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REGULATORY APPROVAL PROCESS OF LOW-RISK, MODERATE-RISK, AND HIGH-RISK MEDICAL DEVICES IN INDIA AND THE USA

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Abstract:

Medical devices play a vital role in modern healthcare by supporting the prevention, diagnosis, monitoring, and treatment of diseases. As these devices directly influence patient safety and clinical outcomes, effective regulatory frameworks are essential to ensure their quality, safety, and performance before they are marketed. Regulatory approval requirements vary according to the device's risk classification and differ between countries, making it important for manufacturers, healthcare professionals, and regulatory affairs personnel to understand these regulatory systems.

The findings showed that medical devices in India are regulated by the Central Drugs Standard Control Organization (CDSCO) under the Medical Devices Rules, 2017, while the United States regulates medical devices through the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. India follows a four-tier classification system (Class A–D), whereas the United States follows a three-tier system (Class I–III). Regulatory requirements become more stringent with increasing device risk in both countries, particularly regarding clinical evaluation, technical documentation, quality management, and post-market surveillance.

The study concludes that both India and the United States adopt risk-based regulatory approaches to ensure patient safety and device effectiveness. The findings provide valuable insights for manufacturers, researchers, and regulatory professionals seeking efficient regulatory approval and global market access.

Keywords: Medical Devices, CDSCO, FDA, Dental Mirror, Nebulizer, Coronary Stent

1. INTRODUCTION

Medical devices are any equipment, machinery, implants, or other similar items used to diagnose, treat, or prevent illness or other body problems in humans. These devices might range from basic equipment such as thermometers and tongue depressors to sophisticated devices such as pacemakers, Magnetic Resonance Imaging (MRI) machines, and robotic surgical systems. The World Health Organization (WHO) defines a medical device as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or another similar or related article, intended by the manufacturer to be used, alone or in combination, for a medical purpose [1].

The global market for medical devices is anticipated to increase at a compound annual growth rate (CAGR) of 5.5% between 2022 and 2029, rising from $495.46 billion in 2022 to $718.92 billion in 2029 [12]. In India, the market for medical devices is anticipated to reach US$ 12 billion by 2020 and increase at a CAGR of 15%, which is 2.5 times the rate of worldwide growth. India ranks in the top 20 medical device markets worldwide and is the fourth-largest market for medical devices in Asia after Japan, China, and South Korea [13]. With a CAGR of 7.10% from 2023 to 2030, the medical devices industry in South Africa is expected to grow significantly during this time.[1]

Due to the direct impact of medical devices on patient safety and public health, robust regulatory systems are essential to ensure their quality, safety, and effectiveness before they are introduced into the market. The regulatory approval process involves a series of evaluations, including assessment of design, manufacturing practices, pre-clinical testing, clinical evidence, risk management, and post-market surveillance activities. The extent of regulatory scrutiny depends largely on the level of risk associated with the device.[2]

Medical devices are generally classified into different categories based on the degree of risk they pose to patients and users. In India, the regulatory framework is governed by the Medical Devices Rules (MDR), 2017, under the provisions of the Drugs and Cosmetics Act, 1940, and is implemented by the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare. The CDSCO classifies medical 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). The classification system follows the principles established by the Global Harmonization Task Force (GHTF).[2]

Similarly, in the United States, medical devices are regulated by the Food and Drug Administration (FDA) through the Center for Devices and Radiological Health (CDRH). The FDA classifies medical devices into Class I (low risk), Class II (moderate risk), and Class III (high risk) depending on the level of control necessary to assure safety and effectiveness. Different regulatory pathways are employed for device approval, including the Premarket Notification [510(k)], De Novo classification process, and Premarket Approval (PMA) process.[3]

Low-risk devices generally require minimal regulatory controls and may be exempt from extensive premarket review. Moderate-risk devices often require demonstration of substantial equivalence to a legally marketed predicate device or additional performance data. High-risk devices, particularly those that sustain life, prevent impairment of human health, or present potential unreasonable risks, are subjected to rigorous scientific evaluation, including clinical investigations and comprehensive review of safety and effectiveness data.[4]

Understanding the regulatory approval processes for medical devices is essential for healthcare professionals, researchers, manufacturers, and regulatory personnel involved in the medical device sector. Comparative evaluation of regulatory systems adopted by different countries provides valuable insights into global regulatory practices and highlights opportunities for harmonization, improved efficiency, and enhanced patient safety.[4]

India has emerged as one of the fastest-growing medical device markets globally, emphasizing the need for a transparent and efficient regulatory framework to facilitate innovation while ensuring public health protection. Likewise, the United States maintains one of the most comprehensive regulatory systems for medical devices, often serving as a benchmark for other regulatory authorities worldwide. Therefore, a comparative study of the regulatory approval processes for low-risk, moderate-risk, and high-risk medical devices in India and the USA is of significant academic and practical importance.[1]

The present study aims to provide a detailed overview and comparison of the regulatory approval pathways applicable to medical devices of varying risk categories in India and the USA. The study focuses on device classification systems, regulatory authorities, documentation requirements, approval procedures, timelines, and post-marketing obligations associated with each risk category. Such an analysis will contribute to a better understanding of the similarities and differences between the two regulatory frameworks and may assist stakeholders in navigating the complex process of medical device approval effectively.[3]

Regulatory body for India: CDSCO

The Central Drugs Standard Control Organisation (CDSCO) under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India, is the National Regulatory Authority (NRA) of India. Its headquarters is located at FDA Bhawan, Kotla Road, New Delhi 110002, and also has six zonal offices, four sub-zonal offices, thirteen Port offices, and seven laboratories spread across the country.

The Drugs & Cosmetics Act, 1940, and rules 1945 have entrusted various responsibilities to central & state regulators for the regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made thereunder for ensuring the safety, rights, and well-being of the patients by regulating the drugs and cosmetics. CDSCO is constantly striving to bring out transparency, accountability, and uniformity in its services in order to ensure safety, efficacy, and quality of the medical product manufactured, imported, and distributed in the country.
Under the Drugs and Cosmetics Act, CDSCO is responsible for the approval of Drugs, the conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country, and coordination of the activities of State Drug Control Organizations by providing expert advice with a view to bringing about uniformity in the enforcement of the Drugs and Cosmetics Act.
Further, the CDSCO, along with state regulators, is jointly responsible for the grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, vaccines, and Sera.

Regulatory body for the USA: US FDA

The primary regulatory authority for pharmacy and pharmaceuticals in the USA is the Food and Drug Administration (FDA), a federal agency under the Department of Health and Human Services that ensures the safety, efficacy, and security of drugs, biologics, and medical devices. The FDA approves new drugs, oversees manufacturing quality (cGMP), and monitors products on the market.

Core Regulatory Functions:

- **Drug Approval Process:** Requires New Drug Applications (NDA) for new medications and Abbreviated New Drug Applications (ANDA) for generics**.**
- **Inspections:** The FDA audits manufacturing sites to ensure compliance with Current Good Manufacturing Practice (CGMP) regulations.
- **Post-Marketing Surveillance:** The FDA uses systems like the FAERS database to monitor drug safety after approval.

Classification of medical devices in India

Risk-based Classification -

Medical Devices are classified into four classes based on the risk parameter as specified in Part I of the First Schedule of the Medical Devices Rules, 2017, as under:

- Low risk - Class A
- Low moderate risk- Class B
- Moderate high risk- Class C
- High risk- Class D

Class A (Low Risk)

- **Description**: These are non-invasive and basic medical tools.
- **Examples**: Absorbent cotton wool, surgical dressings, alcohol swabs, and bandages.

Class B (Low-Moderate Risk)

- **Description**: Devices that are slightly more invasive or carry a higher risk than Class A.
- **Examples**: Digital thermometers, blood pressure monitoring devices, and hypodermic needles.

Class C (Moderate-High Risk)

- **Description**: Highly regulated devices often require clinical evaluation and risk analysis.
- **Examples**: MRI equipment, CT scan equipment, haemodialysis catheters, and orthopaedic implants.

Class D (High Risk)

- **Description**: These are critical, often life-saving devices that require the most stringent regulatory control.
- **Examples**: Heart valves, pacemakers, and implantable defibrillators.[5]

Classification of medical devices in the USA

The U.S. Food and Drug Administration (FDA) classifies medical devices into three categories—Class I, II, and III—based on the risk they pose to the patient and the level of regulatory control needed to ensure safety.

Risk-Based Classification

As the class increases from I to III, the potential risk and the strictness of FDA oversight also increase.

- **Class I (Low Risk)**
  - **Description**: Simple devices with minimal contact or potential for harm.
  - **Controls**: Subject only to General Controls (e.g., registration, labelling, and good manufacturing practices).
  - **Examples**: Bandages, tongue depressors, oxygen masks, and handheld surgical instruments.
- **Class II (Moderate Risk)**
  - **Description**: More complex devices where general controls alone cannot ensure safety.
  - **Controls**: Subject to General Controls plus Special Controls (e.g., performance standards and post-market surveillance).
  - **Examples**: Powered wheelchairs, infusion pumps, pregnancy test kits, and catheters.
- **Class III (High Risk)**
  - **Description**: Critical devices that support life, are implanted, or present a potential high risk of injury.
  - **Controls**: Subject to the most stringent controls, requiring Premarket Approval (PMA) based on clinical evidence.
  - **Examples**: Pacemakers, heart valves, implantable defibrillators, and breast implants.[3]

2. LITERATURE AND REVIEW

1. *Jayanti VR, Madisi P, Murthy KVR (2018).* *Jayanti et al.* conducted a comparative study on the regulatory requirements for introducing medical devices in the Indian and US markets. The authors reported that the United States has a well-established regulatory framework under the FDA, whereas India had limited regulations before the implementation of the Medical Devices Rules (MDR), 2017. The study highlighted significant differences in classification systems, clinical evidence requirements, and approval pathways between the two countries. The authors concluded that harmonization of regulatory practices could facilitate global market access for medical devices.

2. *Sagar D, Gupta P (2022)* compared the regulatory frameworks governing medical devices in India and the USA. The authors described the role of CDSCO and FDA in ensuring the safety and effectiveness of medical devices. They emphasized that India's regulatory system evolved substantially following MDR 2017 through the adoption of risk-based classification. The study concluded that India still requires strengthening of its regulatory infrastructure to align with international standards.

3. *Pawar KN, Gore RT, Palekar SR (2023).* *Pawar et al.* reviewed the approval processes and regulatory requirements for medical devices under the US FDA and CDSCO. The authors explained the classification systems adopted by both regulatory authorities and outlined the approval pathways, including FDA's 510(k), De Novo, and PMA processes. They also discussed the licensing procedures under the Medical Devices Rules, 2017. The review concluded that regulatory affairs professionals require comprehensive knowledge of both systems to facilitate successful product registration.

4. *Van Norman GA (2016)* provided a detailed overview of FDA approval processes for medical devices. The author described the risk-based classification system used by the FDA and discussed the regulatory pathways applicable to Class I, II, and III devices. The article emphasized that Class III devices undergo the most rigorous evaluation through the Premarket Approval (PMA) process, often requiring extensive clinical evidence. The author highlighted the importance of balancing innovation with patient safety.

5. *Bhatt D, Movaliya V, Baldaniya L, Patel H, Parejiya P (2025).* *Bhatt et al.* performed a systematic review comparing Indian medical device regulations with established international regulatory systems. The study evaluated various regulatory parameters, including classification systems, quality management requirements, clinical evaluation, post-market surveillance, and unique device identification systems. The authors observed that India's regulatory framework has progressed considerably; however, further capacity building and regulatory harmonization are necessary.

6. *Naga Swaroopa S, Venkateswara Raju K, Prasanthi NL (2023).* The authors reviewed medical device regulations in the USA, EU, India, and China. The study compared regulatory authorities, classification principles, approval procedures, and post-market requirements. The authors concluded that the FDA maintains one of the most mature regulatory frameworks, whereas emerging economies such as India continue to refine their regulatory systems to ensure safety while promoting innovation.

7. *Kumavat SN, Kothari LP, Mundada AS (2023).* *Kumavat et al.* reviewed the registration and approval process of medical devices in India. The authors highlighted the role of CDSCO in regulating medical devices and emphasized the importance of risk-based classification in determining regulatory requirements. The review indicated that strengthening regulatory mechanisms is critical to ensuring public health protection.

3. RESULTS AND DISCUSSION

Comparison of Regulatory Requirements for Dental Mirror (Low-Risk Device)

Parameter	**India**	**USA**
Device	Dental Mirror	Dental Mirror
Definition	A hand-held instrument used by dentists to examine oral cavities indirectly and improve visibility during dental procedures.	A diagnostic dental instrument used for indirect visualization of teeth and oral tissues.
Risk Classification	Class A (Low Risk)	Class I (Low Risk)
Regulatory Authority	CDSCO under the Ministry of Health and Family Welfare	FDA through CDRH

Applicable Regulation	Medical Devices Rules, 2017	Federal Food, Drug, and Cosmetic Act
Approval Pathway	Manufacturing licence through State Licensing Authority (Form MD-5/MD-6)	General controls: many Class I devices are exempt from 510(k)
Import Approval	Import licence from CDSCO (Form MD-14/MD-15)	Establishment registration and device listing with the FDA
Export Requirement	Export licence and compliance with the importing country's requirements	Compliance with the importing country's requirements

Comparison of Regulatory Requirements for Nebulizer (Moderate-Risk Device)

Parameter	**India**	**USA**
Device	Nebulizer	Nebulizer
Definition	A medical device that converts liquid medication into aerosol form for inhalation into the respiratory tract.	An electrically powered device that aerosolizes medications for pulmonary delivery.
Risk Classification	Class B (Low-Moderate Risk)	Class II (Moderate Risk)
Regulatory Authority	CDSCO	FDA (CDRH)
Applicable Regulation	Medical Devices Rules, 2017	FD&C Act and 21 CFR regulations
Approval Pathway	Manufacturing licence through the State Licensing Authority after conformity assessment	Premarket Notification [510(k)] demonstrating substantial equivalence
Import Approval	Import licence from CDSCO (Form MD-14/MD-15)	FDA establishment registration, device listing, and 510(k) clearance
Export Requirement	Export licence and Free Sale Certificate, if applicable	Certificate to Foreign Government (CFG) for export

Comparison of Regulatory Requirements for Coronary Stent (High-Risk Device)

Parameter	India	USA
Device	Coronary Stent	Coronary Stent
Definition	A small expandable mesh tube is implanted in the coronary arteries to maintain blood flow following angioplasty.	An implantable device intended to prevent arterial restenosis and maintain coronary artery patency.
Risk Classification	Class D (High Risk)	Class III (High Risk)
Regulatory Authority	CDSCO (Central Licensing Authority)	FDA (CDRH)
Applicable Regulation	Medical Devices Rules, 2017	FD&C Act and Medical Device Amendments
Approval Pathway	Manufacturing/import licence from CDSCO following technical review and clinical evidence assessment	Premarket Approval (PMA) application
Import Approval	Import licence from CDSCO (Form MD-14/MD-15) after evaluation of technical documentation	PMA approval, FDA establishment registration, and device listing
Export Requirement	Export licence and compliance with destination country requirements	Certificate to Foreign Government (CFG) and compliance with importing country regulations

4. Discussion

The present study demonstrated that India and the United States adopt risk-based approaches to regulate medical devices, although differences exist in their classification systems and approval mechanisms. Lower-risk devices benefit from simplified regulatory procedures, whereas high-risk devices undergo comprehensive scientific evaluation before commercialization.

The findings indicate that India's regulatory framework has evolved considerably with the implementation of the Medical Devices Rules, 2017, moving toward international harmonization. However, the United States continues to maintain a more mature regulatory system characterized by well-defined approval pathways and extensive regulatory guidance.

Understanding these similarities and differences is essential for manufacturers seeking market authorization in multiple jurisdictions. Furthermore, harmonization of regulatory practices may contribute to improved patient access to safe and effective medical devices while reducing unnecessary regulatory burdens.

5. SUMMARY

Medical devices play an indispensable role in modern healthcare by contributing to the prevention, diagnosis, monitoring, and treatment of diseases. Owing to their direct impact on patient health and safety, effective regulatory oversight is essential to ensure that only safe, effective, and quality-assured devices are made available to the public.

The present study was undertaken to understand and compare the regulatory approval processes applicable to low-risk, moderate-risk, and high-risk medical devices in India and the United States.

The study initially reviewed the concept and significance of medical devices and highlighted the importance of regulatory systems in safeguarding public health. The regulatory authorities responsible for overseeing medical devices in both countries were examined. In India, the **Central Drugs Standard Control Organization (CDSCO),** functioning under the Ministry of Health and Family Welfare, regulates medical devices through the provisions of the **Medical Devices Rules, 2017**. In the United States, medical devices are regulated by the **Food and Drug Administration (FDA)** through the **Center for Devices and Radiological Health (CDRH)** under the **Federal Food, Drug, and Cosmetic Act**.

The classification systems adopted by both countries were analyzed. India follows a four-tier risk-based classification system comprising **Class A (low risk), Class B (low-moderate risk), Class C (moderate-high risk), and Class D (high risk)**. The United States employs a three-tier classification system consisting of **Class I (low risk), Class II (moderate risk), and Class III (high risk)**. The classification of devices is determined by factors such as intended use, invasiveness, duration of contact with the body, implantability, and potential risks associated with device failure.

To facilitate comparative evaluation, representative devices from different risk categories were selected. A **dental mirror** was considered a low-risk device, a **nebulizer** as a moderate-risk device, and a **coronary stent** as a high-risk device. The regulatory requirements associated with these devices in both countries were studied with respect to definitions, classification, approval pathways, import and export requirements, clinical evidence requirements, quality management systems, and post-market surveillance obligations.

The findings indicated that low-risk devices are subjected to minimal regulatory scrutiny in both jurisdictions. Moderate-risk devices require evidence demonstrating safety and performance, whereas high-risk devices undergo extensive scientific evaluation involving detailed technical documentation, quality system assessment, and clinical evidence review before receiving market authorization.

The study further revealed that the FDA has well-defined approval pathways such as **Premarket Notification [510(k)]**, **De Novo classification**, and **Premarket Approval (PMA)** processes. In contrast, India's regulatory framework relies primarily on licensing mechanisms administered by CDSCO and State Licensing Authorities, supported by the provisions of the Medical Devices Rules, 2017.

Overall, the study highlighted both similarities and differences between the Indian and United States regulatory systems and emphasized the significance of understanding country-specific regulatory requirements for successful market access and continued regulatory compliance.

6. Conclusion

The present study concludes that both India and the United States have established risk-based regulatory frameworks to ensure the safety, quality, and effectiveness of medical devices throughout their life cycle. Although the regulatory approaches differ in structure and implementation, both systems prioritize patient protection by imposing regulatory requirements proportional to the degree of risk associated with the device.

The comparative analysis demonstrated that low-risk devices benefit from simplified regulatory pathways, thereby facilitating timely market access. Moderate-risk devices require additional regulatory oversight to verify performance and conformity with applicable standards. High-risk devices are subjected to the most rigorous evaluation processes because of their potential to significantly affect patient health and survival.

The United States regulatory framework, administered by the FDA, represents a mature and highly structured system supported by detailed guidance documents and established premarket pathways. India's regulatory framework, governed by the CDSCO under the Medical Devices Rules, 2017, has evolved considerably in recent years and reflects a growing commitment toward international harmonization and strengthening of regulatory controls.

The findings of this study underscore the importance of regulatory awareness among healthcare professionals, regulatory affairs personnel, manufacturers, and researchers involved in the medical device sector. Comprehensive knowledge of approval procedures, documentation requirements, and post-market obligations can facilitate regulatory compliance and contribute to the efficient introduction of safe and effective medical devices into the healthcare system.

In conclusion, continued advancement of regulatory frameworks, enhanced international collaboration, and adoption of globally harmonized practices will play a pivotal role in promoting innovation while maintaining high standards of patient safety. The comparative insights generated through this study may serve as a valuable reference for regulatory professionals and stakeholders seeking to understand the approval processes governing medical devices in India and the United States.

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