

## Mechanical Design and Manufacturing Processes in Medical Device Development

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### ABSTRACT

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Medical device development heavily relies on the manufacturing techniques and mechanical design of medical devices since it ensures safety, functionality and reliability. The whole process of development is shown in this work, including the fundamentals of design, the selection of materials, method of production, prototype, quality control, and regulation. It highlights the importance of CAD modeling, biocompatible materials and particular manufacturing techniques such as machining, injection molding and additive manufacturing. Additional concerns that the work tackles include sterilization, packaging and significant concerns like cost and regulatory complexity. It explores future trends like smart devices, use of AI, and new materials and continuous innovation to improve the ambitions of health and personalized medicine.

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## INTRODUCTION

Development Medical development of medical devices is a multidisciplinary process involving engineering, medicine, and regulatory science to develop products that enhance patient care and quality of life. These devices include simple equipment like syringes and thermometers to complex equipment like surgical robots, implantable pacemakers and diagnostic imaging equipment [1]. The process of development consists of several steps, such as the generation of concepts, design, prototyping, testing, production, and approval by the regulatory authority. Every phase should be thoroughly implemented to ensure that the end product is safe, effective and reliable to use in medicine [2].

The mechanical design is the key to the development of medical devices, as it is concerned with the physical appearance, functionality, and performance of the medical device. Some of the factors that engineers should take into account include the strength, durability, precision, and compatibility with the human body [3]. To give an example, implantable devices should be engineered to endure physiological factors like temperature changes, body fluids and long-term mechanical forces. Besides, devices requiring direct interaction with patients or medical workers should be ergonomically designed to make their usage comfortable and reduce the chances of making a mistake in the process [4].

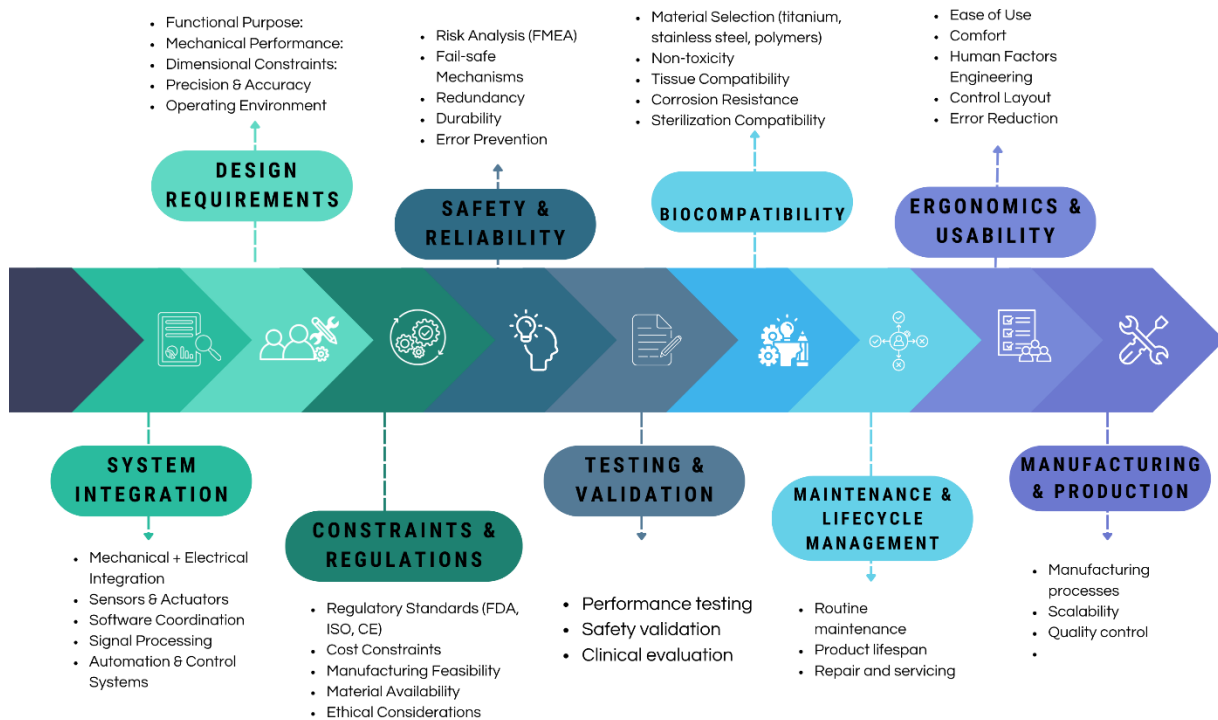
Also critical is the manufacturing processes, which define how a medical device is scaled and at high-quality standards. The manufacturing process needs to be well chosen with regard to the design of the device, material, and the purpose of use. Commonly used processes include machining, injection molding and additive manufacturing, each of which presents certain benefits in regards to accuracy and cost efficiency as well as efficiency of production [5]. The manufacturing process in the medical sphere is highly regulated and it is followed to guarantee the consistency of a product and the safety of a patient. Compliance with international standards and regulations is another important factor in the development of medical devices [6]. The regulatory authorities need rigorous testing and validation to ensure that appliances comply with safety and performance standards. These involve mechanical testing, biocompatibility testing, and risk analysis. The inability to achieve these standards may lead to recall of the product, legal actions, or injuries among patients [7].

The mechanical design and manufacturing processes introduction to the development of medical devices accentuate the need to combine engineering principles and healthcare demands. An excellent device, coupled with efficient and controlled manufacturing procedure, will deliver high-quality medical products. With the ever-growing technological advancement, the field is changing at an alarming rate, resulting in more innovative, accurate and patient-centered medical solutions.

**PRINCIPLES OF MECHANICAL DESIGN IN MEDICAL DEVICES**

The principles of mechanical design in the medical devices are all about coming up with products that are safe, reliable, efficient and appropriate to their medical purpose. Compared to general engineering products, medical devices have to comply with high standards of functionality and safety as they have a direct impact on human health and well-being. The design process, therefore, necessitates extensive knowledge in engineering concepts as well as the medical requirements [8]. Identification and definition of design requirements and constraints is one of the key elements of mechanical design. These are requirements that depend on the purpose that the device will be used, be it diagnostic, therapeutic or implantable [9]. The engineers need to put into consideration such factors as load bearing capacity, size limitations, precision, and environmental conditions. Examples of constraints can be regulatory, cost, material, and manufacturing constraints. An example is a surgical instrument should be lightweight, precise, and easy to sterilize, whereas, an implant should be tough and not corroded in human body [10].

**MECHANICAL DESIGN IN MEDICAL DEVICES**



**Figure 1.** Mechanical Design in Medical Devices

The medical device design is also a major concern in terms of biocompatibility and patient safety. Any equipment that has contact with the human body should not lead to any adverse effects like toxicity, irritation or infection. Designers should make sure that materials and surface finishes do not reject biological tissues and fluids [11]. Moreover, mechanical design should ensure that risks

including sharp edges, mechanical failures or unintended movement are reduced and would not put patients or users at risk. The design also tends to have safety features, e.g. fail-safe mechanisms and protective enclosures, to increase reliability [12].

Ergonomics and usability are also important, especially when it comes to devices utilized by people working in healthcare or patients. An effective medical device must be user friendly, comfortable and minimize the chances of human error. The use of handhelds is an example where they should be well gripped, balanced in terms of weight and the location of control to allow ease of use [13]. Clear and simple design can be a huge performance and outcome difference in acute settings like an operating room. The other important core is the coordination of mechanical parts with other systems which include electronic and software parts [14]. A lot of medical equipment today is electromechanical, and in this case, it is necessary to have a smooth connection between control units and mechanical components as well as sensors. It is the responsibility of the designers that the components should be able to operate in harmony without conflict, and this should be accurate and reliable [15].

The principles of mechanical design of medical devices are aimed at the balancing of the performance, safety, and usability. Through cautious consideration of the design requirements, biocompatibility, ergonomics, and system integration, engineers can come up with devices that are responsive to the clinical needs as well as ones that are safe to patients and regulatory compliant [16].

### **MEDICAL DEVICE ENGINEERING DESIGN PROCESS**

Medical device engineering design process is a methodical and well-organized procedure that takes a rough idea and turns it into a safe, efficient, and marketable product. It is a very controlled process consisting of several phases to make sure that the device will satisfy the clinical requirements and high standards of safety. The stages are sequential, with the one built on the others, as the engineers are able to correct the design, reducing risks and errors. It usually starts with development of concepts, whereby a need of a medical device is determined [17]. The step is associated with the cooperation of the engineers, medical workers, and scientists to present the issue unambiguously and offer possible solutions. Such factors include patient needs, clinical effectiveness, and market demand, which are put into consideration. Engineers proceed to come up with several design ideas and compare them in terms of feasibility, cost and performance. The most promising idea is chosen to be developed further [18].

The next step after developing the concept is computer aided design (CAD) modelling and simulation. In this stage, engineers come up with detailed 2 and 3 dimensional models of the device using special software. These models allow the designers to view the product, check dimensions and ensure that everything in the product fits well [19]. The simulation tools are also used to experiment on the

performance of the device in real life conditions such as mechanical strain, temperature, or fluid interaction. This minimises the use of large physical prototypes and assists in detecting possible problems during an early phase of the design process [20].

The next step in the process is design verification and validation since one needs to verify that the device would be designed to accommodate all the requirements and work in such a manner. Verification deals with the assurance that the products of the design are a similarity of the design inputs. This may include mechanical testing, dimensional inspection and performance analysis [21]. Validation, on the other hand ensures that the final product is satisfactory to the need and the intended use of those who will use the product. This may involve clinical trials, usability and practical trials. Regulatory approval and patient safety are both dependent on verification and validation [22].

A design process is important when it comes to documentation. The engineers ought to maintain a clear record of the design decisions, testing results, and changes that have been made during the development process. This documentation plays a crucial role in adhering to the regulations and helps to demonstrate that the device is developed according to the standards [23]. The design process of medical devices engineering is a long and cyclic process that will ensure the production of high quality and safe products. By developing the concept, CAD modeling, and performing thorough verification and validation, the engineers will be able to create medical equipment that will be capable of meeting the healthcare needs, and will also be compliant with the rigorous regulations required [24].

### **MEDICAL DEVICES: MATERIALS SELECTION**

Another factor that cannot be ignored is the selection of materials in the production of medical equipment since it will dictate the performance of the final product, its safety and longevity, and its effectiveness. The choice of material is a fine balance between mechanical, biological, manufacturability and cost. Medical devices are often in contact with the human body or other sensitive environments so materials used should be of good quality and be able to work under various conditions [25].

Three major types of materials are usually used in making medical devices: metals, polymers, and ceramics. The most used ones are the stainless steel, titanium, cobalt-chromium alloys due to their strength, resistance to corrosion and durability. Titanium is a typical example of a metal used in implants because it is light, strong and most importantly is compatible with human tissues. Rather, polymers are enjoyed because of their flexibility, portability and easy working [26]. Common materials used in creating catheters, tubing, and even prosthetic parts include polyethylene and silicone. Specialized applications Ceramics are also used in specialized applications due to their

hardness, wear resistance and chemical stability, e.g. dental implants and joint replacement [27].

## MATERIALS SELECTION IN MEDICAL DEVICES



**Figure 2.** Materials Selection in Medical Devices

One of the most important aspects of the selection of materials is biocompatibility. This is the capability of a substance to be in contact with a human being without the development of undesirable effects like toxicity, inflammation, or immune responses. The materials must be well tested to ensure that they do not emit any harmful substances and that they degrade in such a way that can put the patients at a risk [28]. The behavior of the material with tissues and fluids is also determined by surface characteristics, such as texture and coating. In addition to biocompatibility, mechanical properties are important in the suitability of a material. Depending on the purpose of the device, the factors such as strength, elasticity, fatigue resistance and wear resistance are to be considered. As an example, an orthopedic implant has to be able to support repeated mechanical loads whereas a flexible catheter should bend and not break. It must also be thermally and chemically resistant especially in apparatus that can be subjected to sterilization processes, either heat, radiation, or chemicals [29]. The materials must be selected also based on references to manufacturing processes and cost-

effective. Some of the materials can be easily machineable, moldable or printable than others and this can influence the production efficiency and the final cost [30]. The engineers must ensure that the material they choose suits the manufacturing process they are employing and at the same time it fits the required quality [30]. Selection of materials used in medical devices is an advanced and critical undertaking that requires critical consideration of a number of factors. The selection of appropriate metals, polymers, or ceramics that are capable of meeting mechanical, biological, and manufacturing requirements can help engineers ensure safety of medical devices, reliability, and high performance [31].

### **MEDICAL DEVICES MANUFACTURING PROCESSES**

The processes of manufacturing are very important in the medical devices development since they specify how a design is converted to a working and workable product. These processes should be of high precision, consistency and quality since even a slight defect in the process may have severe consequences in medical cases. The medical sector must also be produced with strict regulatory measures in order to be safe and effective [32]. One of the most popular manufacturing processes in the manufacture of medical devices is machining (and particularly Computer Numerical Control (CNC) machining). It involves cutting and shaping materials such as metals and plastics with computer controlled tools to achieve accurate cuts and shapes [33]. CNC machining is also welcome as it is precise and can produce complex geometries, and is therefore applicable to many components like surgical instruments, implants and prosthetics. It also allows tight tolerances, which are required in machines that need to have accurate dimensions and performance [34].

Another process that is very significant is injection molding; this process is primarily used to manufacture plastic parts on large scale. In this case, a melted material is put into a mold cavity where it solidifies and assumes its shape. Injection molding is particularly useful in manufacturing of such products as syringes, housings, and disposable medical equipment. It has the merits of high rate of production, repeatability and cost effectiveness in mass production. Nevertheless, initial expenses of mold design and fabrication may be high [35].

Additive manufacturing (3D printing) has become a new method of medical devices manufacturing. The technique employs digital models to assemble the components in layers, which enables very customized and complicated designs. It particularly finds application in the development of patient-specific implants, prosthetics, and anatomical models in the process of surgical planning [36]. Additive manufacturing also minimizes wastage of materials and can be used in fast prototyping, though it might be limited in its production rate and the types of materials that it can use in comparison to conventional processes [37].

Besides these processes, micro fabrication processes are employed in the production of very small and precise components especially in devices like sensors, microfluidic systems and minimally invasive surgical instruments. These methods involve such processes as photolithography and etching, which enable the production of complex structures in the microscale level. The medical device industry is no exception to quality control that is part of all manufacturing processes. All products have to go through a stringent inspection and test to guarantee that they are within the design specifications and regulations. This involves dimensional checks, mechanical tests and validation [38]. Medical device development manufacturing processes are highly varied and specialized. Applying the right methods, like machining, injection molding, additive manufacturing, and micro fabrication, manufacturers are able to develop high-quality devices that are safe and meet high performance standards and respond to the changing demands of healthcare [39].

### **PROTOTYPING AND PRODUCT DEVELOPMENT**

Medical device engineering requires the use of prototyping and product development which bridges the gap between initial concepts of designs and the final commercial products. These phases enable engineers to test concept, assess performance, and streamline design until the stage of large-scale production. Since medical devices are sensitive in nature, prototyping is important in the safety, functionality and compliance with the regulations [40]. When the initial design is developed, prototyping starts, and computer-aided design (CAD) models are frequently used. A prototype is the initial model of the device which is constructed to test certain features like form, fit and functionality. Prototypes come in various forms, some being only simple conceptual prototypes and others being very functional prototypes which are similar to the final product [41].

Prototypes can be created at an early stage with low-cost materials and are mostly used to visualize the design and discover some fundamental problems. The further development of the prototype is made by producing more developed prototypes with the help of similar materials and processes as for the final device. The efficiency of this stage has been greatly enhanced by the rapid prototyping techniques [42]. The 3D printing, CNC machining, and laser cutting technologies can now allow engineers to physically make them directly as a result of the computer-generated design. These approaches minimize the development time and enable quicker iteration, particularly in the competitive medical device sector. Rapid prototyping facilitates also customization to create patient-specific devices, including customized implants or prosthetics [43].

Product development is more or less associated with prototyping and entails optimization of the design as a result of the testing and feedback. Engineers have different tests performed on prototypes in order to test their performance, longevity, and safety. This can involve mechanical testing, usability

testing and, in some cases, preclinical or clinical testing [44]. Results of these tests are utilized to point out the flaws in the design, enhance functionality, and to make sure that the device fulfills all the requirements. The iterative design process is an important part of product development. Engineers do not produce a final product in one step, but instead undergo a series of design, prototyping, testing, and adjusting the device. This cycle process can be used to reduce risk and enhance the quality of the product. It is also capable of continuous improvement upon user feedback and the real world conditions [45].

Another important aspect of successful product development is collaboration of multidisciplinary teams. Engineers, medical professionals, regulatory experts and manufacturers collaborate to make sure that the device is capable of meeting clinical requirements and being viable to manufacture and follow regulations. The key process involved in changing innovative ideas into safe and effective medical devices is prototyping and product development [46]. By using rapid prototyping, making improvement iteratively, and extensive testing, engineers can come up with quality products that satisfy the expectations of the user and the regulations.

#### **QUALITY STANDARDS AND REGULATORY STANDARDS**

Another aspect of medical devices development is the quality control and regulatory standards that ensure that products are safe, effective and reliable to use on the patients. The medical world, unlike the majority of other industries, is highly controlled as the failure or malfunction of a device could lead to serious medical consequences because human life is at risk [47]. The manufacturers ought to therefore have a good quality management structure as well as conform to the international regulatory measures throughout the product life cycle.

Quality control can be defined as the processes and procedures applied to guarantee that a medical device is up to the stated standards in terms of design and performance. It begins at the early stage of development up to the production and post-market surveillance. Inspection, testing, and checking the materials, components, and finished products are the major quality control processes [48]. One such method is dimensional checks where they are checked against the right specifications and strength, durability and functionality tests, which are performed through mechanical tests. To demonstrate compliance and traceability, these processes ought to be recorded on a regular basis [49].

The ISO 13485 is one of the quality management systems that have been widely adopted in the medical devices industry. This is an international standard that details what a quality management system needs to be, in particular when it comes to medical device manufacturers. It concentrates on process control and continuous improvement and risk management [50]. The use of such standards will help companies to make sure that products are always manufactured and monitored as per the

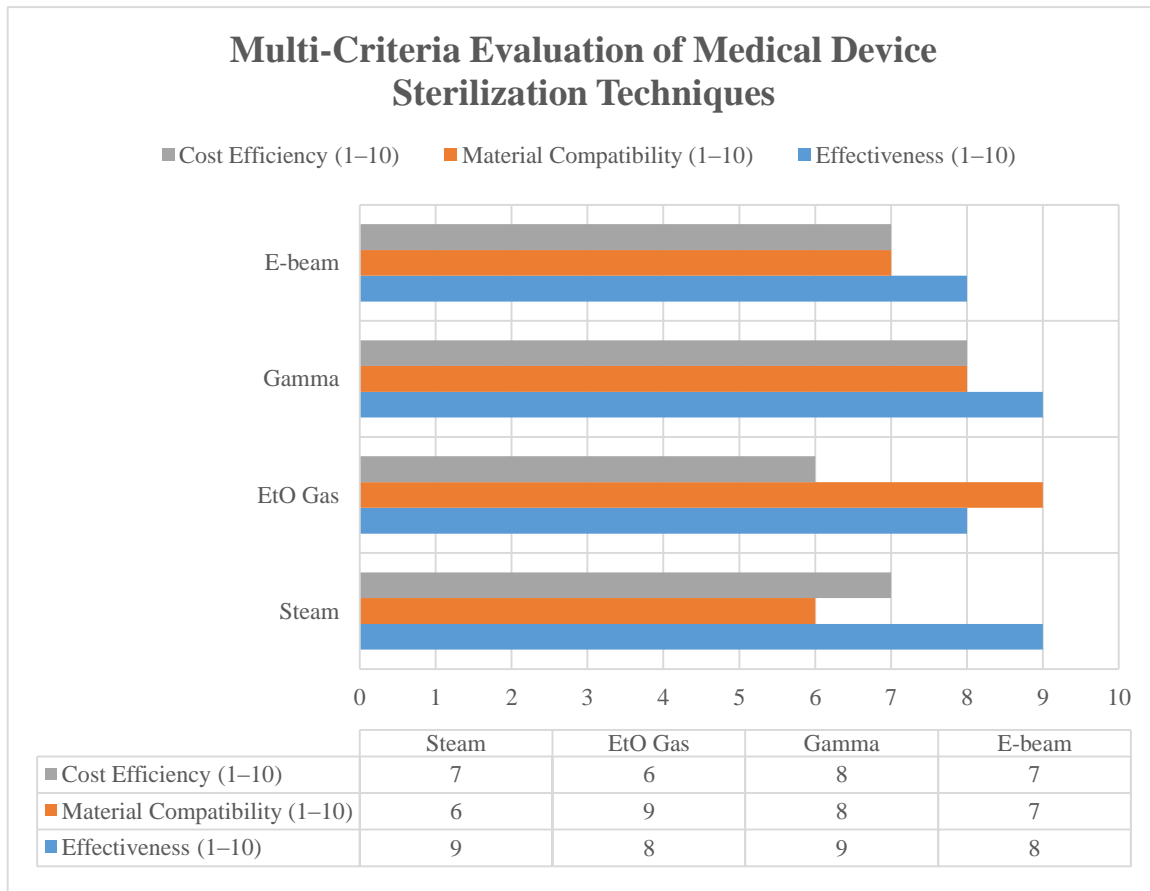
quality standards. Government agencies develop regulatory standards in order to safeguard the health of the population as well as to ensure that medical devices are safe to use. Most countries have regulatory bodies which require manufacturers to have permission before a device can be sold [51]. This involves a detailed documentation which entails design specification, testing results, risk analysis and clinical data. The approval process may be strict and time-consuming, however, there is a need to make certain that the devices are fully compliant with the safety and performance standards. Testing and certification are aspects that are very important in regulatory compliance [52]. Devices will undergo many tests, such as the biocompatibility tests, electrical safety tests and performance testing. In other cases, clinical trials will be required to ascertain how the device performs in real medical situations. Only a device can be tested and certified to pass these tests [53].

The post-market surveillance is the other important quality control and regulation. The manufacturers are advised to monitor the performance of a gadget even after it has been released and relay any issues or adverse incidents. This aids in detection of possible risks and taking corrective measures where necessary. Regulatory standards and quality control make sure that medical equipment is designed and produced to the most safety and reliability standards [54]. Through the aid of strict guidelines, appropriate testing and continuous control, manufacturers will be able to deliver products that may be considered safe to the health of patients and comply with the demands of the global regulations [55].

### **STERILIZATION AND PACKAGING CONSIDERATIONS**

Sterilization and packaging are critical aspects of medical device development, as they directly impact patient safety, product integrity, and regulatory compliance. The medical devices usually touch the human body, sterile tissues and fluids, so it is necessary to guarantee that they are not contaminated with dangerous microorganisms like bacteria, viruses, and fungi. Effective sterilization and packaging of the device are not only capable of protecting the patients against infections, but also preserve the quality and functionality of the device during its shelf life [56].

Sterilization is a procedure of removing any microbial life on a medical device. The sterilization method varies based on the nature of the material used, design of the device, and the intended use. Steam sterilization (autoclaving), ethylene oxide (EtO) gas sterilization, gamma radiation, and electron beam sterilization are common methods of sterilization [57]. Steam sterilization is well adopted in the heat resistant devices because of its effectiveness and reliability. But in the case of heat sensitive materials like some plastics, techniques like EtO gas or radiation are used. Both approaches have their strengths and weaknesses, and it is important to choose the right one to prevent any harm to the equipment and yet fully sterilize it [58].



**Figure 3.** Multi-Criteria Evaluation of Medical Device Sterilization Techniques

The other factor to be considered is sterilization process validation. The manufacturers should show that the method used is able to maintain the necessary level of sterility, commonly known as the Sterility Assurance Level (SAL). This entails tests, observation and recording to ensure that the process is done to meet the regulatory standards. A failure in sterilization may cause a severe health risk, such as patient infections and complications [59]. Packaging is equally important in ensuring the sterility and safeguarding of the device in storage, transportation and handling. Medical device packaging should be such that it offers a protection against contamination and at the same time it should be durable enough to withstand environmental factors like humidity, temperature variations and physical strain [60]. Medical-grade plastics, paper, and foil laminates are common materials used as packaging and are chosen depending on how well they respond to the sterilization method and how long they can retain their sterility [61].

Along with protection, packaging should be easy to use as well. The package should be easily opened by healthcare professionals without affecting sterility. Another necessary requirement is clear labeling, which includes valuable information like expiration dates, how to sterilize, and other instructions. The use of the medical devices is safe and effective only through sterilization and

packaging [62]. The manufacturers can guarantee that the medical devices are sterile, functional and meet regulatory requirements through their lifecycle by selecting suitable sterilization methods, process validation and designing the protective and user friendly packaging [63].

### **CHALLENGES IN MEDICAL DEVICE MANUFACTURING**

The production of medical devices is a very specialized and demanding area whereby various challenges exist. These issues can be explained by the necessity to make the devices not only functional and cost-effective but also safe, reliable, and with high regulatory standards. To solve these problems, proper planning, sophisticated technologies, and constant improvement of the manufacturing process are needed [64]. Cost management is one of the main problems in the manufacturing of medical devices. Medical devices are usually expensive to develop and produce as they require sophisticated machinery and very skilled labor. Also, the expenses of research, testing, regulatory approval, and quality assurance may be high. The manufacturers have to strike a balance between this cost and ensuring that the end product will be affordable to the healthcare providers and patients. This is especially difficult in the developing world, where cost factors are more important [65].

High precision and quality is another significant challenge. Medical equipment may have very strict tolerances and require stability of performance, particularly with medical implants, surgical tools, or medical diagnostic equipment. Even minor imperfections or differences may cause a failure of a device or endangered patient safety [66]. This kind of precision can be attained through sophisticated manufacturing procedures, stringent quality control and constant monitoring of manufacturing activities. Another major challenge in the manufacturing of medical devices is regulatory compliance. Manufacturers have to comply with stringent rules enacted by regulatory bodies, which differ in various countries and regions [67]. These laws take into account the entire product lifecycle, such as designing, production, testing, labeling, and distribution. The processes of satisfying these requirements can be time-consuming and resource-intensive, requiring a lot of documentation, audits, and certification [68].

Material and supply chain management is another challenge. Medical equipment frequently uses special materials that have to satisfy high levels of biocompatibility and performance. Any breakage in the supply chain like shortage or delay may affect production schedules and raise costs. It is necessary to have a stable and consistent supply of quality materials in order to have continuous production [69]. Another technological complexity is related to the emergence of sophisticated and intelligent medical devices. The production process is more complicated, as many of the modern devices combine mechanical, electronic, and software parts into one. The artistry and advanced

production techniques are necessary to achieve a smooth and efficient functionality of the elements involved [70].

Scalability and efficiency in production remain a challenge. Prototypes might work well in small scale, but it might be challenging to scale up production with minimal loss of quality. Manufacturers need to ensure that they streamline processes to produce high volumes of production with consistency and compliance [71]. The production of medical devices is associated with various challenges such as cost, precision, regulatory, supply chain, and technological complexities. Addressing these issues is crucial in providing safe, effective, and accessible medical devices to the healthcare sector [72].

### **RISK MANAGEMENT AND SAFETY CONSIDERATIONS**

Safety and risk management are essential aspects of developing medical devices, particularly once the manufacturing issues are resolved and before the next step of advancing the medical devices is taken. The step aims at recognizing, assessing, and reducing the possible risk in the design, manufacture, and utilization of medical equipment. These devices should be safe because they are in direct contact with patients and healthcare professionals and therefore, their safety should be the most important [73].

Risk management starts with the methodical identification of the possible hazards that might occur in the lifetime of the device. These risks can be mechanical, electrical, biological, or associated with the interaction with users. As an illustration, a device can fail because of material fatigue, software failure or misuse [74]. These risks have to be evaluated thoroughly by engineers and designers in all stages of development to avoid failures that may result in injuries or wrong treatment. After identifying risks, they are considered in terms of their severity and probability. This is done to prioritize which risks need urgent attention [75]. There are multiple tools of analysis, including Failure Modes and Effects Analysis (FMEA) and risk matrices, which are often applied to evaluate and classify risks. Such tools allow engineers to approach the possible problems systematically and work out the strategies that can minimize or eradicate them [76].

The risks are then reduced by implementing risk control measures. Such measures can involve design changes, inclusion of safety measures, use of durable materials, and introduction of protective measures. An example is introducing alarms, fail-safe mechanisms, or automated shut-off mechanisms, which can greatly improve the safety of devices [77]. Also, easy-to-follow instructions and labeling can assist in minimizing the risk of making a user error. Verification and validation is a significant part of risk control measures to ensure that these measures are effective. Devices should go through extensive testing to ensure that all risks that they are found to be having are properly mitigated [78]. This involves mechanical testing, usability testing and occasionally clinical testing.

All risk management activities should be properly documented and approved by the regulators and monitored.

Another important aspect is post-market risk management. Even when a device has been released the performance of the device in the real world environment has to be monitored continuously by the manufacturer. With user feedback, incident feedback and maintenance data, new or unexpected risks are identified. When need be, corrective measures are put in place to ensure safety standards [79]. The safety and risk management are key in designing safe and reliable medical devices. The identification, assessment, and management of risks systematically can help manufacturers to provide patient safety, compliance with regulations, and the success of the product in the long term [80].

### **MEDICAL DEVICE DESIGN AND MANUFACTURING IN THE FUTURE**

Medical device design and manufacturing are changing at an alarming rate with the technological, material, and healthcare demands. The trends of the future lie in enhancing patient outcomes, boosting efficiency, and providing more personalized and accessible healthcare solutions. These innovations are transforming the design, manufacture and use of medical devices in the clinical setting [81]. Among the most notable ones, there can be considered the evolution of smart medical devices. These gadgets have sensors, connectivity functionalities, and data processing capabilities that enable them detect conditions of patients in real time. As an example, wearable devices can monitor vital signs (heart rate, temperature, physical activity) and can offer continuous health monitoring [82]. These intelligent systems will be able to share information with healthcare providers where early diagnosis and service can be done. This move towards integrated healthcare is enhancing patient care and minimizing the processes of frequent visits to the hospitals [83].

The other trend is the adoption of artificial intelligence (AI) and automation in designing and manufacturing. The optimization of device designs is being implemented through the use of AI to analyze large amounts of data and forecasting performance results [84]. Robotics and computer-controlled systems are automation technologies that are improving precision, minimizing human error, and improving production efficiency in manufacturing. Such technologies also facilitate quicker production cycles and uniform quality of products which is needed in the medical sector. Additive manufacturing (3D printing) has become an increasingly popular part of the future of producing medical devices [85]. This technology can be used to produce highly personalized devices that are specific to particular patients, including implants and prosthetics that are produced to fit the anatomy of a patient. It also facilitates quick prototyping, allowing quicker innovation and development. With better materials and printing technology, additive manufacturing will be increasingly applied to small scale and large scale manufacturing [86].

Medical devices are also beginning to be influenced by developments in materials science and nanotechnology. New materials with better properties including better strength, flexibility and biocompatibility are being produced. Nanotechnology allows designing devices on the scale of microscopes, and it has become possible to create things like a system of drug delivery into the body and extremely sensitive diagnostic instruments. These advancements are creating new opportunities of minimally invasive procedures, as well as, effective treatment [87].

The emphasis on sustainability and environmentally friendly production is another new trend. With increasing environmental concerns, manufacturers are looking at how they can minimize the wastage, energy use and the use of damaging materials. This involves the use of recyclable materials, better production efficiency and the designing of devices with extended life cycles [88]. Technological innovation and attention to patient-centered care are the future of the design and manufacturing of medical devices. The industry is shifting to more efficient, accurate, and customized solutions in healthcare with the development of smart devices, AI, additive manufacturing, and innovative materials [89].

## CONCLUSION

The foundation of the modern healthcare innovation is the mechanical design and manufacturing processes in the development of medical devices. They collectively guarantee the medical devices are not only functional and efficient, but also safe, reliable, and fit to human usage. Since the first concept development, all the development stages are well organized to achieve high engineering, clinical and regulatory standards. This marriage of science and engineering with medicine has greatly enhanced the standards of health care provision across the globe. The introduction emphasizes that the development of medical devices is an interdisciplinary area that includes engineering, biology and regulatory science. Mechanical design will make sure that devices are up to performance specification and are safe to patients.

These designs are converted into actual usable products through manufacturing processes with accuracy and conformity. Medical devices cannot meet the expected standards of safety and effectiveness without a solid design and manufacturing foundation. The principles of mechanical design underline the significance of requirements analysis, biocompatibility, ergonomics, and system integration. These principles make sure that devices are human-centric with reduced risks. These fundamentals are further developed in the design process under concept development, CAD modeling, simulation and tough verification and validation. This step-by-step process aids engineers in finding out and rectifying possible problems at an early stage, minimizing failures, and enhancing product dependability.

The choice of the material is a determinant of durability, performance and safety. Each of the metals, polymers, and ceramics has its own benefits in terms of application, and biocompatibility provides the fact that the materials are not harmful to the human body. Precise and scalable production is facilitated by manufacturing processes like machining, injection molding, additive manufacturing, and microfabrication. Such methods make sure that intricate designs can be faithfully transformed into physical devices. The prototyping and product development enable engineers to test and refine design in iterative cycles. This is necessary in enhancing functionality and will guarantee that the end product will satisfy the requirements of the user. Quality control and regulatory standards also ensure that devices meet the international safety standards, and sterilization and packaging ensure the sterility and integrity of the products during distribution and use.

In spite of these improvements, there are some challenges in the medical device production, including high cost, regulatory complexity, and the accuracy, and supply chain restriction. Nevertheless, the ever-evolving technological advances are solving these problems and enhancing performance. Going forward, the industry is changing with the arrival of future trends, including smart devices, artificial intelligence, additive manufacturing, nanotechnology, and sustainable production. The innovations are turning medical devices into increasingly personalized, intelligent, and accessible. High quality medical devices are developed through mechanical design and manufacturing processes. They are constantly evolving to provide safer, more effective, and more innovative healthcare solutions, which ultimately improves patient outcomes and enhances global medical technology.

### REFERENCES

- [1]. Ocampo JU, Kaminski PC. Medical device development, from technical design to integrated product development. *Journal of Medical Engineering & Technology*. 2019 Jul 4;43(5):287-304.
- [2]. Ciurana J. Designing, prototyping and manufacturing medical devices: an overview. *International Journal of Computer Integrated Manufacturing*. 2014 Oct 3;27(10):901-18.
- [3]. Ali KA, Shaw TK, Sarkar S, Bishal A, Mukherjee R, Hossain CM. Physical and mechanical evaluation of medical devices. In *Medical Devices in Modern Healthcare 2026* Jan 1 (pp. 395-436). Academic Press.
- [4]. Hede S, Nunes MJ, Ferreira PF, Rocha LA. Incorporating sustainability in decision-making for medical device development. *Technology in Society*. 2013 Nov 1;35(4):276-93.
- [5]. Gadotti Martins E, Pinheiro de Lima E, Gouvea da Costa SE. Developing a quality management system implementation process for a medical device manufacturer. *Journal of Manufacturing Technology Management*. 2015 Sep 7;26(7):955-79.

- [6]. Joung YH. Development of implantable medical devices: from an engineering perspective. *International neurology journal*. 2013 Sep 30;17(3):98.
- [7]. Morrison RJ, Kashlan KN, Flanagan CL, Wright JK, Green GE, Hollister SJ, Weatherwax KJ. Regulatory considerations in the design and manufacturing of implantable 3D-printed medical devices. *Clinical and translational science*. 2015 Oct;8(5):594-600.
- [8]. Marešová P, Klimova B, Honegr J, Kuča K, Ibrahim WN, Selamat A. Medical device development process, and associated risks and legislative aspects-systematic review. *Frontiers in public health*. 2020 Jul 30;8:308.
- [9]. Zadpoor AA. Design for additive bio-manufacturing: from patient-specific medical devices to rationally designed meta-biomaterials. *International journal of molecular sciences*. 2017 Jul 25;18(8):1607.
- [10]. Crisp S. The medical device directives and their impact on the development and manufacturing of medical implants. *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*. 1996 Dec;210(4):233-9.
- [11]. Shamim MM. Electrical And Mechanical Troubleshooting in Medical And Diagnostic Device Manufacturing: A Systematic Review Of Industry Safety And Performance Protocols. *American Journal of Scholarly Research and Innovation*. 2022 Apr 28;1(01):295-318.
- [12]. Guy Erdman A. Lessons learned from kinematics research applied to medical device design. *Journal of biomechanical engineering*. 2018 Feb 1;140(2):021006.
- [13]. Peto M, García-Ávila J, Rodríguez CA, Siller HR, da Silva JV, Ramírez-Cedillo E. Review on structural optimization techniques for additively manufactured implantable medical devices. *Frontiers in mechanical engineering*. 2024 Mar 1;10:1353108.
- [14]. Festas AJ, Ramos A, Davim JP. Medical devices biomaterials—A review. *Proceedings of the institution of mechanical engineers, part L: Journal of Materials: Design and Applications*. 2020 Jan;234(1):218-28.
- [15]. Almeida HA, Ruben RB. Medical devices: from design to production. *Advances in Mechanical Engineering*. 2017 Sep;9(9):1687814017729895.
- [16]. Hanawa T. Research and development of metals for medical devices based on clinical needs. *Science and technology of advanced materials*. 2012 Dec 1;13(6):064102.
- [17]. da Silva LR, Sales WF, Campos FD, de Sousa JA, Davis R, Singh A, Coelho RT, Borgohain B. A comprehensive review on additive manufacturing of medical devices. *Progress in Additive Manufacturing*. 2021 Aug;6(3):517-53.

- [18]. Santos IC, Gazelle GS, Rocha LA, Tavares JM. Medical device specificities: opportunities for a dedicated product development methodology. *Expert Review of Medical Devices*. 2012 May 1;9(3):299-311.
- [19]. Jelínek F, Breedveld P. Design for additive manufacture of fine medical instrumentation—DragonFlex case study. *Journal of Mechanical Design*. 2015 Nov 1;137(11):111416.
- [20]. Yamazaki T. Development of a hybrid multi-tasking machine tool: integration of additive manufacturing technology with CNC machining. *Procedia Cirp*. 2016 Jan 1;42:81-6.
- [21]. Gafford J, Ranzani T, Russo S, Degirmenci A, Kesner S, Howe R, Wood R, Walsh C. Toward medical devices with integrated mechanisms, sensors, and actuators via printed-circuit MEMS. *Journal of Medical Devices*. 2017 Mar 1;11(1):011007.
- [22]. Wimpenny DI, Pandey PM, Kumar LJ. *Advances in 3D printing & additive manufacturing technologies*. Springer. 2017.
- [23]. Gibson I, Srinath A. Simplifying medical additive manufacturing: making the surgeon the designer. *Procedia Technology*. 2015 Jan 1;20:237-42.
- [24]. De Maria C, Di Pietro L, Lantada AD, Madete J, Makobore PN, Mridha M, Ravizza A, Torop J, Ahluwalia A. Safe innovation: On medical device legislation in Europe and Africa. *Health Policy and Technology*. 2018 Jun 1;7(2):156-65.
- [25]. Bastin A, Huang X. Progress of additive manufacturing technology and its medical applications. *ASME Open Journal of Engineering*. 2022 Jan 1;1.
- [26]. Kumar LJ, Pandey PM, Wimpenny DI. 3D printing and additive manufacturing technologies. published in. 2019.
- [27]. Stephenson K. A detailed five-year review of medical device additive manufacturing research and its potential for translation to clinical practice. In *International Design Engineering Technical Conferences and Computers and Information in Engineering Conference 2015 Aug 2* (Vol. 57106, p. V003T14A014). American Society of Mechanical Engineers.
- [28]. Kumar A, Jain PK, Pathak PM. Reverse engineering in product manufacturing: an overview. *DAAAM international scientific book*. 2013 Jan 1;12:665-78.
- [29]. Gadde SS, Kalli VD. *Technology Engineering for Medical Devices-A Lean Manufacturing Plant Viewpoint*. Technology. 2020 Apr;9(4).
- [30]. Gibson I, Rosen D, Stucker B, Khorasani M. Development of additive manufacturing technology. In *Additive manufacturing technologies 2020 Nov 11* (pp. 23-51). Cham: Springer International Publishing.

- [31]. Wang Z, Yang Y. Application of 3D printing in implantable medical devices. *BioMed Research International*. 2021;2021(1):6653967.
- [32]. Pavan Kalyan BG, Kumar L. 3D printing: applications in tissue engineering, medical devices, and drug delivery. *Aaps Pharmscitech*. 2022 Mar 17;23(4):92.
- [33]. Ye L. Design and manufacturing of mechanical parts based on CAD and CAM technology. *Engineering Research Express*. 2024 Dec 1;6(4):045411.
- [34]. Sousa AC, Veiga A, Maurício AC, Lopes MA, Santos JD, Neto B. Assessment of the environmental impacts of medical devices: a review. *Environment, Development and Sustainability*. 2021 Jul;23(7):9641-66.
- [35]. Lim S, Buswell RA, Le TT, Austin SA, Gibb AG, Thorpe T. Developments in construction-scale additive manufacturing processes. *Automation in construction*. 2012 Jan 1;21:262-8.
- [36]. Kirkire MS, Rane SB, Jadhav JR. Risk management in medical product development process using traditional FMEA and fuzzy linguistic approach: a case study. *Journal of Industrial Engineering International*. 2015 Dec;11(4):595-611.
- [37]. Eberhardt AW, Johnson OL, Kirkland WB, Dobbs JH, Moradi LG. Team-based development of medical devices: An engineering–business collaborative. *Journal of biomechanical engineering*. 2016 Jul 1;138(7):070803.
- [38]. Husainy AS, Patil SD, Kokane RS, Upadhye CR, Chougule AV. Medical additive manufacturing: challenges and features. *Asian Review of Mechanical Engineering*. 2023 Mar 16;12(1):15-23.
- [39]. Morrison RJ, Hollister SJ, Niedner MF, Mahani MG, Park AH, Mehta DK, Ohye RG, Green GE. Mitigation of tracheobronchomalacia with 3D-printed personalized medical devices in pediatric patients. *Science translational medicine*. 2015 Apr 29;7(285):285ra64-.
- [40]. Rekowska N, Huling J, Brietzke A, Arbeiter D, Eickner T, Konasch J, Riess A, Mau R, Seitz H, Grabow N, Teske M. Thermal, Mechanical and Biocompatibility Analyses of Photochemically Polymerized PEGDA250 for Photopolymerization-Based Manufacturing Processes. *Pharmaceutics*. 2022 Mar 12;14(3):628.
- [41]. Mohammadpourfazeli S, Arash S, Ansari A, Yang S, Mallick K, Bagherzadeh R. Future prospects and recent developments of polyvinylidene fluoride (PVDF) piezoelectric polymer; fabrication methods, structure, and electro-mechanical properties. *RSC advances*. 2023;13(1):370-87.
- [42]. Overhoff M, Lumpe TS, Shea K. A Product Life Cycle Approach to Medical Device Development for Low-Resource Settings-A Systematic Literature Review. *In International*

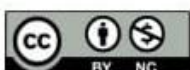
- Design Engineering Technical Conferences and Computers and Information in Engineering Conference 2023 Aug 20 (Vol. 87349, p. V006T06A041). American Society of Mechanical Engineers.
- [43]. Wang B, Hu X, Cao Y, Wu G, Gu B, Yao A, Cheng J, Ni Z, Zhao G. On-demand configuration of poly (L-lactic acid) monofilaments with degradation rate and mechanical performance for implanted medical devices. *Polymer Degradation and Stability*. 2025 Jul 30:111580.
- [44]. Pradel P, Zhu Z, Bibb R, Moultrie J. Investigation of design for additive manufacturing in professional design practice. *Journal of Engineering Design*. 2018 May 4;29(4-5):165-200.
- [45]. Culbreath CJ, Gaerke B, Taylor MS, McCullen SD, Mefford OT. Effect of infill on resulting mechanical properties of additive manufactured bioresorbable polymers for medical devices. *Materialia*. 2020 Aug 1; 12:100732.
- [46]. Rezvova MA, Klyshnikov KY, Gritskevich AA, Ovcharenko EA. Polymeric heart valves will displace mechanical and tissue heart valves: a new era for the medical devices. *International journal of molecular sciences*. 2023 Feb 16;24(4):3963.
- [47]. Kardos K, Told R, Pentek A, Sahai N, Banfai K, Vizi A, Koltai A, Szabo P, Gurdan Z, Bovari-Biri J, Pongracz JE. Surface disinfection change the mechanical, structural and biological properties of flexible materials used for additive manufacturing of medical devices. *Materials & Design*. 2024 Jan 1; 237:112616.
- [48]. Pal AK, Mohanty AK, Misra M. Additive manufacturing technology of polymeric materials for customized products: recent developments and future prospective. *RSC advances*. 2021;11(58):36398-438.
- [49]. Kuo CC, Chen HW, Farooqui A, Huang SH, Tseng SF. Enhancing the mechanical integrity of Polylactic acid components via ultrasound-assisted rotary friction welding for sustainable medical device fabrication. *Journal of Manufacturing Processes*. 2025 May 15;141:1324-36.
- [50]. Zhang L, Liu G, Guo Y, Wang Y, Zhang D, Chen H. Bioinspired functional surfaces for medical devices. *Chinese Journal of Mechanical Engineering*. 2022 Dec;35(1):43.
- [51]. Miranda Cid A, Pérez Mendoza GJ, Corro Valdez N, López Perrusquia N, Doñu Ruiz MA, González Rebattú y González A, Hernández Acosta HY. Study of mechanical properties of heat-treated peek for medical devices through additive manufacturing. *Progress in Additive Manufacturing*. 2025 May;10(5):3129-44.
- [52]. Reyes DR, van Heeren H, Guha S, Herbertson L, Tzannis AP, Ducrée J, Bissig H, Becker H. Accelerating innovation and commercialization through standardization of microfluidic-based medical devices. *Lab on a Chip*. 2021;21(1):9-21.

- [53]. Reyes DR, van Heeren H, Guha S, Herbertson L, Tzannis AP, Ducrée J, Bissig H, Becker H. Accelerating innovation and commercialization through standardization of microfluidic-based medical devices. *Lab on a Chip*. 2021;21(1):9-21.
- [54]. Ali SM, Noghianian S, Khan ZU, Alzahrani S, Alharbi S, Alhartomi M, Alsulami R. Wearable and flexible sensor devices: Recent advances in designs, fabrication methods, and applications. *Sensors*. 2025 Feb 24;25(5):1377.
- [55]. Tan M, Xu Y, Gao Z, Yuan T, Liu Q, Yang R, Zhang B, Peng L. Recent advances in intelligent wearable medical devices integrating biosensing and drug delivery. *Advanced Materials*. 2022 Jul;34(27):2108491.
- [56]. Kasoju N, Remya NS, Sasi R, Sujesh S, Soman B, Kesavadas C, Muraleedharan CV, Varma PH, Behari S. Digital health: trends, opportunities and challenges in medical devices, pharma and bio-technology. *CSI Transactions on ICT*. 2023 Apr;11(1):11-30.
- [57]. Morrison TM, Dreher ML, Nagaraja S, Angelone LM, Kainz W. The role of computational modeling and simulation in the total product life cycle of peripheral vascular devices. *Journal of medical devices*. 2017 Jun 1;11(2):024503.
- [58]. Huang SH, Liu P, Mokasdar A, Hou L. Additive manufacturing and its societal impact: a literature review. *The International journal of advanced manufacturing technology*. 2013 Jul;67(5):1191-203.
- [59]. Rani S, Jining D, Shoukat K, Shoukat MU, Nawaz SA. A human-machine interaction mechanism: additive manufacturing for Industry 5.0—design and management. *Sustainability*. 2024 May 15;16(10):4158.
- [60]. Klahn C, Leutenecker B, Meboldt M. Design for additive manufacturing—supporting the substitution of components in series products. *Procedia Cirp*. 2014 Jan 1;21:138-43.
- [61]. Johnson M, Chen Y, Hovet S, Xu S, Wood B, Ren H, Tokuda J, Tse ZT. Fabricating biomedical origami: a state-of-the-art review. *International journal of computer assisted radiology and surgery*. 2017 Nov;12(11):2023-32.
- [62]. Kumar SA, Prasad RV. Basic principles of additive manufacturing: different additive manufacturing technologies. In *Additive manufacturing 2021* Jan 1 (pp. 17-35). Woodhead Publishing.
- [63]. Gardan J. Additive manufacturing technologies: state of the art and trends. *Additive Manufacturing Handbook*. 2017 May 19:149-68.

- [64]. Martínez Raya A, Aranda-Ruiz J, Sal-Anglada G, Jaureguizar SM, Braun M. Effect of printing orientation on the mechanical properties of low-force stereolithography-manufactured durable resin. *Applied Sciences*. 2024 Oct 18;14(20):9529.
- [65]. Wong KV, Hernandez A. A review of additive manufacturing. *International scholarly research notices*. 2012;2012(1):208760.
- [66]. Khalaf AB, Hamam Y, Alayli Y, Djouani K. The effect of maintenance on the survival of medical equipment. *Journal of Engineering, Design and Technology*. 2013 Jul 5;11(2):142-57.
- [67]. Overhoff M, Diaz Palacios FR, Lumpe TS, Shea K. A Product Life Cycle Approach to Medical Device Development for Low-Resource Settings—A Systematic Literature Review Validated in Bolivia. *Journal of Mechanical Design*. 2026 Sep 1;148(9):091402.
- [68]. Singh S, Ramakrishna S. Biomedical applications of additive manufacturing: Present and future. *Current opinion in biomedical engineering*. 2017 Jun 1;2:105-15.
- [69]. Wang L, Jiang K, Shen G. Wearable, implantable, and interventional medical devices based on smart electronic skins. *Advanced Materials Technologies*. 2021 Jun;6(6):2100107.
- [70]. Javaid M, Haleem A. Current status and challenges of Additive manufacturing in orthopaedics: an overview. *Journal of clinical orthopaedics and trauma*. 2019 Mar 1;10(2):380-6.
- [71]. Kumar R, Kumar M, Chohan JS. Material-specific properties and applications of additive manufacturing techniques: a comprehensive review. *Bulletin of Materials Science*. 2021 Sep;44(3):181.
- [72]. Youssef HA, El-Hofy HA, Ahmed MH. *Manufacturing technology: materials, processes, and equipment*. Crc Press; 2023 Aug 17.
- [73]. Kumar S, Gopi T, Harikeerthana N, Gupta MK, Gaur V, Krolczyk GM, Wu C. Machine learning techniques in additive manufacturing: a state of the art review on design, processes and production control. *Journal of Intelligent Manufacturing*. 2023 Jan;34(1):21-55.
- [74]. Moetazedian A, Gleadall A, Han X, Ekinici A, Mele E, Silberschmidt VV. Mechanical performance of 3D printed polylactide during degradation. *Additive Manufacturing*. 2021 Feb 1;38:101764.
- [75]. Arefin AM, Khatri NR, Kulkarni N, Egan PF. Polymer 3D printing review: Materials, process, and design strategies for medical applications. *Polymers*. 2021 May 6;13(9):1499.
- [76]. Oldhoff MG, Mirzaali MJ, Tümer N, Zhou J, Zadpoor AA. Comparison in clinical performance of surgical guides for mandibular surgery and temporomandibular joint implants



- fabricated by additive manufacturing techniques. *Journal of the mechanical behavior of biomedical materials*. 2021 Jul 1;119:104512.
- [77]. Ricles LM, Coburn JC, Di Prima M, Oh SS. Regulating 3D-printed medical products. *Science translational medicine*. 2018 Oct 3;10(461):eaan6521.
- [78]. Schramm B, Risse L, Brüggemann JP, Richard HA, Kullmer G. Overview of structural mechanical investigations on additively manufactured medical products. *Journal of 3D Printing in Medicine*. 2018 Apr 30;2(2):59-68.
- [79]. Wang J. Research and Thinking on the Future Development Direction of Mechanical Design, Manufacturing and Automation. *International Journal of Frontiers in Engineering Technology*. 2023 Jun 1;5(6):53-6.
- [80]. Rodriguez NM, Burlison G, Linnes JC, Sienko KH. Thinking beyond the device: an overview of human-and equity-centered approaches for health technology design. *Annual review of biomedical engineering*. 2023 Jun 8;25(1):257-80.
- [81]. Maqsood N, Rimašauskas M, Ghobakhloo M, Mordas G, Skotnicová K. Additive manufacturing of continuous carbon fiber reinforced polymer composites using materials extrusion process. Mechanical properties, process parameters, fracture analysis, challenges, and future prospect. A review. *Advanced Composites and Hybrid Materials*. 2024 Dec;7(6):202.
- [82]. He X, Zou H, Geng Z, Wang X, Ding W, Hu F, Zi Y, Xu C, Zhang SL, Yu H, Xu M. A hierarchically nanostructured cellulose fiber-based triboelectric nanogenerator for self-powered healthcare products. *Advanced Functional Materials*. 2018 Nov;28(45):1805540.
- [83]. Srivastava M, Rathee S. Additive manufacturing: recent trends, applications and future outlooks. *Progress in Additive Manufacturing*. 2022 Apr;7(2):261-87.
- [84]. Lueders C, Jastram B, Hetzer R, Schwandt H. Rapid manufacturing techniques for the tissue engineering of human heart valves. *European Journal of Cardio-Thoracic Surgery*. 2014 Oct 1;46(4):593-601.
- [85]. Aziz S, Jung DW, Aqeel AB. Digital Twins in Smart Manufacturing. In *Handbook of Manufacturing Systems and Design 2024*. Taylor & Francis.
- [86]. Polisena J, Castaldo R, Ciani O, Federici C, Borsci S, Ritrovato M, and Clark D, Pecchia L. Health technology assessment methods guidelines for medical devices: how can we address the gaps? The International Federation of Medical and Biological Engineering perspective. *International journal of technology assessment in health care*. 2018 Jan;34(3):276-89.



- [87]. Gupta A, Pal P. Micro-electro-mechanical system–based drug delivery devices. In Bioelectronics and medical devices 2019 Jan 1 (pp. 183-210). Woodhead Publishing.
- [88]. Mladenovska T, Choong PF, Wallace GG, O’Connell CD. The regulatory challenge of 3D bioprinting. Regenerative medicine. 2023 Aug 1; 18(8):659-74.
- [89]. Wu Y, Lu Y, Zhao M, Bosiakov S, Li L. A critical review of additive manufacturing techniques and associated biomaterials used in bone tissue engineering. Polymers. 2022 May 23; 14(10):2117.