The Performance of A Few Medical Devices Made in India and Other Nations, Along with Regulatory Considerations

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***Abstract*—The performance and regulatory compliance of medical devices are critical factors influencing patient safety, treatment outcomes, and healthcare efficiency. This study investigates the clinical performance of selected medical devices including IV cannulas, urinary catheters, intraocular lenses, and coronary stents manufactured in India and other nations. Data were collected from government and private hospitals across multiple cities, examining device utilization, efficacy, and patient outcomes. The study also evaluates regulatory considerations, comparing the Indian framework under the Medical Device Rules (2017) with international practices such as the U.S. FDA regulations. Results indicate that while Indian-made devices generally meet functional and safety standards, there are variations in performance metrics when compared to imported devices, particularly for high-risk devices like coronary stents and intraocular lenses. Government hospitals demonstrated higher usage due to accessibility and affordability, whereas private hospitals reported selective usage of specialized devices. The study underscores the importance of stringent regulatory compliance, post-market surveillance, and quality management systems to ensure safety and effectiveness. Furthermore, alignment with global standards is recommended to enhance the competitiveness of Indian medical devices in the international market. Overall, this research highlights the interplay between device performance, clinical outcomes, and regulatory frameworks, providing insights for policymakers, healthcare providers, and manufacturers.**

***Index Terms*— Medical Devices, Device Performance, Regulatory Compliance, Indian Medical Device Rules, U.S. FDA Regulations.**

I. INTRODUCTION

The study of health and disease has evolved in parallel with human civilization, reflecting both cultural beliefs and empirical knowledge. Ancient societies sought to explain illness through a blend of supernatural, environmental, and physiological concepts, which gradually developed into organized systems of medicine. Archaeological and textual evidence suggests that early civilizations, including those of Mesopotamia, Egypt, China, and India, established codified traditions of healthcare based on herbal remedies, surgery, and spiritual healing.[1,2]

In Egypt, the Ebers Papyrus (c. 1550 BCE) documented over 700 prescriptions using plant- and mineral-based drugs, representing one of the earliest systematic medical texts.[3] Similarly, in India, the Charaka Samhita emphasized internal medicine and preventive care, while the Sushruta Samhita attributed to Sushruta, often called the "Father of Surgery" outlined over 300 surgical procedures and 120 instruments, including detailed descriptions of excision, puncturing, extraction, and suturing[4]. In China, the Huangdi Neijing (The Yellow Emperor's Classic of Medicine) established the theoretical foundations of Traditional Chinese Medicine through the principles of yin-yang balance and qi circulation [5]. These ancient traditions not only shaped indigenous healthcare systems but also influenced Greek, Roman, and later European medicine through cross-cultural exchanges facilitated by trade and conquest. The gradual shift from supernatural interpretations of disease to rational, observation- based practices laid

the foundation for modern biomedical science [1]. Today, many of these traditional principles continue to inform complementary and alternative medicine, reflecting the enduring legacy of early medical knowledge.

So, healthcare systems are very important for keeping the population healthy and making it better. Frameworks and models have been developed to illustrate the healthcare system and its proposals. The models that are utilized most often are from the World Health Organization (WHO) models of 2007; 2009.

Figure 1 shows that there are six building pieces that need to be put together to reach the objectives. The building components include service delivery, the health workforce, information, medicinal items, vaccines, and technology, funding, and governance, as shown in figure 1. A system is made

Liaropoulos (1997) drew a schematic representation as shown in Figure 2 of the alternative definitions of biomedical, medical, healthcare and health technology[6].

Medical devices are a subset of health technologies as seen in figure 2. It plays an important role in improving patient's health. The professionals involved make critical decisions with respect to healthcare using the devices for identification of patient problems[7-9].

Medical devices include syringes, catheters, prosthetics, artificial joints, inhalation and infusion equipment's, laboratory equipment's and even masks. The use of medical devices involves some considerable risk to health. Regulating them is one of the mechanisms to balance the risk and benefits[10]. Hence it is necessary to fulfil the regulatory requirements and to develop in a way they are safe to use[11].

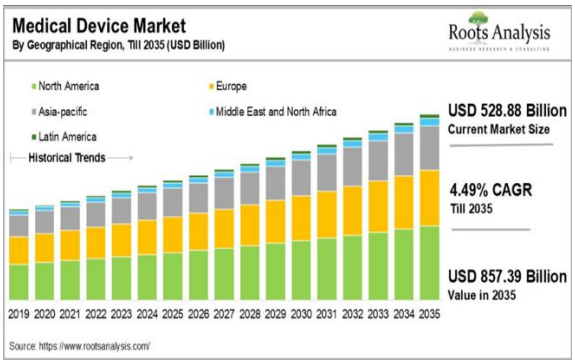
Medical devices are the newest technology of the 90's which is used to save lives of the persons having different medical conditions. These devices are used in many forms like diagnosing, monitoring and treating the disease or a condition. The devices vary from simple to complex

devices like sticking plasters, syringes or latex gloves, spectacles, wheelchairs, hearing aids, heart stents, pacemakers and replacement joints for knees and hips etc. In today's world, we have more than 500,000 medical technologies used to improve and extend the lives of the patients[12-14]. This is one of the major industries having worldwide sales of more than £110 billion per year[15-19].

The market is one of the fastest growing and most complex in the world[20]. In 2017 there were approximately 2 million devices that can be categorized into more than 22000 generic devices groups in the global market[21]. According to the statistics of US Department of Commerce, the global sales of device in 2016 reached $339.5 billion and in 2019 it was 412 billion as shown in Figure 3.

The global medical market is expected to grow at a compound annual growth rate (CAGR) of 4.1%, and reach $522 billion by 2022[22]. The market is further expected to grow at a CAGR of 6.2% in the period of 2023-2031 to reach a value of about $965.2 billion by 2031.

Ramakrishna et al. in 2015 has stated that there are 3 main driving forces behind the growth of medical device market. 1) Ageing population and longer lifespan, 2) Changing life style and sophisticated life quality and 3) Increased public awareness as shown in figure 4[23-27].



A medical device is any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, for a medical purpose. These devices are used for the diagnosis, prevention, monitoring, treatment, or alleviation of disease, or for the compensation of an injury or disability, among other medical objectives.

According to the World Health Organization (WHO), a medical device can range from simple tools like tongue depressors and thermometers to complex technologies such as pacemakers and magnetic

resonance imaging (MRI) machines. WHO defines a medical device as:

"Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes"[29]

Unlike pharmaceutical products, which achieve their primary intended action by pharmacological, immunological, or metabolic means, medical devices typically work by physical or mechanical means. For example, a stent physically props open a blood vessel, while a hearing aid amplifies sound waves.

Medical devices are regulated to ensure safety and effectiveness, and regulatory standards vary by country. In the United States, the Food and Drug Administration (FDA) classifies medical devices into three categories based on risk Class I (low risk), Class II (moderate risk), and Class III (high risk) (FDA, 2023).

Examples of Medical Devices:

- Low-risk: Bandages, surgical masks, thermometers
- Moderate-risk: Blood pressure monitors, infusion pumps
- High-risk: Implantable defibrillators, artificial heart valves

The role of medical devices in healthcare is indispensable, particularly in modern diagnostics, treatment, and patient care management. With the advancement of technology, new devices now incorporate digital health technologies, such as artificial intelligence (AI), robotics, and wireless connectivity, expanding their capabilities in managing chronic diseases, remote monitoring, and personalized medicine.

The medical device market grew at a projected rate of 6-7% in the year 2009 with increased in growth rate of 2% by 2011. In the year 2023 the Indian market stood at 6.0 billion USD and it is projected to grow at a rate of 8.50% and will reach.0 billion USD by 2028. The trends show that the Indian medical device market is growing at a fast rate. The reason behind the fast growth rate is the economy and global economic crisis has helped. The other factor helping the growth is low-cost manufacturing and resources as we have more than 1 billion young population[9].But still the import ratio is higher than domestic medical devices, which is 70 percent. The market share of Indian medical device industry is about 2.5 billion with an annual growth rate of the sector is about 8.5% which will be further increase as years to come. The main factors responsible for the growth are increased public and private sector investments in healthcare, wealthier populations and rapid increase and proliferation of government and private health insurances.[32]

Challenge: Global Harmonization of Medical devices in the world

The medical device industry has expanded rapidly over the past few decades, becoming one of the most dynamic segments of the global healthcare sector. However, the regulatory environment governing medical devices remains highly fragmented across countries and regions. Each nation has its own legal framework, approval procedures, classification systems, and quality standards, which often differ significantly from one another. While these regulatory systems aim to safeguard patient safety and ensure product efficacy, the lack of harmonization creates substantial challenges for manufacturers, regulators, and healthcare providers.

Global harmonization of medical device regulations is therefore seen as a critical need to promote innovation, enhance patient access to safe technologies, reduce duplication of testing and evaluation, and streamline market entry. Organizations such as the International Medical Device Regulators Forum (IMDRF) and earlier initiatives like the Global Harmonization Task Force (GHTF) have sought to build consensus among regulators. Yet, differences in economic development, healthcare priorities, technical capacities, and political considerations continue to hinder full alignment.

This challenge highlights the ongoing tension between ensuring rigorous oversight at the national level and building a consistent global framework that can support international trade, faster innovation, and equitable access to life-saving technologies.[33, 34, 35, 36.]

The main challenge faced throughout the world is harmonization of medical devices. To counter these problems countries like US, European Countries, China Japan have formed a consortium and a common set of guidelines to sell the device in their countries. There are other countries who have their own set of regulation for medical devices such as Australia, Canada, the research studies have focused on the US, EU, China, Korea and Japan as they are the hub of

medical device manufacturing and control the medical device market in the world. Talked about US it is the largest market for medical devices with a market share of 38%. EU union is the second medical device market having value of €100 billion making up 31% of the world, while China has become the third largest medical device market. Earlier Korea was also fast developing medical device market as it had the highest expenditure in healthcare sector. Japan is the economic powerhouse and you cannot leave it behind in the medical device industry. The projection of Japan medical device industry will reach around US $31.7 billion.

The gap of synchronization around the world has also created an issue for the recognition of different class of medical device based on design complexity, its application, and features safety concern if misused. Around the world it is defined in different categories but they are typically grouped in 3 classes: class I, II and III (or A, B,). The classification is based on the risk related to health from low risk to high risk.

Table: 2-Medical Devices Classification[37]

Class IIb	Moderate–High Risk	Ventilators, Infusion pumps, Orthopedic implants	General + Special controls, clinical data required
Class III	High Risk (life-supporting, life-sustaining, or implanted devices)	Pacemakers, Heart valves, Implantable defibrillators, Deep brain stimulators	Strictest regulatory controls, pre- market approval, post-market surveillance
In-vitro Diagnostic (IVD)	Varies by risk (Class A–D in EU, low–high in WHO)	Blood glucose monitors, HIV test kits, COVID-19 diagnostic kits	Separate regulatory pathway with performance validation and risk-based approval

US Medical Device Regulation[58-60]

In 1938, the law for Federal Food, Drug, and Cosmetic Act was formed and it covered medical devices to a certain extent. In 1976, the Food and Drug Administration (FDA) received its jurisdiction to regulate devices prior to reaching the market and its use in US. Upon integration, the medical devices were classified into three types based on the risk it had. The most significant change was in 1997 and 2016 which was "least burdensome provisions." The Federal law is under 21CFR Part 800 – 861. The details will be given in the results and discussion. The majority of medical devices are subject to market via any one of three pathways: Premarket Notification (commonly known as 510(k) Clearance), Premarket Approval (PMA), and Humanitarian Device Exemption (HDE). There are other pathways, also such as the De Novo, and Investigational Device Exemption (IDE), however these are less frequently used for commercial approval. The 510(k) is the most commonly utilized regulatory pathway. These devices never receive FDA approval, but rather clearance. Devices cleared by 510(k) do not require supporting clinical research. It helps in cost effective manufacturing but the drawback is no clinical studies are done. Premarket Approval, the most rigorous process, requires supporting clinical data to demonstrate safety and effectiveness. Based on the risk classification of the devices the decision of which pathway a device will get clearance is followed by FDA.

Class	Risk Level	Examples	Regulation / Control
Class I	Low Risk	Bandages, Examination gloves, Stethoscope, Tongue depressors	General controls (basic safety, labeling, quality standards)
Class IIa	Low–Moderate Risk	Hearing aids, Contact lenses, Dental fillings, Ultrasound equipment	General + Specific controls (performance standards, clinical evaluation, manufacturing requirements)

Regulatory Authority

- FDA (Food and Drug Administration), specifically the Center for Devices and Radiological Health (CDRH), regulates medical devices in the U.S.
- Authority comes from the Federal Food, Drug, and Cosmetic Act (FD&C Act) and amendments, such as the Medical Device Amendments of 1976.

Device Classification

Devices are classified based on risk:

- Class I (Low risk): General controls are sufficient.

Examples: Bandages, stethoscopes, manual wheelchairs

II. REVIEW OF LITERATURE

Teodora Miclăuș et al [2020][38] The growing number of emerging medical technologies and sophistication of modern medical devices (MDs) that improve both survival and quality of life indexes are often challenged by alarming cases of vigilance data cover-up and lack of sufficient pre- and post-authorization controls. Combining Quality with Risk Management processes and implementing them as early as possible in the design of MDs has proven to be an effective strategy to minimize residual risk. This article aims to discuss how the design of MDs interacts with their safety profile and how this dipole of intended performance and safety may be supported by Human Factors Engineering (HFE) throughout the Total Product Life-Cycle (TPLC) of an MD in order to capitalize on medical technologies without exposing users and patients to unnecessary risks.

Noam Tau et al [2020][39] Medical Device Safety Communications (MDSCs) are used by the US Food and Drug Administration (FDA) to convey important new safety information to patients and health care professionals. The sources of initial safety signals that trigger MDSCs have not been described previously. To assess the sources of initial safety signals that trigger publication of MDSCs and the potential associations among MDSC data source, type of safety issue, and subsequent FDA action. Design, Setting, and Participants In this cross-sectional study, all MDSCs published on the FDA website between January 1, 2011, and December 31, 2019, were assessed. The MDSC characteristics, sources of initiating safety signals, regulatory approval or clearance pathways of the related medical devices, and subsequent FDA actions were collected from the FDA website. Main Outcomes and Measures The main outcome were the distribution of sources of initial safety signals that led to publication of MDSCs. Secondary aims included exploration of potential associations among safety signal sources (direct reporting vs other), type of safety issue (death vs other), and FDA action (withdrawal vs other). A total of 93 MDSCs were evaluated. Median time from device approval to MDSC posting was 10 years (interquartile range, 6-16 years). The most common data sources that triggered MDSCs were direct reports to the FDA through the Medical Device Reporting (MDR) program (44 of 93 [47%]) followed by regulator-initiated assessments (32 [34%]). Common safety issues included patient injury (25 [27%]), potential wrong diagnoses (19 [20%]), and death (18 [19%]). Frequent FDA action after MDSC posting included recommendation for increased vigilance and caution (47 [51%]), complete device withdrawal (12 [13%]), and warnings of specific lots or clinics (12 [13%]). There was a statistically

III. OBJECTIVES AND SCOPE

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Objective:

- To compare specific device performance metrics (e.g. failure rate, complication rate, longevity, precision) between Indian-made devices and foreign-made devices in selected categories.
- To review regulatory frameworks in India and in comparator countries (e.g. USA, EU, Japan) for those device categories focusing on pre-market approval, post-market surveillance, recall mechanisms.
- To examine case studies of device failures or inferior performance (both Indian and foreign) to illustrate regulatory strengths and weaknesses.
- To assess the capacity of domestic infrastructure in India (manufacturing, testing labs, standardization, reporting systems) that supports or limits device performance.

To propose regulatory and policy recommendations that would improve device performance, safety, and global competitiveness of Indian-manufactured devices.

IV. METHODOLOY

Stage	Activities
Device Category Selection	Pick 2-4 device categories for comparison. For example: hip implants, transcatheter heart valves, in vitro diagnostics (IVD) kits (e.g., RT-PCR kits), imaging equipment (e.g. digital X-ray, portable ultrasound).

Data Collection	Gather published data: clinical studies, cohort studies, registry data (if available), recall/failure/complication reports. For foreign devices, use literature, FDA/EMA recalls, etc. For Indian devices, hospital audits, published Indian studies, manufacturer data.
Regulatory Review	Identify concrete examples of device underperformance or failure. For each case: timeline, how the issue was discovered, regulatory response, patient impact. Some cases might be from India, some from abroad.
Case Studies	Identify concrete examples of device underperformance or failure. For each case: timeline, how the issue was discovered, regulatory response, patient impact. Some cases might be from India, some from abroad.
Stakeholder Interviews / Surveys	Interviews with clinicians, hospital procurement heads, device manufacturers (Indian & foreign), regulatory officials to get qualitative data on perceptions of device reliability, regulatory burdens, challenges, etc.
Statistical / Comparative Analysis	Where quantitative data exist, compare failure rates, complication rates, device lifespan etc. Possibly meta-analysis or comparative risk ratios. Adjust for context (e.g. usage environment, maintenance).
Infrastructure & Capacity Assessment	Evaluate number and capabilities of certified testing labs, regulatory inspection frequency, traceability/registry systems in India vs elsewhere. Check whether Indian devices are subjected to same levels of post-market surveillance.
Synthesis & Recommendations	Based on findings, draw regulatory gaps, infrastructural gaps, propose policy/regulation improvements.

Example	What happened / Performance issue	Regulatory Considerations & Lessons
Johnson & Johnson ASR Hip Implants	The DePuy (J&J) Articular Surface Replacement (ASR) hip implants were globally recalled because of high failure rates. In India, despite the global recall in 2010, about 4,700 surgeries had been done using those implants before the import license was revoked and recall notice issued.	Highlights delay in India's regulatory response; lack of timely adverse event reporting; failure to act even when foreign regulatory authorities had raised alarms. India lacked robust registries/tracing systems to reach affected patients. Regulatory gap: import licensing did not compel rapid action post foreign recall.
Meril Life Sciences – Myval TAVR Valve & MeRes100 Bioresorbable Scaffold	Indian company Meril developed Myval (TAVR) which got CDSCO approval in Nov-2018 and then European CE mark in mid-2019; similarly, MeRes100 BRS was approved and has begun export etc. Indicates that Indian devices are reaching high technical performance standards competitive internationally.	Regulatory success: that Indian firm could satisfy both Indian and European conformity assessment. Shows that with appropriate R&D, manufacturing, and regulatory compliance, Indian devices can perform at global levels. But these are high-investment devices; many Indian devices are lower-risk/disposable. Lessons: need to build capacity, maintain standards; ensure proper clinical data; quality manufacturing.
BETiC (Biomedical Engineering & Technology Innovation Centre, IIT Bombay)	Developed ~50 innovate medical devices, licensed ~20 to industry; many designed for low-resource settings. However, these devices often struggle with market access, standardization, scale-up.	Performance in innovation vs performance in real-world utility depends on adherence to standards, ability to certify, manufacturing quality, regulatory approval. Regulatory challenges: getting clear product specifications, navigating clinical validation, obtaining approvals; ensuring compatibility with hospital/clinical workflows; cost etc.

Regulatory Considerations & Gaps:

From the above examples, here are regulatory issues that affect device performance, especially in India:

1. Pre-market clinical evidence
   - Foreign approvals sometimes accepted in India via "free sale certificate" without requiring local clinical trials or validation. This can allow devices whose performance in Indian settings (environment, surgical training, patient population) is uncertain.
2. Post-market surveillance & adverse event reporting

- In India, for a long time, adverse event reporting was more voluntary or had weak mandates. Delays seen in taking action even after known failures abroadLack of mandatory device registries or robust tracking of implanted devices. Hard to trace patients if devices recalled

3. Regulatory response delays

- As with the J&J hip implant example: despite recall elsewhere, Indian regulatory agencies delayed revoking import licenses or issuing warnings.

4. Standards & manufacturing quality

- Even when Indian devices perform well in lab/test settings, reliability can drop in field use due to problems in manufacturing consistency, quality control, environmental robustness.Certification and standardization (ISO, IEC, BIS) are improving but unevenly applied.

5. Infrastructure and capacity limitations

- Testing labs, certification bodies, skilled human resources, regulatory inspection capacity sometimes lacking.Weakness in health technology assessment (HTA) for devices: cost-effectiveness, real-world performance data often missing.

6. Regulatory framework clarity

- Earlier, many devices were regulated loosely under drug rules; medical devices rules were introduced in 2017 but implementation, clarity, amendments are still evolving. Guidance documents, product specification norms, etc., are sometimes missing or not detailed

V. RESULTS AND DISCUSSION

Indian Medical device regulation:

In India, the regulation of medical devices is governed by the Medical Devices Rules (MDR), 2017, framed under the Drugs and Cosmetics Act, 1940, and amended in 2020 to bring all medical devices under regulation. The process begins with the classification of devices into four categories based on risk: Class A (low risk), Class B (low-moderate risk), Class C (moderate- high risk), and Class D (high risk). Regulatory oversight is divided between the State Licensing Authorities (SLAs), which handle Class A and B devices, and the Central Drugs Standard Control Organization (CDSCO), which regulates Class C and D devices. Manufacturers and importers are required to register their devices on the Sugam portal, apply for licenses (Forms MD-3/MD-4 for imports and MD-7/MD-8 for manufacturing), and demonstrate compliance with a certified Quality Management System (QMS) under ISO 13485:2016. For high-risk devices, clinical investigations may be required before approval. Once applications are reviewed and conditions are met, licenses are granted by the competent authority. After approval, devices are subject to post-market surveillance under the Materiovigilance Programme of India (MvPI), which monitors adverse events and ensures safety and effectiveness. In addition, the National Pharmaceutical Pricing Authority (NPPA) regulates the prices of certain critical medical devices such as coronary stents and knee implants to ensure affordability. Overall, the Indian medical device regulatory framework seeks to balance patient safety, quality assurance, and accessibility, while aligning with global best practices through harmonization with international standards.

India has been a major business sector for investment for healthcare industries as to meet the needs of growing population. Although it is growing medical device market is still dependent on imports for high end products. The equipment distribution is through the regional players having network of sub distributors hence it is difficult for smaller manufacturer to compete with large players. Prior to the formation of the rules, medical devices were governed under the legislation of Drugs & Cosmetic Act, 1940. The main objective of the government was to distinguish medical devices from drugs and therefore the rules were formed and termed as medical device regulation, 2017 and was made effective on 1st January, 2018. It not only classified the medical

devices from drugs, but also eased the process for obtaining licence. The regulation will not only classify medical devices from drugs, and ease the process of licensing and clinical examinations. It will also help the manufacturers to develop quality devices and make India a hub for medical devices in the PM's vision of "Make in India". The regulation has 97 rules with 8 schedules and around 40 forms in 12 chapters for registration to market the medical devices.

Chapter I defines the medical devices as "(i) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant (ii) substances including

mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides and (iii) devices notified from time to time under the Drugs and Cosmetics Act, 1940 (23 of 1940)". The definition is very clear and simple to understand and it is in line with the guidelines of WHO for medical devices but can be elaborated by mentioning the use as support therapy, or treatment of disease, diagnosis of diseases.
Chapter II is on Regulation of medical devices where the classification of medical devices based on the risk has been done. Here both medical devices and in vitro diagnostic medical devices are classified in four risk categories A, B, C and D having low to high risk.

- Class A– Cotton wool, Examination gloves, enema devices, IV cannula, bandages etc.
- Class B– anesthesia breathing circuits syringes and sets for infusion pumps, urinary catheter etc.
- Class C– removable dental prosthesis, urethral stent, contact lens, harmodializers etc.
- Class D– dedicated disposable cardiovascular surgical instruments, angioplasty balloon catheters, spinal needles etc.

The classification is done by the central licensing authority based on the use of the device. Based on the classification the list will be published on the website of CDSCO. The authority from time to time makes additions and deletions from the list, or modifies the class. It also covers the product standards for medical device as per Bureau of Indian Standards and if for device having no relevant standard have to confirm to ISO or IEC standards.
Chapter III covers the Authorities, Officers and Bodies. The central licensing authority is they competent authority for enforcement of the rules and approval of medical devices for Class C and Class D devices. The state licensing authority is the approval authority for Class A and Class B devices. Various institute, firms and Govt. aided organizations are listed as National Accreditation Body they provide the quality certification as per Government of India. The accreditation body shall not act as Notified bodies. The main function of the Accreditation body is to lay down the conformity assessment activities for Notified bodies and standard for accreditation and audit the notified bodies. The notified body is any institute, organization or corporate that are accredited for conducting audits of manufacturing sites of Class A and Class B in conformance with quality systems and other standards. The notified bodies are identified and approved by central licensing authority. Once approved the certification as notified body will remain valid in perpetuity till 5 years.
Chapter IV Manufacture of Medical Devices for Sale or for Distribution for Class A and B devices is to be done to state licensing authority and the approval is given by them upon submission of all the relevant documents pertaining quality, safety. No audit of the premises will be conducted prior grant of license for Class A medical devices and the audit will be done by notified bodies within four months from the grant of licence. In Class B devices the audit will be conducted upon application within three months for quality and safety by notified bodies. Upon submission of reports and other documents by the notified bodies the state authority will grant licence. For Class C and D devices application has to be done to central authority for licence and within 2 months the audit will be conducted with experts, notified bodies. The report will be submitted to the central authority and upon scrutiny and found satisfactory they will issue the licence.
Chapter V Import of Medical Devices, the authorized agent has to apply for the grant of license to the central authority. The central authority may inspect the overseas manufacturing site. If the device of Class C and Class D is not from US, EU, UK than clinical investigation is required and for Class A and B the licence is granted on safety and performance data published in the country of origin.
Chapter VI Labelling of Medical Devices, all the particulars shall be printed in indelible ink having name of the device, details necessary for user to identify, the name of manufacturer with address of manufacturing premises, the quantity in terms of weight, measure, volume, number of units etc. month and year of manufacturing with expiry date. In case of sterile devices date of sterilization is required. In case of devices made from steel or titanium or non- sterile devices expiry date is not required. The device must have a global trade item number and serial number, batch number with manufacturing and or expiry date.
Chapter VII covers the clinical investigation and performance evaluation. Clinical investigation must be done with respect to approval from central licensing authority and ethics committee of the drugs and cosmetic rules. If the authority requires the clinical investigation, it needs to be carried out for class C and

D devices. However, it is not required for Class A and B devices, the manufacturer has to submit the safety performance report.

Chapter VIII covers the manufacture of device which is not having predicate devices, for such devices clinical investigation is necessary, if the device has drugs incorporated then toxicological data, reproductive studies and teratogenic studies have to carried out if the drugs are not approved by the Indian government. If the device is approved from any of the listed countries United Kingdom or the United States of America or Australia or Canada or Japan and device has been marketed for at least two years then clinical investigation are not required.

Chapter IX describes the duties of medical device officer, testing officers and Notified bodies. They have to inspect yearly all the manufacturing sites collection of samples, investigation of any compliant made in writing to the control authority.

Chapter X describes the Registration of Laboratory for performing test or evaluation, while Chapter XI covers the sale of medical devices where it has to document the details of the vendors and hospitals as per legal regulations, Chapter XII is for export of medical devices where a manufacturer requires a free sale certificate regarding the quality, safety and performance of the device as required by the importing authority to the central authority.

The benefits of the regulation are Single window clearance – the application for import, manufacture, sale/distribution etc will done though a single online portal of the central government under the initiative of Digital India. It will reduce the clearance time for grant of license and make the business easy. Clinical investigation will also be conducted for class C and D devices and if necessary for Class B devices having higher risk. It will guarantee the quality and performance. A timeline has been fixed of 90 days for clearance of permission to conduct trials. The license will be for life time for the distributor or manufacturer; however, they have to pay renewal fees every 5 years. In case of Class A and B devices the licenses will be cleared by the state licensing authority and for C and D will be cleared by Central Licensing authority. Labelling requirements is to done with name of the device, month & year of manufacturing and expiry, License number.

The process for registration of medical device in India is shown in table bellow

Step	Description	Authority / Requirement	Relevant Forms /Standards
1. Classification	Devices classified into four categories based on risk: Class A (low), Class B (low-moderate), Class C (moderate-high), Class D (high).	CDSCO (final authority)	MDR, 2017 – Risk-based classification
2. Regulatory Authority	Oversight divided between central and state authorities.	SLA: Class A & B; CDSCO: Class C & D	–
3. Registration	Device registration through the Sugam portal before license application.	Manufacturer / Importer	Online registration (Sugam portal)
4. License Application	Import/manufacturing license required for marketing.	CDSCO / SLA	Import: Form MD-3 & MD-4; Manufacturing: Form MD-7 & MD-8

US Medical Device Regulation:

In the United States, the regulation of medical devices is overseen by the Food and Drug Administration (FDA), specifically through its Center for Devices and Radiological Health (CDRH). The U.S. system follows a risk-based classification framework, dividing devices into three classes: Class I (low risk), such as bandages and stethoscopes, which are subject to general controls; Class II (moderate risk), such as infusion pumps and diagnostic imaging devices, which require special controls and may need clearance through the 510(k) premarket notification process; and Class III (high risk), such as pacemakers and heart valves, which posethe greatest risk and require rigorous Premarket Approval (PMA) based on clinical data. Manufacturers must register their establishments with the FDA, list their devices, and comply with Quality System Regulations (QSR) under 21 CFR Part 820, which ensure good manufacturing practices. In addition to premarket evaluation, the FDA enforces post-market surveillance through adverse event reporting, recalls, and compliance inspections to ensure device safety and effectiveness throughout its lifecycle. This framework is designed to balance innovation and patient safety, while ensuring that

medical devices introduced into the U.S. market are safe, effective, and of high quality.

US medical device amendment act was published in 1976 and the regulatory agency is FDA (Food and Drug Administration) to provide safety and effectiveness of medical devices intended for human use. The rules for medical device were covered under the title 21CFR parts 800 –861. Centre for Devices and Radiology Health (CDHR) is responsible for implementing medical devices rules. Classification of medical device in US is also on risk methodology, but mainly classified into 3 categories.

- Class I Medical Devices have minimal or no risk,
- Class II devices have moderate risk and require to prove safety and efficacy,
- Class III provide support to life and their failure can be life threatening and has high risk.

The definition of medical device as per the regulation is "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or any other similar or related article, including any component, part or accessory which is recognized in official National Formulary or the US Pharmacopoeia, or supplement, intended for use in the diagnosis of disease or other conditions or in cure, treatment, prevention or affecting the structure or function of the body and does not achieve any of its intended purposes."

Part 800 General which as 3 subparts subpart A is reserved, subpart B is for requirement for specific medical devices – contact lens solutions must be sterile and the quality to be suitable for safe use in the eyes including the primary packaging. Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration. Subpart C is Administrative Practices and Procedures for the detention of medical devices intended for human use believed to be adulterated or misbranded.

Part 801 is for labelling where it needs to have the name of device, address of manufacturer, packer or distributor, intended used of the device and adequate direction for usage. The label to have a unique device identification number and the details of the device.

Part 803 is for medical device reporting that covers the reporting requirements for adverse events using platform. It also covers the initial and supplemental follow up reports, Requirements for developing and maintaining, implementation of MDR procedures, user friendly reporting requirements covering information to submit for individual adverse events and annual report in case of user facility. It also covers importer and manufacturer reporting requirements against the adverse events.

Part 806—Medical Devices; Reports of Corrections and Removals. Here the manufacturers and importers have to report to FDA for corrections and removal and to have to maintain all the records of the corrections and removals including the person under whom the reports are maintained. Also, the FDA makes the reports open to public domain

Part 807—Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices: The owner or the manufacturer has to register if he intends for commercial manufacturing by providing all the relevant details of the device and of manufacturing site. It also covers the premarket notification procedure for devices introduced for the first time and does not have similar devices in the market for class I & II. For devices under commercial distribution or reintroduced with change in material of composition has to follow pre market procedure application.

Part 808—Exemptions from Federal Pre-emption of State and Local Medical Device Requirements covers the exemptions application its processing and revocation of exemption in states of US as per their local medical device requirements.

Part 809—In Vitro Diagnostic Products for Human Use. The section covers the confidentially of submitted information regarding in vitro diagnostic products, its labelling requirements and exception or alternatives of labelling requirements and the general requirements for manufacturers, restriction on sale, distribution and use of specific reagents

Part 810—Medical Device Recall Authority It describes the procedures thatthe Food and Drug Administration will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act. It includes cease of distribution and notification order, regulatory hearing, written request for review, recall order recall strategy communications done for cease in distribution and recall and its reports and public notices.

Part 812—Investigational Device Exemptions. The FDA in protection of public health and safety the development of devices intended for human use need

to conduct clinical investigation. For scientific research provide exemptions for medical device.

Part 814—Premarket Approval of Medical Devices: The section deals with efficient and through device review process for approval for devices are safe and effective which meet the statutory criteria for approval and disapproval of PMA for devices that not have been shown safe and effective but having statutory approval.

Part 820—Quality System Regulation It enforces the Current good manufacturing practice (CGMP) requirements to govern the methods used, facilities and controls used for the design, manufacture, packaging, labelling, storage, installation, and servicing of all finished devices intended for human use for all the class of medical devices. Audit is also part of this system where regular audits have to be conducted and audit reports have to be furnished to FDA. The gaps identified needs to be complied and corrective reports needs to submitted.

Part 821—Medical Device Tracking Requirements The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act stating that the manufacturer adopts a method for tracking class II and class III devices if the devices meets any one the following criteria: failure of device having serious adverse health consequences or a device implanted for more than 1 year, a life sustaining or supporting device use outside the user facility. It is intended to ensure the devices can be traced from manufacturing facility to patient. It covers the manufacturer who has stopped manufacturing the device is liable to legal action in case of adverse events.

PART 822—Postmarket Surveillance This part implements the procedures and requirements of post market surveillance of II and III devices to meet the criteria failure of device would have serious adverse health consequences, if the device is implanted for more than a year or a device used outside the user facility to support or sustain life. It is done to maximize surveillance plans

to collect the data for any unforeseen adverse events, actual rate of anticipated adverse events to protect the public health.

Part 830—Unique Device Identification is given to all device to track the lifecycle of the device and misbranding. It also covers the ANSI standards or ISO standards to be incorporated. The unique device numbering is given by the FDA. The certification is given by certified agencies approved from FDA.

Part 860—Medical Device Classification Procedures Covers the classification and reclassification of devices intended for human use. The criteria and procedures to be used for classification in I, II or III devices. It also provides procedure for manufacturers to participate in proceedings to classify the devices. It also describes the data required for determination on safety and efficacy of the device for classification.

Part 861—Procedures for Performance Standards Development- This part implements the establishment, amendments in procedure for performance and revocation of performance standard applicable to devices intended for human use.

To market the medical device in US market it has to follow any of the bellow mentioned methodology

VI. CONCLUSION

In modern healthcare industry there are three main pillars drugs, vaccines and medical devices. Medical devices are a range of products covering from bandages, syringes to complex and sophisticated devices incorporating bioinformatics, nanotechnology, artificial intelligence designed and manufactured for improvement and treatment of patients. Therefore, in 2003 World Health Organization set a framework for defining the term medical device. It was need as the definition of medical devices is different in different countries. Also, voluntary group of various countries and regulatory bodies made a task force named Global Harmonization Task Force (GHTF) for creating uniformity of medical device regulation though the regulations vary in different countries. In the study we have studied medical device regulations of India, USA and EU.

Indian Medical Device Regulation

Indian medical device regulation is framed under the guidelines of Central Drug Standard Control Organizations (CDSCO) and it falls under the Drug and Cosmetics Act 1948. Earlier the formation of regulation they were regulated as drugs and at present few of the medical devices are still regulated as drugs to control the prices. As drug evolution pathway is different from medical devices and to control the quality and safety medical device regulation was introduced. Medical device regulation was introduced

in 2017 and implemented in the year 2018. As per the regulation the definition of medical devices is "Medical equipment includes anything from household appliances to computer software. used by itself or in combination with other items, and is meant to be used for diagnosing, preventing, monitoring or providing support therapy is called medical devices" Upon introduction of regulation further amendments are introduced till present the latest amendment was in the year 2023. Medical devices are classified based on health risk into four categories Class A – low risk, Class B – low to moderate risk, Class C – moderate to high risk and Class D – High risk. This classification was used to harmonize with other countries. The content of regulation has 12 chapters for device registration. The application has to be done through SUGAM portal for all categories for obtaining license. The application for Class A and B will be assessed by state level authorities/central level authorities. Till 2023 state level authorities were issuing license for class A and B devices. But as per the recent amendment central level authority will issue the licenses for all class of medical devices for better control fortracking, safety and efficacy. The devices must have conformity of BIS or ISO 13485. Timeline to receive the license is around 1 year from the date of application and the validity is 5 years from the date of approval. However, no clinical investigation or performance studies are conducted for imported devices as they have to provide their performance report conducted previously. Notified bodies have been identified for evaluation of medical devices but their role is not clearly defined in the regulation. There are also no clear clinical performance or investigation methodologies defined in the regulation. No unique identification number is also given to the approved devices to track during the life cycle. There is also no provision for auditing of premises for their quality and processes in the regulation. It is very easy for importers to register their medical devices than compared to local manufacturers. Also BIS is not accepted around the world. CDSCO maintains the records of approved medical devices but no details are available.

Regulations of Medical Devices in US

US medical device regulation was first implemented in 1976 under the code of federal regulation (CFR) under the Title 21: Food and Drugs Part 800-861. Food and Drug Administration (FDA) and Centre for Devices and Radiology Health (CDHR) are responsible for implementation of medical device rules. Regular amendments are added on yearly basis for better implementation and control of the regulation. As per the regulation the definition is "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which isintended to treat, cure, prevent, mitigate, diagnose disease in man". Medical devices are classified into three categories Class I – Low risk, Class II – Moderate Risk and Class III – High risk. To market medical devices in US market they have to follow Pre-market notification (510K), Premarket Approval (PMA), HDE, De novo process, product development protocol. QMS is the basic requirement of GMP in 21 CFR; clinical data needs to be submitted for Class II and III while in case of Class I self-declaration is sufficient. The device is given a unique identification number and is valid till its life cycle. The licence validity is indefinite but regular audits are conducted of the premises for production activities by FDA agencies. If the premises do not comply with the requirements warning is issued and even the licence of the facility is revoked till it gives the compliance. Timeline for approval is 1 month for class I devices, 3-6 month for Class II and 18-30 months for Class III devices. The regulation is so stringent that the manufacturer has to keep all the data regarding the devices till its life cycle and have to share it with FDA and they are available online for common public

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