VALIDATION STRATEGIES FOR EMERGING TECHNOLOGIES IN MEDICAL DEVICES

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Abstract: *The future of medical devices is being radically reshaped by converging technologies. The medical devices are recognized as drugs, leading to stricter regulatory oversight. These devices, defined by their non-pharmacological mechanism, play a crucial role in diagnosis, treatment, prevention, and rehabilitation. Classified into four categories (Class A to D) based on risk, medical devices span consumables to high-risk implants. With rapid industry growth and 80% of devices imported, the sector is focusing on innovation and self-reliance. Emerging trends such as Artificial Intelligence (AI), 3D Printing, Blockchain, Internet of Things (IoT) and Digital Health are transforming the sector. AI aids in diagnostics and clinical decision-making, while 3D printing supports personalized healthcare. Blockchain ensures secure patient data management, IoT enables real-time monitoring, and digital health facilitates remote care. Validation of medical devices, including IQ, OQ and PQ, is critical to ensure quality and safety, following ISO 13485 and FDA 21 CFR 820.30. Process validation includes installation and operational checks, performance testing, and compliance with regulatory protocols. Software used in medical devices must also undergo rigorous validation as part of system design. These innovations and validation protocols aim to enhance healthcare delivery, improve patient outcomes, and promote regulatory compliance in India's growing medical device landscape.*

KEYWORDS
Medical Devices, AI, 3D Printing, Blockchain, IoT, Digital Health, Validation, IQ, OQ, PQ, Regulatory Compliance, ISO 13485, Software Validation

1. INTRODUCTION

In India, the Drugs & Cosmetics Act, 1940, governs all medical devices. The government has designated specific devices for use as pharmaceuticals in humans or animals as of April 1, 2020 following consultation with the pharmaceuticals Technical Advisory Board**.** All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder
- Diagnosis, monitoring, treatment, alleviation or assistance for any injury or disability
- Investigation, replacement or modification or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Disinfection of medical devices
- Control of conception [1]

The Indian medical device industry is expanding quickly and is predicted to play a significant role in the future. Only low- to moderately technological equipment, such as cardiac stents, surgical instruments, consumables and disposables, are manufactured domestically, with 80% of sales coming from imported devices.

An essential component of India's healthcare system, the medical devices industry helps prevent, diagnose, treat and manage illnesses and disabilities, helping to fulfil the National Health Policy (NHP) of 2017, the medical devices sector constitutes a multi-disciplinary field with the following broad classifications:

- Electronic equipment
- Implants
- Consumables and disposables
- Surgical instruments
- In-Vitro Diagnostic Reagents

The US, Europe, and Japan now control the majority of the global medical devices market, which has expanded dramatically over the past ten years to reach USD 433 billion by 2025. Thailand's market is predicted to increase by 8–10%, Brazil's by 5.8% and China's by more than 20% these emerging markets are also expanding. [2]

2. CLASSIFICATION

Medical device classification is determined based on the level of risk and potential hazard associated with its use. Devices posing minimal risk are placed in lower classes, while those with higher potential for harm fall into higher classes, requiring stricter regulatory controls, clinical evidence and post-market surveillance.

SI NO	CLASSIFICATION	SUB CLASS	LEVEL OF RISK	EXAMPLES	IMAGES
1.	CLASS A	-	Low risk	Stethoscopes, Thermometer &Endoscope	
2.	CLASS B	CLASS 2a CLASS 2b	Low moderate risk	Ultra sound equipment & Hearing aids	
3.	CLASS C	-	Moderate risk	Infusion pump, Ventilators, Intensive care monitoring equipment	

Table 1: Classification Of Medical Devices

In both rich and developing nations, the healthcare industry is essential to social welfare and raising living standards. To address illnesses and health problems, research and development

4.	CLASS D	-	High risk	Cardiac pacemakers, Deep brain stimulators, Breast implants, Heart valves.	

should continue. Technological developments can expand the sector's potential, especially in the medical domain. New computer technologies can help in early disease diagnosis and increase the precision of early disease detection. Thus, it is crucial that the healthcare industry continuously improves. [3] In view of growing importance of medical devices and the evaluate status as drugs. It is important to make note on future trends in the sector, because they are 1000 of medical devices ranging from a simple pricking needle to the sophisticated pacemaker. The following future trends appears to be significant.

- Artificial Intelligence in Medical devices
- 3D Printing in Medical devices
- Blockchain for Health Data Security
- Internet of Things (IoT)
- Digital health in medical devices

3. ARTIFICIAL INTELLIGENCE IN MEDICAL DEVICES

A Plan Turing first proposed the idea of simulating critical thinking and intelligent behaviour using computers in 1950. AI is the science and engineering of building intelligent machines, according to John McCarthy's 1956 definition. Simple 'if, then rules' gave way to complex algorithms as AI developed.[16]

AI is a quickly developing paradigm in many scientific domains, including the treatment of those suffering from diseases. By strengthening the existing method, it allows machines to learn and identify patterns from many models, advancing decision-making processes in particular domains.[17]

3.1. Trend: AI and machine learning are increasingly used in medical devices for tasks such as image analysis, diagnostics, predictive analytics and personalized treatment recommendations.

3.2. IMPLICATIONS

3.2.1. Diagnostic Accuracy: AI algorithms are capable of analysing medical images (such as X-rays and MRIs) and diagnostic data with high precision, often detecting subtle abnormalities or patterns that may be difficult for human clinicians to identify.

3.2.2. Personalized Medicine: By analysing large datasets of patient information, AI can identify individualized treatment options based on genetic profiles, disease progression and response to therapy. This personalized approach improves treatment outcomes and reduces adverse effects.

3.2.3. Clinical Decision Support: AI-powered decision support systems assist healthcare professionals by providing evidence-based recommendations for diagnosis, treatment

planning, and patient management. These systems help reduce diagnostic errors, improve clinical efficiency and promote standardized care across different healthcare settings.

3.2.4. Drug Discovery and Development: AI accelerates drug discovery processes by predicting drug interactions, identifying potential therapeutic targets and optimizing clinical trial designs. This fosters innovation in pharmaceutical research and expedites the introduction of new therapies to market. [4]

4. 3D PRINTING IN MEDICAL DEVICES

The capacity of additive manufacturing or 3D printing to produce intricate geometries and patient-specific equipment has made it a major breakthrough in the medical industry. Originally created for prototyping, it is now used to produce functioning medical devices, including surgical instruments, implants and prostheses. By addressing issues with conventional production procedures, this technique makes it possible to employ cutting-edge biomaterials and make iterative improvements. Additionally, it makes production more economical, which makes it a desirable choice for customized healthcare solutions. But issues like production consistency, regulatory approval and biocompatibility need to be resolved. This study offers insights into the possibilities and constraints of this game-changing technology by summarizing current trends, obstacles, and future directions in the development of 3D medical devices.[5]

Example for 3D printing: **3D printer guide to producing a customized pill or tablet in pharmaceutical formulation development**

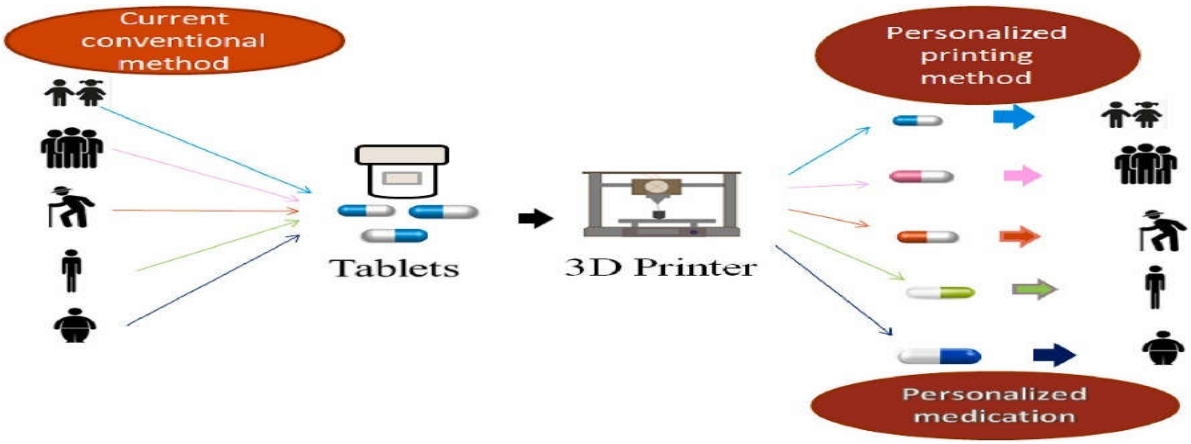


Fig1: 3D printer guide to producing a customized pill or tablet in pharmaceutical formulation development [6]

4.1. CURRENT TRENDS

- Personalized Healthcare By increasing each patient's unique anatomy, 3D printing produces customized medical devices such as hearing aids, dental implants and prostheses that improve comfort, functionality and patient outcomes
- Advances in bioprinting make it possible to use biomaterials to generate organ-like structures, which could help with organ shortages and provide useful tissues for transplantation and study
- 3D printing makes it possible for decentralized, on-demand manufacture during the COVID-19 epidemic, which lowers big stock levels and speeds up the creation of vital medical supplies

- The development of scaffolds that promote tissue regeneration through the use of 3D printing and stem cell technologies has the potential to completely transform reconstructive surgery and wound healing [5]

4.2. APPLICATION

- In orthopaedics, 3D printing is essential for the precise production of titanium and polymer-based implants and tailored prosthetics that increase osseointegration and patient comfort and functionality
- Dental implants are being revolutionized by 3D printing since it allows for unique devices, cuts down on production time and uses cutting-edge materials for strength, longevity, and aesthetic appeal. It helps with accurate implant placement as well
- Surgical instruments that are complex and ergonomic are made possible by additive manufacturing, which also lowers the danger of contamination and enhances performance. Precision and efficiency are improved with custom tools, particularly in minimally invasive procedures
- Organ transplantation and regenerative medicine may benefit from the use of living cells in bioprinting, a 3D printing process. Successful research aims to lower transplant rejection by examining cartilage, vascular systems and skin
- 3D printing helps with surgical planning by creating anatomical models tailored to each patient using medical imaging data, increasing patient safety, decreasing operating times, and improving precision
- Drug delivery methods based on 3D printing provide controlled-release capsules, tablets, customized implants and exact dosage control for better therapeutic results and long-term condition treatment efficacy [5]

3D printing technology offers numerous advantages over traditional methods, but its medical applications depend on selecting safe, biocompatible, and sterilizable materials. It is crucial to develop novel, sterilizable and biocompatible materials that can withstand extreme human body conditions.

5. BLOCKCHAIN FOR HEALTH DATA SECURITY

Blockchain technology namely Bitcoin, is a decentralized ledger that safely records transactions in a peer-to-peer network, ensuring its transparency and verifiability. Engineering, automotive, computers, aerospace, business, accounting, finance, defines and healthcare are just a few of the industries it is transforming by enabling safe transactions without the need for middlemen.

Industry sectors like engineering, automotive, computers, aerospace, business, accounting, and healthcare have all seen a transformation due to the adoption of smart technologies like machine learning, IoT, virtual reality, and artificial intelligence. Blockchain technology has transformed healthcare by enhancing patient-provider communication and transparency. However, because of duplicates, different names, and network availability, the increasingly complicated healthcare records have not been streamlined. To stop criminal activity and protect

patient privacy, healthcare security is essential. Patient data is accessible to unauthorized individuals, which permits personal information to be misused or sold. Industry 4.0-enabled blockchain technology can address these problems by guaranteeing data integrity and avoiding failure and tampering at any one time.[7]

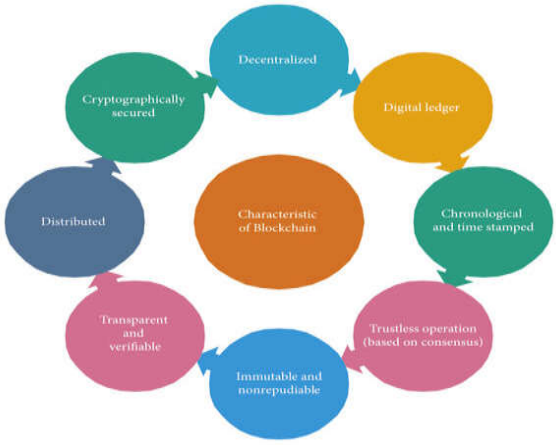


Fig 2: Characteristic of blockchain

6. INTERNET OF THINGS (IOT)

Kevin Ashton created the Internet of Things (IoT) in 1999 as a result of cutting-edge information and communications technology research. It can improve the standard of living for city dwellers and meet the rising need for affordable healthcare systems. Video conferencing can be used to connect with doctors, improve health and save time and money in light of the growing global population and the prevalence of chronic diseases. Additionally, patients can use their phones to record their medical issues, which leads to more tailored care and better patient outcomes. It is anticipated that the Internet of Things would result in better patient outcomes and lower healthcare management expenses.[8] The four layers component structure of IOT,

- Sensing layer
- Aggregated layer
- Processing Layer
- Cloud Platform

The integration of the physical world into computer-based systems and the reduction of human intervention, the Internet of Things (IoT) makes it possible to remotely sense and regulate parameters, improving efficiency, accuracy, and economic benefits.[9] A vulnerability rate of 9.97% was obtained from the vulnerability assessment, which found 3,964 vulnerabilities in 1,604 devices, of which 345 had "Critical" vulnerabilities, 411 had "High" vulnerabilities, 1,468 had "Medium" vulnerabilities, and 1,740 had "Low" vulnerabilities.[10] The Internet of Things (IoT) provides advantages like better security, less human labour, increased resource efficiency, and the development of artificial intelligence. The connect, analyse, and integrate modules make up its three primary sections. Connect includes endpoint administration, high-speed messaging, and device visualization. Real-time incoming streams are analysed by the Analyse domain, which also filters and corrects data and adds context to raw data.

Enterprise connectivity and the dynamic dispatch of vital IoT data and events to applications and process flows are the focus of the integration domain. Additionally discussed is API-based integration with cloud apps and Internet of Things devices. link, analyse, and integrate are the three submodules that make up an IoT base system. These modules link things to IoT platforms, analyse data, create business intelligence and enhance user experiences.[11]

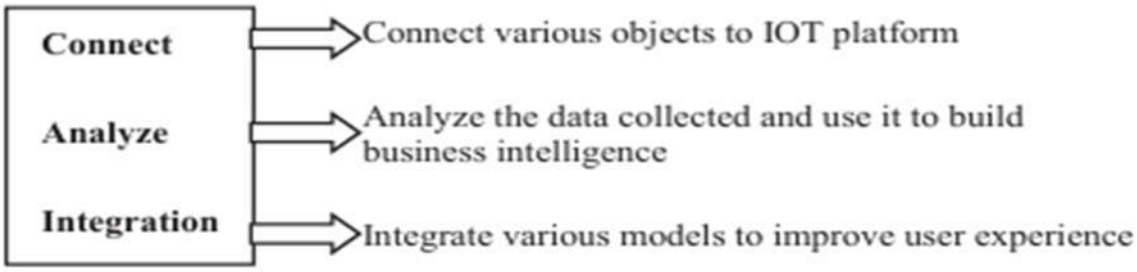


Fig 3: Basic Feature of an IOT based system

6.1. CHALLENGES

The Internet of Things has the potential to improve human health, but there are still issues with functionality, performance, data privacy, accuracy, security and stability. These issues fall into the following categories: security, performance, energy, integration, computational intelligence, and disease prediction.[8]

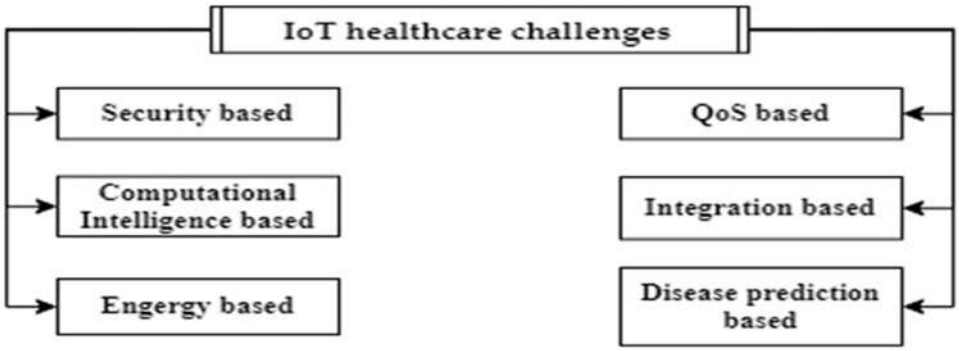


Fig 4: IOT healthcare challenges

7. DIGITAL HEALTH IN MEDICAL DEVICES

The global market for digital health, estimated at $288.55 billion in 2024, is projected to expand at a compound annual growth rate (CAGR) of 22.2% between 2025 and 2030. Manufacturers of wearable technology, mHealth app providers, e-prescription systems and domestic demand for telehealth care platforms are some of the factors propelling this rise. The market is also being driven by government initiatives, trends in preventive healthcare, and more funding for mHealth entrepreneurs. Digital health tools facilitate communication with healthcare practitioners, treatment adherence and patient tracking.[12] The market for digital health is projected to reach a value of US$258.25 billion by 2029, with a compound annual growth rate (CAGR) of 6.88% and revenue of US$197.88 billion in 2025. It is anticipated that the average ARPU will be $135.28. With Digital Treatment & Care being the largest market, the US is anticipated to produce the highest revenue.[13]

The growing use of smartphones, the need for telemedicine and remote monitoring services and the creation of digital health solutions to address COVID-19 issues are all driving the growth of the digital health industry. Digital health is a topic that many organizations are working on, and in recent years, the number of scholarly publications in this field has grown significantly.

The combination of internet-based healthcare with wearable sensors, cell phones and mobile apps is known as digital health.[18] Its main purpose is to interpret data, assist in decision-

making, or even cause the body to take automatic activities that are frequently set off by software. The goal of this technology is to improve general health outcomes and patient care.[19]

Digital technologies that improve healthcare delivery by facilitating remote patient monitoring, expanding access to services, and cutting costs are known as digital health-focused medical equipment. Through early detection and intervention, they also present the possibility of better patient outcomes. But there are obstacles like cybersecurity threats, privacy issues, and regulatory control that call for close monitoring of these gadgets.[14]

EXAMPLE

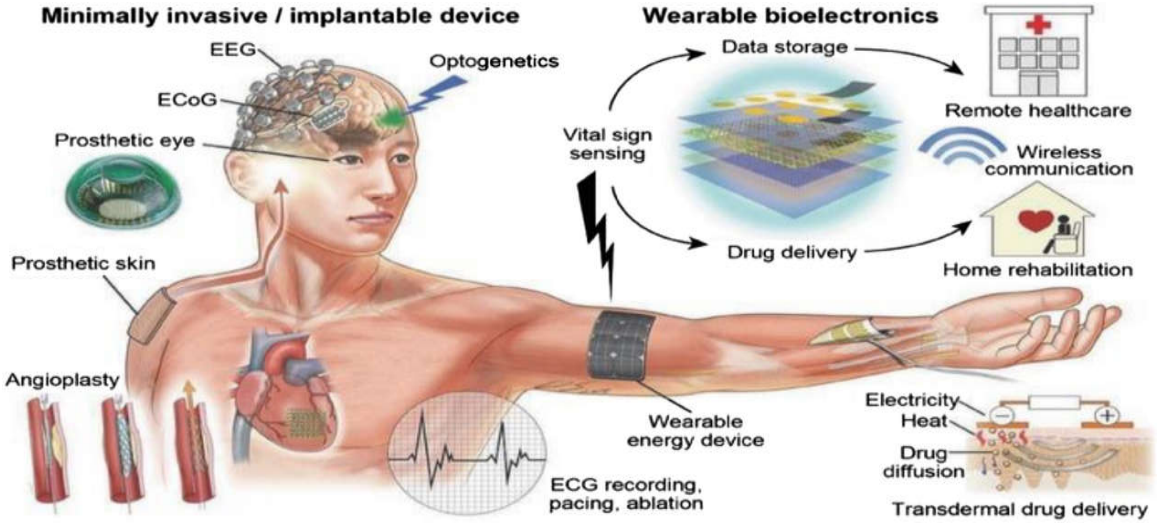


Fig 4: Illustration of Wearable and Implantable Biosystems Connected through Digital Health Technologies

Wearable technology is transforming biomedicine by making it possible to monitor patients' health continuously and longitudinally outside of the clinic. Wearables are being used by medical professionals to monitor patients and build algorithms for automated health event prediction, prevention, and intervention. In a variety of contexts, such as hospital intensive care units, in-home chronic illness treatment and resource-constrained field settings, new wearables-based analytical systems are revolutionizing the quality and accessibility of healthcare. Improved intensive care unit alarms, ongoing arrhythmia detection, and rural neonatal temperature monitoring are examples of recent developments. The constraints of current work, future directions and significant advancements in wearable sensing for healthcare are covered in this article.[15]

8. VALIDATION FOR MEDICAL DEVICES

The process of verifying through analysis and impartial proof that particular needs for a particular intended use can be reliably satisfied is known as validation.

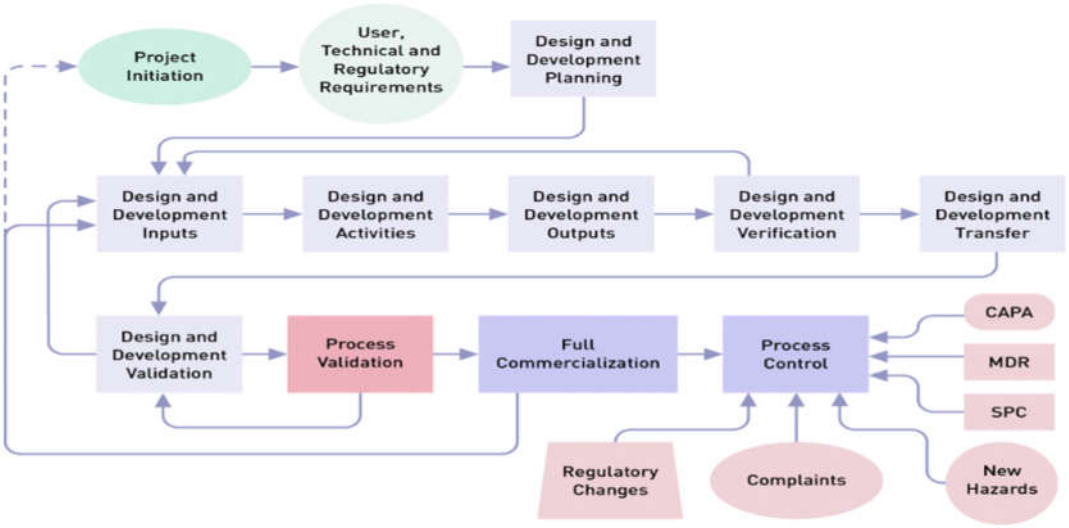
8.1 CORRELATION BETWEEN DESIGN VALIDATION AND PROCESS VALIDATION

Process validation concentrates on producing products, design validation makes sure that gadgets fulfil intended functions and user demands. Companies usually carry out validation in the last phases of developing new products and processes, following FDA design control criteria 820.30 and ISO 13485 standard clause 7.3. Device quality features and process factors are determined by the design control process. Validation should be done for new processes as well as for current processes that require frequent qualification, have been expanded, changed,

or have seen a drop in performance or a rise in customer complaints. The following are some instances of procedures that need to be verified:
This includes sterilization, packaging sealing, maintaining clean room conditions, heat treating, plating, welding, soldering, painting and plastic injection moulding.

In addition, process validation is needed if the following conditions exist:

- Routine testing of the final product may not be sensitive enough to confirm the required safety and effectiveness of the medical devices
- Demonstrating that the manufacturing process consistently delivers the intended product may require clinical evaluation or destructive testing
- Standard end-product tests might not detect every possible variation that could affect the device's safety or performance
- The manufacturing process capability is either not well established or is suspected to be just barely meeting the product specifications



By contrast, Product verification is effective in certain processes like manual cutting, visual inspection of printed circuit boards and testing of wiring harnesses, ensuring high reliability and accuracy. However, understanding and controlling variation sources is crucial.

8.2 BASIC STEPS FOR PROCESS VALIDATION IN MEDICAL DEVICE

The basic principles of process validation must:

- Verify that the equipment can function effectively within the specified operating parameters
- Confirm that all equipment and instruments are capable of maintaining performance within those limits
- Conduct multiple tests runs or cycles that reflect the full operational range of the equipment
- Continuously monitor the validated process during regular production activities

- Requalify and recertify the equipment periodically or whenever necessary to maintain reliability

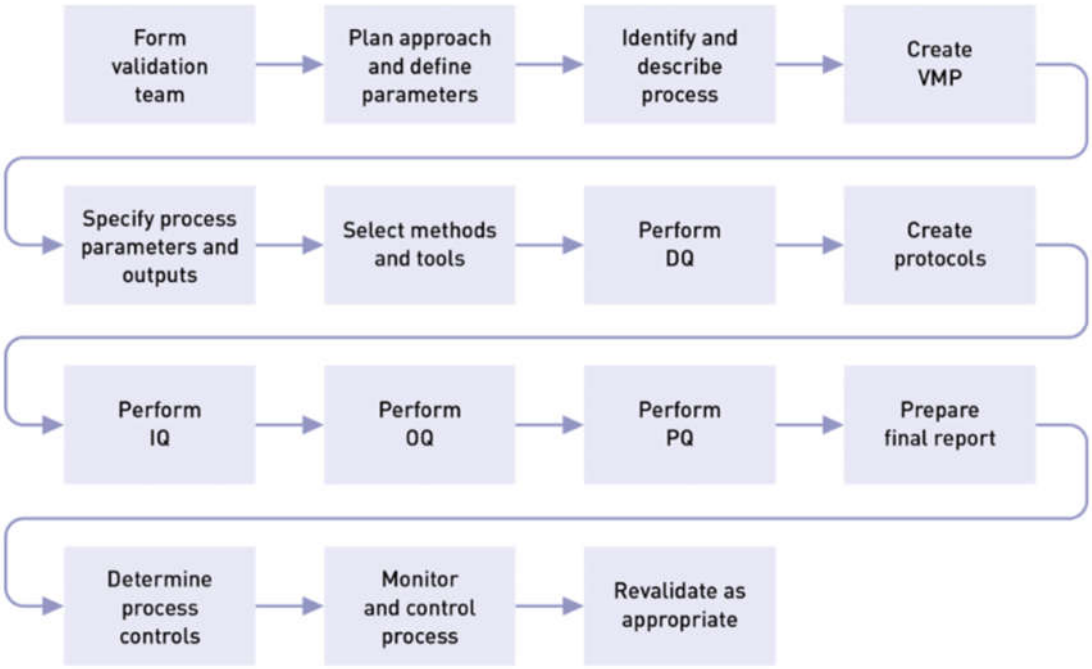


Fig 5: Basic steps for process validation in medical device

8.3 Content of Validation Protocols

There are three types of validation protocols (IQ, OQ, PQ) and we will talk more about those later. But first let's discuss the contents of a protocol. The details of what should be included in your process validation protocol can be found in Here's what the guidance suggests:

- Determine which processes require validation
- Specify the medical device(s) to be produced using the validated process
- Define clear, measurable criteria for successful validation outcome
- Establish the duration and scope of the validation period
- Identify the work shifts, personnel and equipment involved in the process
- List the utilities needed for the equipment (e.g., power, water, air), including quality standards for each
- Ensure all operators involved are properly trained and qualified
- Provide a detailed overview of the manufacturing process being validated
- List all relevant specifications for the final product, components, materials
- Mention any specific controls or conditions required for upstream processes during validation
- Define process parameters to be monitored, along with methods for their control and measurement
- Specify product characteristics to be monitored and how they will be checked
- Include any subjective evaluation criteria for the product
- Clearly define what constitutes nonconformance for both objective and subjective metrics
- Identify statistical tools and techniques to be used for data collection and analysis

- Take into account the need for equipment maintenance and potential repairs during validation
- Establish the conditions or triggers that would necessitate revalidation of the process

8.4 Format of a Basic Medical Device Process Validation Protocol

A well-prepared protocol defines the appropriate rules, procedures and policies to be followed throughout process validation. As illustrated below, it covers aspects such as facilities, equipment, methods and personnel training. It also specifies process inputs and limits, outlining all the essential steps needed to successfully complete the validation project. While the outline provided here is not exhaustive, it highlights the level of detail expected in a thorough protocol. For a deeper understanding, it is recommended to review the GHTF process validation guidance or participate in specialized training on this topic. The following section presents the basic structure of a process validation protocol.

9 Overview of IQ, OQ and PQ for Medical Device Manufacturing Processes: The process validation plan (PVP) carries out three essential steps in the validation process with the goal of developing a stable, predictable, and minimally variable medical device manufacturing process.

9.1 Installation Qualification (IQ): Checks that all equipment and components are installed correctly, following design specifications and manufacturer guidelines**.**

9.2 Operational Qualification (OQ): Verifies that the equipment operates as intended within defined conditions, with all critical operating limits clearly established and understood.

9.3 Performance Qualification (PQ): Confirms that the process reliably produces the desired results under actual operating conditions, demonstrating its stability and capability**.**

9.1 Installation qualification

IQ is a procedure that guarantees that pipes, instruments, equipment, and services are installed correctly. It entails comparing engineering drawings, functional specifications created during the project design phase and pipe and instrument diagrams. All gauges, service conduits and system components are identified and recorded at this phase. Examining processes, equipment specifications, reports, documentation, protocols, and acceptance requirements for test findings are all part of IQ. The creation of a C report and QA approval mark the conclusion of the procedure.

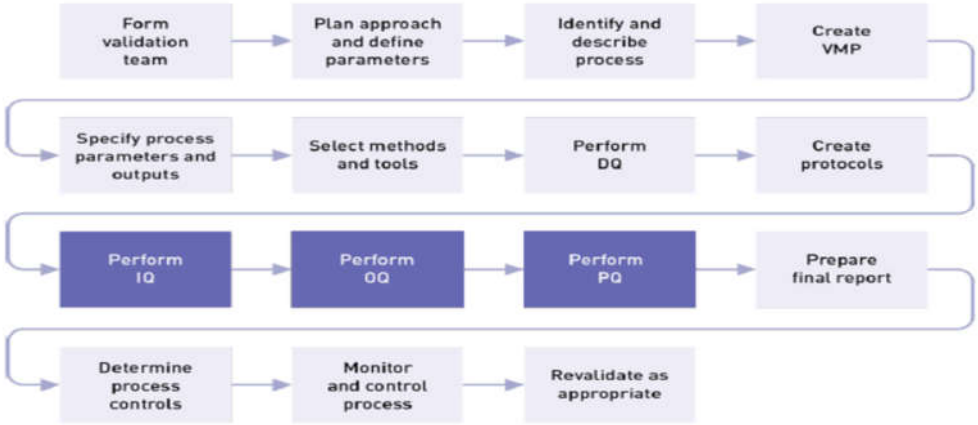


Fig 6: Installation Qualification Process for Medical Device

US FDA Requirements for IQ

The US FDA outlines the key areas of IQ in 21 CFR 820.70(g)

1. Maintenance schedule: To achieve production criteria, manufacturers must create and adhere to schedules for cleaning, maintenance and equipment adjustments. They should keep the updated records and also, they should mention the record people who did that work
2. Inspection: In order to maintain equipment schedules, manufacturers are required to do periodic inspections in accordance with SOP, recording the date and the personnel performing the inspections
3. Adjustment: Equipment that has to be adjusted on a regular basis must have inherent restrictions or permissible tolerances displayed by the manufacturer or be readily available to the people making the changes
4. Automated processes: Manufacturers must make sure that the computers or data processing systems they employ for their manufacturing processes are operating properly

9.2 Operational Qualification (OQ)

Operational qualification (OQ), which tests parameters to guarantee equipment function, comes after IQ and installation inspections. OQ guarantees that, in all expected operating ranges within the chosen environment, machinery, measuring devices, utilities, and production areas operate as intended. It highlights crucial process factors and offers proof that devices will still fulfil requirements even if they go beyond them. The OQ procedure seeks to guarantee the performance and quality of the final product.

- Highlights the critical operating parameters
- Specifies the experiments to be performed on these key variables
- Outlines the order in which the experiments should be conducted
- Details the measuring equipment required
- Confirms that the product can meet the defined acceptance criteria

9.3 1Performance qualification (PQ)

Performance Qualification (PQ) is the last step in the validation process, following the completion of the Initial Quality Check (IQ) and Operational Qualification (OQ). This step guarantees that, over time, the system will continuously generate a satisfactory output under typical operating circumstances. PQ is applied to the whole production process rather than just specific parts. To guarantee the system's functioning, it is essential to make sure that all operational test data complies with established acceptance criteria from earlier qualifications.

10. SOFTWARE DEVELOPMENT AS PART OF SYSTEM DESIGN

During system design, the choice to use software to accomplish system functions is usually decided. The general system requirements and design for the system components that will be implemented with software are usually the source of software requirements. Users usually do not specify whether they want hardware, software or a combination of both to meet their demands and planned applications for a final gadget. Consequently, software validation needs to be taken into account in relation to the system's overall design validation. Using software to implement system functions is decided upon during system design. The design for particular system components and the overall system needs are the sources of software requirements.

Since user requirements and planned applications for a completed device are not stated, software validation must be taken into account as part of the system's overall design validation.

CONCLUSION

The medical device industry in India is rapidly evolving, propelled by technological innovations such as Artificial Intelligence (AI), 3D Printing, Blockchain, the Internet of Things (IoT) and Digital Health. These advancements are not only enhancing diagnostic accuracy, treatment personalization and patient monitoring but also paving the way for smarter, safer, and more efficient healthcare solutions. Ultimately, the convergence of engineering, IT and healthcare in medical devices presents an immense opportunity to transform patient care, making it more personalized, accessible and effective while adhering to robust regulatory and quality assurance frameworks.

As India positions itself as a significant player in the global medical devices landscape, there is a growing need to enhance domestic manufacturing capabilities, adopt global best practices, and invest in R&D. Embracing emerging technologies and ensuring regulatory compliance, data integrity and patient safety will be crucial in meeting the healthcare demands of the future.

With regulatory frameworks like the Drugs & Cosmetics Act, 1940 and standards such as ISO 13485, validation processes (IQ, OQ, PQ) ensure that both products and manufacturing systems meet stringent quality and safety benchmarks. The integration of software into medical devices further emphasizes the importance of software validation in the broader scope of design and process validation.

REFERENCES

[1] Central Drugs Standard Control Organization. Download file division. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTI5Ng

[2] Department of Pharmaceuticals, Government of India. Strategy document on NMDP 2023. 2023. Available from: https://pharmaceuticals.gov.in/sites/default/files/Strategy%20Document%20on%20NMDP%202023_0.pdf

[3] Ratta P, Kaur A, Sharma S, Shabaz M, Dhiman G. Application of blockchain and Internet of Things in healthcare and medical sector: applications, challenges, and future perspectives. J Food Qual. 2021; 2021:7608296.

[4] Badnjević A, Avdihodžić H, Pokvić LG. Artificial intelligence in medical devices: past, present and future. Psychiatr Danub. 2021;33(Suppl 3):101-6.

[5] Geetha V. 3D medical device development: current trends, challenges, and future prospects. Multidiscip Res Arts Sci Commer. 2025; 18:4.

[6] Mamo HB, Adamiak M, Kunwar A. 3D printed biomedical devices and their applications: a review on state-of-the-art technologies, existing challenges, and future perspectives. J Mech Behav Biomed Mater. 2023; 143:105930.

[7] Hussien HM, Yasin SM, Udzir NI, Ninggal MI, Salman S. Blockchain technology in the healthcare industry: trends and opportunities. J Ind Inf Integr. 2021; 22:100217.

[8] Abdulmalek S, Nasir A, Jabbar WA, Almuhaya MA, Bairagi AK, Khan MA, Kee SH. IoT-based healthcare-monitoring system towards improving quality of life: a review. Healthcare. 2022;10(10):1993.

[9] Kumar R, Rajasekaran MP. An IoT-based patient monitoring system using Raspberry Pi. In: Proceedings of the International Conference on Computing Technologies and Intelligent Data Engineering (ICCTIDE'16). 2016 Jan 7–9. IEEE. p. 1–4.

[10] McMahon E, Williams R, El M, Samtani S, Patton M, Chen H. Assessing medical device vulnerabilities on the Internet of Things. In: Proceedings of the 2017 IEEE International Conference on Intelligence and Security Informatics (ISI). 2017 Jul 22. IEEE. p. 176–8.

[11] Bhardwaj R, Gupta SN, Gupta M, Tiwari P. IoT-based healthware and healthcare monitoring system in India. In: 2021 International Conference on Advance Computing and Innovative Technologies in Engineering (ICACITE). 2021 Mar 4. IEEE. p. 406–8.

[12] Grand View Research. Digital health market size, share & trends report, 2030. Statista. Digital health—India. Available from: https://www.statista.com/outlook/dmo/digital-health/India

[13] Kasoju N, Remya NS, Sasi R, Sujesh S, Soman B, Keshavadas C, et al. Digital health: trends, opportunities and challenges in medical devices, pharma and biotechnology. CSI Trans ICT. 2023;11(1):11–30.

[14] Dunn J, Runge R, Snyder M. Wearables and the medical revolution. Pers Med. 2018;15(5):429–48.

[15] Kaul V, Enslin S, Gross SA. History of artificial intelligence in medicine. Gastrointest Endosc. 2020; 92:807–12.

[16] Luchini C, Pea A, Scarpa A. Artificial intelligence in oncology: current applications and future perspectives. Br J Cancer. 2022;126(1):4–9.

[17] Klonoff DC, Kerr D. Overcoming barriers to adoption of digital health tools for diabetes. J Diabetes Sci Technol. 2018; 12:3–6.

[18] Dunn J, Runge R, Snyder M. Wearables and the medical revolution. Pers Med. 2018; 15:429–48.

[19] U.S. Food and Drug Administration. Process validation: general principles and practices. Available from: https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf

[20] Oriel STAT. Medical device process validation. Available from: https://www.orielstat.com/blog/medical-device-process-validation/