to

the equipment. The mass-spring system is an extremely effective model that is used to capture this response by device manufacturers [13]. There are a high number of devices that are used during surgical procedures, which means that they must be put through some type of surgical simulation during the design process. The use of haptic devices is one of the most prevalent ways to adequately achieve this complicated requirement [14]. These devices help to observe the collision detection and response between the virtual tools and organs during surgical simulation [12].

Healthcare practitioners must be experts in the operation of the medical devices that they treat patients with. The devices cannot be too complicated for them to use, or they will not be able to provide safe and effective care. The most prevalent training methods include peer to peer training and computer aided learning, so they must be taken into consideration during the design process [15]. Another important factor to consider during training is to ensure that content uniformity is transparent throughout the process for the optimum impact with the clinicians [16]. The frequency of surgical procedures creates the need for surgical training for healthcare practitioners. The utilization of haptic interfaces is an effective training method to provide these individuals with the required motor skills during surgery [18].

The FDA has the ultimate control over the medical device design process, and it imposes its regulations upon device manufacturers with patient safety in mind. The CDRH and its subsidiary the ODE are the two most important parts of the FDA in regards to device design [19]. PMA and 510k notifications must be coordinated with the ODE during the design process [20]. The FDA requires manufacturers to have GMP so that devices will have the most quality and reliability as possible [21].

6 CONCLUSION

Product development, tissue modeling, training, and FDA regulations are integral parts of the medical device design process. We must address each of these factors during this process in order to produce the best device possible. It is from this approach that we can describe the process as interdependent upon multiple factors. Patient safety is definitely the underlying theme behind all design approaches because it should always be assumed that any device will be used on someone from our family. Device efficacy is the ultimate indicator of commercial success, and manufacturers should focus on achieving this goal to the best of their ability. Product reliability is most important to healthcare practitioners because it illustrates the integrity of the device. The mass-spring system is currently the most successful tissue modeling simulation being utilized, but there is definitely a need for more research to be done in that area. It may be possible to use a more accurate model for manufacturers to consider during the design process. Healthcare practitioner training can be best achieved through a systematic approach by peer to peer training or computer aided learning. We must be familiar with the structure of the FDA and its regulations in order to effectively proceed through the medical device design process. There is also a need for further investigation into additional factors that might have a greater influence on the design process. It is important that we become more familiar with this process in order to produce the safest devices possible. This will give us the opportunity to provide the best patient outcomes, which in essence should be the most effective measuring stick for medical devices.

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