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Review of Medical Device Design

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Abstract: ***Medical devices play a vital role in the health care system. There has been rapid technological innovation and product development in the field of medical devices due to high demand among users. These devices can range from elastic bandages to highly sophisticated pacemakers, stents, etc. Information related to the development of products, product design, quality, and regulatory requirements is an integral part of every medical device development process. But nowadays due to the constant increase in the number of standards, regulations, and extended complexity of the functionality of devices, the process of designing and producing medical devices has become gradually more challenging. Also, the expectations of the customer related to price, tractability, and life cycle costs have become more demanding. Several types of comparative methods and multiple literature are available for designing medical devices to achieve the desired conclusion. The proficiency of the manufacturers is also significant in the designing process of the medical device. Device efficacy has been the principal element of medical device design, but now there is an increased understanding of human factors in designing and developing medical devices.***

Keywords: Medical device, Device Classification, Product Development, Design phase, Design controls

1. Introduction

Medical device design is a complex multistage process. The design and development of medical devices have witnessed remarkable advancements in recent decades, revolutionizing the healthcare landscape and the delivery of patient care. As medical technology continues to evolve at an unprecedented pace, ensuring the safety, efficacy, and quality of these devices is paramount. This comprehensive review paper embarks on a journey through the intricate world of medical device design, encompassing the principles, processes, challenges, and regulatory aspects that underpin this critical facet of modern healthcare.

Medical devices encompass a vast spectrum of products, ranging from simple bandages to complex implantable systems and diagnostic equipment. They serve diverse purposes, such as monitoring, diagnosis, treatment, and rehabilitation, offering healthcare professionals an extensive toolkit to enhance patient outcomes. This paper delves into the multifaceted nature of medical device design and the role it plays in shaping the future of healthcare.

The process of designing medical devices is a multifaceted endeavor that combines engineering precision, clinical expertise, and regulatory compliance. As such, this review paper endeavors to provide a holistic overview of the steps involved in medical device design, from conception and ideation to prototyping and testing. We will explore the significance of user - centered design, risk management, and human factors engineering, highlighting their pivotal roles in creating devices that are both functional and user - friendly.

Throughout this comprehensive exploration of medical device design, we aim to underscore the pivotal role of research and innovation in driving progress. By acknowledging the challenges and opportunities in this field, we hope to inspire future breakthroughs and enhance our collective understanding of the intricate world of medical device design. Ultimately, this review paper serves as a valuable resource for researchers, designers, healthcare professionals, and policymakers striving to ensure that medical devices continue to meet the highest standards of quality, safety, and effectiveness.

1) Medical Device Design

Designing a medical device is a complex procedure which involves multiple stages. This designing process can be divided into three categories - mechanical, electrical, and software. But not all devices require all three aspects. Example - Medical devices like Clamps and bandages do not need electrical components or software to function, they only need mechanical components. The final working of the device depends upon the design stage so it must be conducted properly.

2) Various aspects of medical device design

a) Mechanical aspects involve factors like required strength of device, how tension it can withstand. It affects the choice of material used for construction while considering the biomechanical requirement of the product. Factors like the expected timeline, single - use or multiple use of the device should also be considered.
b) Medical device designing also involves electrical engineering like powering mechanical movements like the pump acting as a drug delivery device. In case of devices like defibrillators or electrocautery instruments require delivery of electric current for performance of their primary function. The electric components of the device must function consistently and reliably, as it will affect the operation of the device.
c) Another aspect in medical device designing is Software. Nowadays, medical components are increasingly complex and are often controlled by an internal operating system. It can involve programs managing simple device operation and data collection to complex systems incorporating algorithms to make critical decisions related to functioning of a medical device. Ex - software control insulin pumps.

3) Distinct stages involved in medical device design

a) Research and Discovery - Medical device design starts from this phase. The focus is on figuring out requirements that can supply parameters of the design. Device design functionality and needs of the customer can act as a

starting point and can help in conceptualization. During these phases factors like risk associated, overall cost, time - to – market, lifecycle of device, operational environment must be considered while designing.

b) Development of Specifications - During this phase specifications related to electrical, mechanical and software are developed. Several factors like safety, functionality, operation ability are considered, and their interdependency can be studied.

c) Development of actual medical device design – By the help of design tools and software, the manufacturing process is done. Choice of materials, type of process, method to join parts should be carefully decided as it can affect

d) The safety and operation of the medical device. To check whether the design specifications are met or not, digital simulation in design phase can be performed.

e) Prototyping - by this working model are developed that can be tested to provide validation and verification, with design problems being addressed through repetition approach. After the final design is approved, the manufacturing process can be designed, and full - scale production can begin

f) Iteration - During this prototype testing it is repeated several times to check whether the specifications are met or not.

g) Manufacturing Process Design – By following Good Manufacturing Practices and Quality management system of medical devices, manufacturing process is done.

2. Design Phase

1) Hazard And Risk Analysis

a) Hazard is a conclusively threatening condition that can be triggered by an event. Risk is a hazard that is interrelated with severity and a probability of occurrence of hazard; if the occurrence of the hazard is more often or the obtained results are rigorous, then it will lead to increased risk.

b) It helps in designing safe and efficient medical devices. The purpose of this analysis is to identify what are the potentially created hazards by a device, process, or application. While analyzing the potential hazards and risks, the intended use and the environment of the device must be considered.

c) Risk management procedures for medical devices comes under ISO 14971: 2007 “Application of Risk Management to Medical devices”. Risk management involves the identification, controlling and preventing failures that can cause hazards.

d) There are some hazards that must undergo evaluation:

- Raw materials and waste: toxicity, flammability and reactivity of material
- Environmental factors: Temperature sensitivity, humidity
- Mechanical or Electronic Hazards:
- User device interface: Hazards associated with human factors

2) Hardware Design

a) The foundation of product development is given by design input. The process of design input helps in establishing and documenting the requirements of the design input for the device. The document must be inclusive and as precise as possible. The information necessary to direct the remaining design process like design constraints is present in that document.

b) The actual design work starts after the documentation describing the design and the organized approach to the design is completed. Development of a block diagram of the device is the initial step in an organized design progression.

c) By using the method of redundancy, that is, the use of more than one component for the same purpose in the circuit, high failure rates can be addressed. The process of assuring the reliability of a component is a multistep procedure, which involves Initial vendor assessment, Vendor audit, Vendor evaluation and Vendor qualification.

d) Component history informs component selection for design. Analyzing rejection rates, field performance, and failure history of previous products guides decision - making. Understanding the interaction between strength and stress levels aids in predicting component failures. When operational stress surpasses rated strength, failure rates increase.

e) Statistical methods streamline experimentation for identifying key effects and interactions in multivariable scenarios. In large projects with diverse teams, frequent design changes make it challenging to assess impacts thoroughly. Employing revision control is vital for tracking design history and managing project dynamics effectively.

3) Software Design

a) Nowadays most medical devices are rapidly becoming software intensive. In these devices the operation, collection and analysis of information can be done by Software controls that help in constructing treatment decisions and generating a pattern for users to interface with the medical device. Software engineering consists of both managerial and technical aspects. Good management and Planning of software development is imperative for supplying high quality, reliable products. During Planning, the project is observed from management’s view including schedule and resources, as well as looking at how the work will be done.

b) Safety risk is pivotal for planning medical device software. The most critical factor that can result from a software failure is the greatest severity of injury. Software requirements analysis refines the system requirements which are distributed to software to supply a model of the software behaviour.

4) Human Factors Engineering

a) The application of scientific knowledge of human competences and limitations related to the design of systems and equipment to produce products that are more efficient, safe, effective, and reliable operation are the Human factors. For characterization of the operating environment and analysis of the skill level of the intended users, all the points of interface between the user and the equipment should be found and addressed by the designer. The environment in which the device will be used must be characterized for determination of areas that may cause issues for the user, like lighting, noise level, temperature.

b) Human Factors Engineering figures out how these areas interact within the device. Human Factors study is the sum

of several processes including the analytic process that focuses on the aims of the proposed device and the functions that should be conducted to fulfil the goals.

c) In Human factors study there is interaction between the human and product/ device. It has synergistic role with Risk Management in Design Control.

5) BIOCOMPATIBILITY

a) Determination of the potential toxicity resulting from contact of the component materials of the device with the body can be done by biological evaluation of medical devices. To select the suitable tests for biological evaluation of a medical device, factors like the chemical characteristics of device materials, the nature, degree, frequency, and duration of its exposure to the body must be considered. The tests include acute sub chronic and chronic toxicity irritation to skin, eyes, and mucosal surfaces sensitization hemocompatibility genotoxicity carcinogenicity effects on reproduction including developmental effects.

6) Reliability Assurance

a) Reliability is a characteristic that describes how good a device is. It is a measure of the dependability of the device. It must be planned for, designed, and manufactured into a device. The inclusion of reliability in manufacturing is considered crucial because reliable manufacturing and servicing is necessary for designing a reliable device. Thus, reliability is the state of mind in which all personnel associated with a product must be. It directs how good a device will be.

b) Reliability is dependent upon other technical areas as a basis for its functionality. These can include Basic mathematics and statistics Current regulatory standards, Design principles, Software Quality Assurance, System interface principles.

7) Product User Guidelines

a) The user manual is part of the product, and it affects how customers view usability, capability, performance, reliability. and maintainability of the product. Writers take the complex theory of operation and reduce it to comprehensive, concise instructions. Illustrators work from simplified text and help to create a visual cue or path for the customers to follow.

8) Design Controls

a) Design controls are a framework of quality procedures and practices integrated into the design and development process of medical devices. It helps to assure that device specifications meet user needs and intended use.

b) It helps in figuring out what the customer wants, who is the real competition and what the competition is doing. Identification of inconsistencies can be done by design controls which lead to reduced amount of redesigning and rework. Therefore, it helps in enhancing the quality of the product.

c) It ensures better communication between the departments and that the right information gets to the people responsible for the other aspects of the project and therefore gets introduced into the final product that is to be shown to the customer. Properly performing design controls helps in making conformance with all other regulatory requirements easier. Identification of the problem can be done which helps in fixing it and adjusting limited resources early enough not to waste time and money.

d) Design controls are applied after prototyping. A point where designing the final product is done or prior to commencement of any clinical investigation (21 CFR 812)

e) Design control guidelines need to be followed by medical device manufacturers. It covers the complete life cycle of medical device from design, production, distribution, use and maintenance.

9) Design Verification and Validation

a) Verification and validation ensure that the device meets the needs of the customer, and it delivers the intended solution.

b) Design Verification supplies evidence that design requirements have been achieved and if they have not been achieved, then it shows to the extent they have or have not been achieved. It also helps in verifying whether the design output meets the design input requirements or not. And confirms whether the output meets the device functional and operational specifications. It displays that the design is both safe and dependable.

c) Design Validation evaluates whether the product delivers benefit according to the targeted audience or not.

d) After the completion of the validation the design and all its specifications, conditions, quality data, SOPs must be transferred to manufacturing. Manufacturing personnel need to be trained in the correct way to make the product and everything needs to be documented.

e) Verification activities may include design reviews, inspection biocompatibility testing risk analysis, thermal analysis, package integrity, demonstration, documentation review.

10) Design History File (DHF)

a) It consists of compilations of records containing the design history of a finished device.

b) It must be created and maintained for every type of device.

c) It is a summarized record of design actions from the starting to transfer. It must have information showing that the design was created using a design plan and quality system requirements.

d) It shows the linkage between all the design controls and helps to trace the changes throughout the product development.

3. Conclusion

In the field of healthcare, medical devices represent a fusion of innovative technology and the commitment to improving patient care. This comprehensive review has journeyed through the multifaceted landscape of medical device design, offering insights into the principles, processes, challenges, and regulatory intricacies that define this critical domain.

Medical devices have become indispensable tools in healthcare, spanning a wide range of applications. From diagnostic equipment that aids in early disease detection to implantable devices that restore quality of life, these innovations have left an indelible mark on patient care. The design of medical devices plays an instrumental role in this

paradigm shift, with user - centered principles, risk management, and human factors engineering standing as the pillars of excellence.

The design process, as elucidated in this review, embodies a carefully orchestrated series of steps. From the inception of an idea to the realization of a functional device, meticulous planning, prototyping, and testing are essential. This process demands a fusion of clinical insight, engineering acumen, and adherence to regulatory standards, ensuring the delivery of safe, efficacious, and quality medical devices to patients.

Regulatory oversight, as explored in this review, remains a dynamic and evolving facet of the medical device landscape. The importance of aligning with robust standards and fostering global regulatory harmony cannot be overstated. As medical device design transcends borders, international collaboration and adherence to rigorous compliance standards are pivotal to safeguarding patient welfare.

As the field of healthcare continues to evolve, the central tenets of research and innovation must remain steadfast. The pursuit of excellence in medical device design hinges on our ability to identify and address emerging challenges, harnessing opportunities for improvement and expansion.

In conclusion, this comprehensive review of medical device design illuminates the vital role these innovations play in shaping the future of healthcare. From ideation to realization, from clinical utility to regulatory compliance, medical device design exemplifies the intersection of technology and human compassion. With each advancement, we step closer to a future where medical devices continue to meet the highest standards of quality, safety, and effectiveness, ultimately enhancing the health and well - being of individuals worldwide

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References

[1] Sognafjord Y, Thawesaengskulthai N. Medical device innovation development process. Int J Innova Technol Manag. (2014).
[2] Goldenberg SJ, Gravagna J. A real - world perspective: building and executing an integrated customer engagement roadmap that bridges the gaps in traditional medical device development processes. J Med Market. (2018).
[3] Gupta B, Thomke S. An exploratory study of product development in emerging economies: evidence from medical device testing in India. R&D Manag. (2018).
[4] Lubowitz JH, Brand JC, Rossi MJ. Medical device and pharmaceutical industry employees as medical research publication authors. Arthroscopy. (2018).
[5] Alexander K, Clarkson PJ. A validation model for the medical devices industry. J Eng Design. (2002).
[6] Moher D, Liberati A, Tetzlaff J, Altman DG, Group TP. Preferred reporting items for systematic reviews and meta - analyses: The PRISMA statement. PLoS Med. (2009).
[7] Shaw B. Innovation and new product development in the UK medical equipment industry. Int J Technol Manag. (1998).
[8] Niimi S. Practice of regulatory science (Development of medical devices). Yakugaku Zasshi. (2017)
[9] Gerber C, Goevert K, Schweigert - Recksiek S, Lindemann U. Agile development of physical products—A case study of medical device product development. Smart Innov Syst Technol. (2019)
[10] Privitera MB, Evans M, Southee D. Human factors in the design of medical devices – Approaches to meeting international standards in the European Union and USA. Appl Ergonom.
[11] Panescu D. Medical device development. In: 2009 Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Minneapolis, MN: IEEE; (2009).
[12] Johnson J, Moultrie J. Technology confidence in early - stage development of medical devices. Int J Innov Sci. (2012)
[13] Hede S, Nunes MJL, Ferreira PFV, Rocha LA. Incorporating sustainability in decision - making for medical device development. Technol Soc. (2013)
[14] Girling A, Young T, Brown C, Lilford R. Early - stage evaluation of medical devices: the role of developmental uncertainty. Value Health. (2010)
[15] Medina LA, Kremer GEO, Wysk RA. Supporting medical device development: a standard product design process model. J Eng Design. (2013).
[16] Ferrusi IL, Ames D, Lim ME, Goeree R. Health technology assessment from a canadian device industry perspective. J Am Coll Radiol. (2009).
[17] Özcan - Top Ö, McCaffery F. How does scrum conform to the regulatory requirements defined in MDevSPICE Commun Comp Inform Sci. (2017).
[18] Bruse JL, Zuluaga MA, Khushnood A, McLeod K, Ntsinjana HN, Hsia T - Y, et al. Detecting clinically meaningful shape clusters in medical image data: metrics analysis for hierarchical clustering applied to healthy and pathological aortic arches. IEEE Trans Biomed Eng. (2017).