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COMPARATIVE STUDIES BETWEEN INDIAN REGULATORY REQUIREMENTS AND GLOBAL BENCHMARKS FOR SURGICAL ROBOTS

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ABSTRACT

Surgical robots have emerged as advanced medical technologies that enhance surgical precision and patient outcomes. Their increasing global adoption has prompted regulatory authorities to strengthen oversight to ensure safety and performance. Major jurisdictions such as India, USA, European Union, and Japan classify surgical robots as high-risk devices and require comprehensive evaluation. This work aims to conduct a comparative assessment of Indian regulatory requirements for surgical robots against the established frameworks of the United States, European Union, and Japan. A qualitative comparative analysis based on regulatory frameworks outlined in the provided documents. It systematically examined key regulatory domains across major jurisdictions. The parameters evaluated included risk classification, pre-market approval pathways, clinical evidence requirements, quality management systems, software/AI governance, and post-market surveillance mechanisms. India classifies surgical robots as Class C/D high-risk devices and increasingly aligns with International Medical Device Regulators Forum (IMDRF) and ISO 13485 principles. Compared to the USA and EU, India presents lack in regulatory benchmark. Global regulators maintain more stringent and structured approval pathways. While India's regulatory framework for surgical robots is progressing toward global harmonization, significant gaps remain in clinical evidence standards, software oversight, and post-market monitoring. Addressing these gaps is essential for ensuring safe adoption and global competitiveness of robotic-surgical technologies in India.

KEYWORDS: Surgical robots, CDSCO, FDA, EU MDR, PMDA, High- risk medical devices, AI-enabled systems.

1. INTRODUCTION

The integration of robotic systems into surgical practice represents a significant technological advancement in operative care over the past two decades, offering enhanced instrument dexterity, tremor filtration, three-dimensional visualization, and the potential for less invasive procedures with faster recovery.[1] The evolution of surgical robotics can be traced from early prototypes, such as the PUMA 560 robot used for neurosurgical procedures in the 1980s,[2]to modern platforms like the da Vinci Surgical System which are developed from industrial robotic technology, modern surgical robots are now deployed across multiple specialties including urology, gynecology, general surgery, and cardiothoracic surgery.[3]

Robotic surgery has demonstrated clinical benefits including reduced blood loss, smaller incisions, lower postoperative pain, shorter hospital stays and improved functional and oncological outcomes.[4] Despite these advantages, widespread adoption remains limited by high costs, training requirements, and workflow integration challenges. Emerging trends, such as the incorporation of artificial intelligence and augmented reality, are poised to further enhance precision, safety, and surgical decision-making in the coming years.[5]

The surgical robotic systems are classified as high- risk medical devices because they combine hardware, software, artificial intelligence (AI), and human interaction in complicated manner.[6] Due to this complexity, surgical robotic systems require strict regulatory oversight to ensure patient safety, clinical effectiveness and ethical use.[7] Regulatory frameworks determine how these devices are classified, approved, clinically evaluated, manufactured, monitored after market entry, and controlled for cybersecurity and software updates.[8]

Globally, major regulatory jurisdictions have responded with structured frameworks for medical devices. Such as the U.S. Food and Drug Administration (FDA) allows clearance via 510(k)[9] or approval via Premarket Approval (PMA) [10]and has reviewed numerous surgical robotic platforms.[8] In the European Union, the implementation of Regulation (EU) 2017/745 (MDR)[11] has aimed to enhance device traceability, post-market surveillance and conformity assessment, establishing rigorous standards for manufacturers and notified bodies.[12] Even with these frameworks, there are still regulatory problems, because innovation happens so quickly (for example, with AI/ML software, network connectivity), demands that classifications, oversight pathways, software validation, and post-market monitoring must always change.[13] Japan regulates surgical robots under its Pharmaceuticals and Medical Devices Act (PMD Act),[14] with the Ministry of Health, Labour and Welfare (MHLW) overseeing approval and safety, and the PMDA (Pharmaceuticals and Medical Devices Agency)[14] handling technical review and post-market surveillance.

In contrast India's regulatory system for high-risk medical devices, including surgical robots, is governed under the Medical Device Rules (MDR) 2017[15] regulated by the Central Drugs Standard Control Organization (CDSCO).[16] Surgical robots fall under Class C or Class D (the highest-risk categories).[17] However, within the specific domain of surgical robotics and AI-enabled systems, several regulatory gaps are identified in the Indian context such as device-specific guidance is minimal, software and autonomy frameworks are not extensively articulated and post-market surveillance and digital traceability systems are still evolving.[18,19]

This review article conducts a comparative analysis of Indian regulatory requirement for surgical robotics against global regulatory requirements (USA, Europe and Japan). The analysis focus on key regulatory domains such as, device classification and risk categorization, approval and registration process, investigation requirements, quality

management and post marketing surveillance. The review aims to highlight gaps and identify Indian regulatory evolution in field of surgical robotics.

2. OVERVIEW OF REGULATORY FRAMEWORK FOR SURGICAL ROBOTS

2.1 Device Classification of Surgical Robots

Different ways that jurisdictions designate high-risk technologies like surgical robots affect how they get to market, how much regulation they have to deal with, and how they plan to innovate. The classification of medical devices is a pivotal regulatory step, determining subsequent requirements for conformity assessment, clinical investigation, manufacturing control, and post-market surveillance. Comparative summary of device classification of surgical robot in India, USA, Europe and Japan is given in Table 1.

Table 1: Comparative summary of device classification of surgical robot in India, USA, Europe and Japan.

Country	Classification Scheme (risk ascending)	Typical Class for Surgical Robots	Description	Reference
India (MDR 2017)	Class A Class B Class C Class D	Class C / D	Technical dossier as per MDR-2017 for imports use MD-14/MD-15	[20]
USA (FDA)	Class I Class II Class III	Class II (most) / III (novel)	510(k) (substantial equivalence)	[21]
EU (MDR)	Class I Class IIa Class IIb Class III	Class IIb / III	CE marking via Notified Body	[22]
Japan (PMD Act)	Class I Class II Class III Class IV	Class III / IV	PMDA review/approval (Shonin) for high-risk devices	[23]

2.2 Regulatory Landscape and Approval Pathways for Surgical Robotic Systems

The regulatory framework for medical devices, including surgical robots is important for safety, performance and patient welfare. The Central Drugs Standard Control Organization (CDSCO) is the main regulatory body in India. It works under the Drugs and Cosmetics Act of 1940 and subsequently the Medical Devices Rules of 2017 (MDR 2017).[15,24]

In the United States, the regulatory framework is administered by the U.S. Food and Drug Administration (FDA), which classifies medical devices into three major risk classes (Class I–III) based on the level of control necessary to assure safety and effectiveness. As per FDA devices designated Class III typically require pre-market approval (PMA), while many Class II devices may be cleared via the 510(k) pathway which demonstrates “substantial equivalence” to a legally marketed predicate device.[25]

In the European Union, the regulatory framework for medical devices has recently been consolidated under the Regulation (EU) 2017/745 (EU MDR).[11] The Surgical Robotics must obtain CE marking in accordance with the Medical Device Regulation (MDR). In effect since 2017, this regulation is considered one of the world’s most stringent frameworks for medical devices. It categorizes devices by risk level; due to their invasive application, surgical robots

are classified in a high-risk category that requires particularly comprehensive evidence of technical, clinical, and application-specific safety.[22]

Japan's regulatory system is overseen by the Pharmaceuticals and Medical Devices Agency (PMDA) under the Pharmaceuticals and Medical Devices Act (PMD Act).[26]

2.2.1 Regulatory approval pathways for surgical robots

The regulatory approval pathway for medical devices is a critical determinant of market entry timelines, evidentiary burden and resource allocation. For surgical-robotic systems given their high complexity, integration of hardware, software and possible AI components the pathway often involves rigorous assessment of safety, performance, equivalence or novelty, and post-market obligations.

India

Medical devices are subject to registration, licensing and clinical investigation processes based on risk class. [27] For higher-risk devices (Class C/D)the Figure 1 represents the detailed flow of regulatory procedure for surgical robots in India.[28]

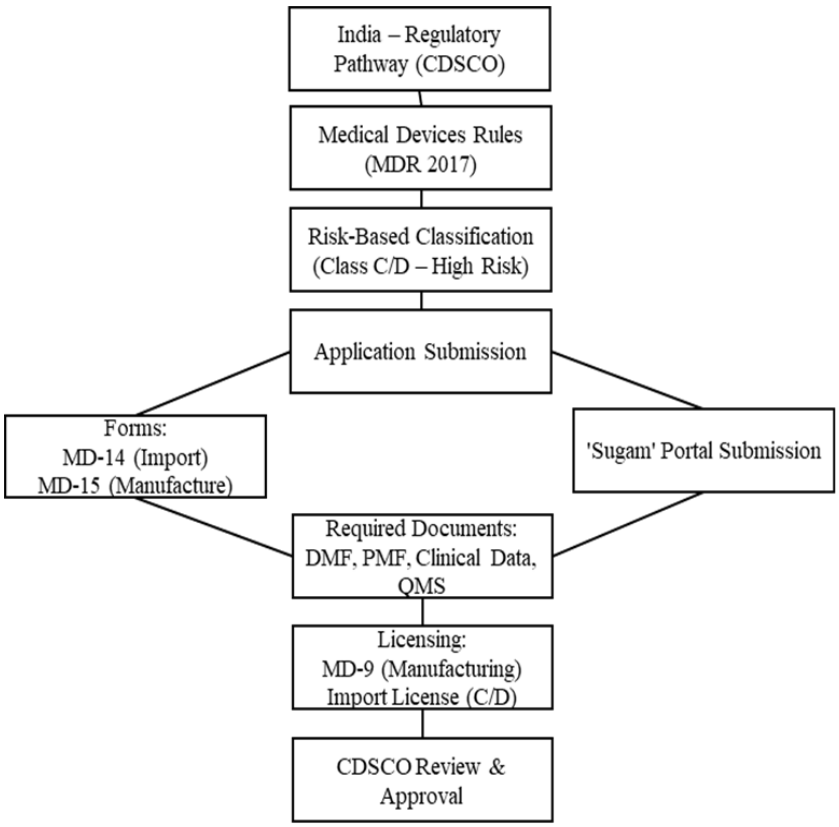

Figure 1: Regulatory approval pathway for surgical robots in India.

United States

In the United States, the U.S. Food and Drug Administration (FDA) offers several main pathways for device marketing depending on risk and novelty: the 510(k) Premarket Notification, the De Novo Classification Request, and the Premarket Approval (PMA) pathway.[29]The chosen pathway directly influences data requirements, review time and cost.[30,31] The regulatory approval pathway is depicted in Figure 2.

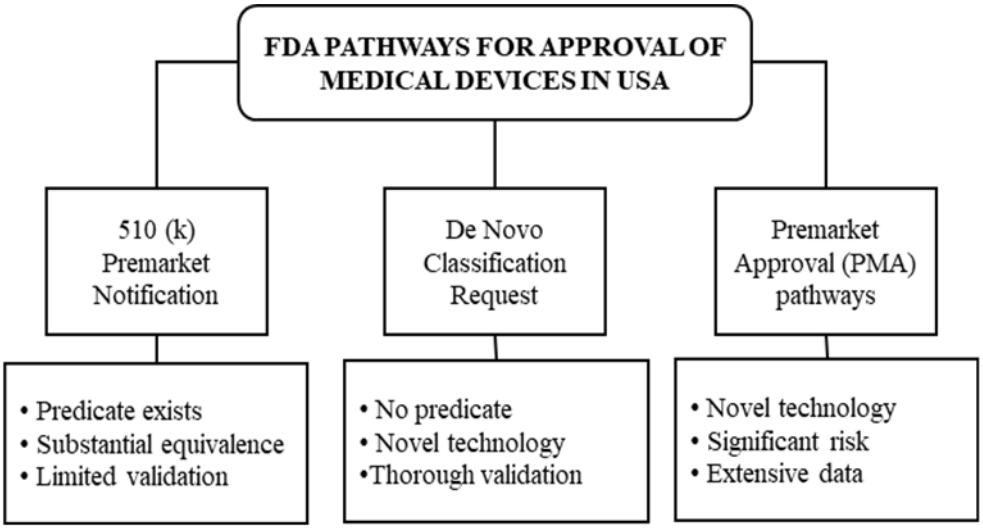

Figure 2: Regulatory approval pathways in USA.

Europe

In the European Union, the regulatory framework is the Regulation (EU) 2017/745 on medical devices (EU MDR).[11] Surgical-robotic systems frequently fall into Class IIb or III depending on invasiveness and function. Manufacturers must undergo conformity assessment via a Notified Body; prepare technical documentation including a Clinical Evaluation Report (CER) and meet quality management (ISO 13485) and software lifecycle (IEC 62304) obligations.[32] Following successful assessment, a CE-mark enables market access across EU Member States.[33,34,35] The regulatory process for approval of high risk medical device is concisely depicted in Figure 3.

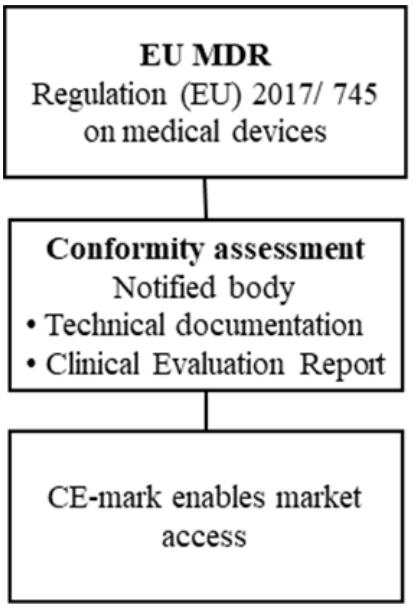

Figure 3: Regulatory approval for high- risk medical devices in EU.

Japan

In Japan, medical devices are regulated under the Pharmaceuticals and Medical Devices Agency (PMDA). Class III and IV devices high or potentially fatal risk require a full application for approval and pre-market review by the PMDA.[36,37,38] In the Figure 4 the regulatory pathway for surgical robots is shown.

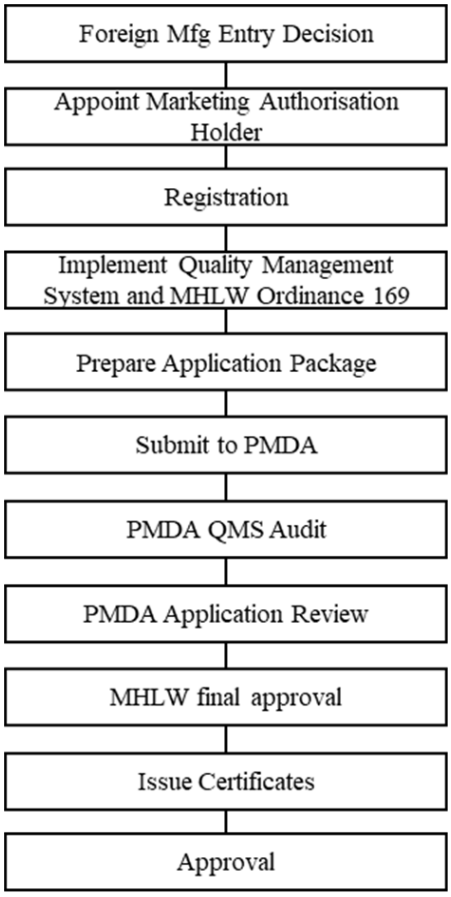

Figure 4: Japan Regulatory Pathway for Surgical Robots.

3. COMPARISON BETWEEN INDIAN REGULATORY REQUIREMENTS AND GLOBAL BENCHMARKS FOR SURGICAL ROBOTS

Table 2 represents the comparison of Indian regulatory requirements with the global benchmarks such as United States (USA), Europe and Japan.

Table 2: Comparison between India, USA, Europe and Japan Regulatory Framework for surgical robots.

Topic	India	USA	Europe	Japan
Regulatory authority & legal basis	CDSCO; Medical Devices Rules, 2017	FDA (CDRH) device rules in Title 21 CFR	EU Commission / Member States; MDR 2017/745	PMDA & MHLW under the PMD Ac
Risk classification for surgical robots	Surgical robots typically fall into moderate-high to high risk (Class C or D) depending on intended use	FDA class assignment is device-specific (Class II often via 510(k) or novel functions may require PMA-class III)	Surgical robots are treated as Class IIb (software that can lead to surgical intervention may be IIb/III)	Surgical robots are reviewed as higher-risk devices; higher classes require Shonin/approval
Premarket pathway	Technical dossier as per MDR-2017 for imports use MD-14/MD-15	510(k) (substantial equivalence)	CE marking via Notified Body	PMDA review/approval (shonin) for high-risk devices
Clinical evidence & clinical investigations	Clinical investigation permission required	Device-specific performance and bench/animal/clin	clinical evaluation report (CER) and clinical	PMDA requires appropriate clinical data; Japan has

	(Form MD-23) for investigational devices	ical data required per submission type	investigation (if needed) MDR demands strong clinical data	established routes for expansion/modifications post-approval
Quality Management System (QMS)	MDR-2017 includes QMS requirements aligned with ISO 13485	FDA enforces QSR (21 CFR 820) & ISO 13485	QMS and vigilance system; ISO 1348	QMS requirements via MHLW Ordinance No.169
Software / SaMD / AI (critical for surgical robots	CDSCO recently released/updated guidance on Medical Device Software (SiMD / SaMD)	Expect software lifecycle documentation, validation, cyber security, human factors. Adaptive AI/ML has specific draft guidance	Strict clinical and post-market requirements for MDSW/MDAI	Japanese guidance and MO169 cover software validation in QMS.
Post-market surveillance (PMS) & vigilance	CDSCO requires PSURs: every 6 months for first 2 years, then annually	Adverse event reporting, corrective actions, recalls, post-market studies as require	MDR imposes strengthened PMS: PSURs, periodic safety update	Requires vigilance reporting, post-market measures;
Labeling & UDI	Progressive UDI implementation; English labeling	UDI required; detailed IFU	UDI mandatory; language rules	Local language labeling; traceability
Local presence / agent & import rule	Indian Authorized Representative mandatory	US Agent/Distributor for foreign companies	EU Authorized Representative required	Local MAH mandatory
Indian Authorized Representative mandatory	US Agent/Distributor for foreign companies	EU Authorized Representative required	Local MAH mandatory	Indian Authorized Representative mandatory

Table 2 shows the comparison that surgical robots are treated as high-risk medical devices across all major regulatory systems India (CDSCO), USA (FDA), EU (MDR 2017/745), and Japan (PMDA/PMD Act). While each region follows its own laws and submission formats, their core expectations are increasingly harmonized around safety, clinical evidence, quality systems, and post-market monitoring. Concluding the above table India's regulatory system is increasingly aligned with global standards such as IMDRF, ISO 13485, and EU/FDA frameworks. However, compared to the USA and EU, India still offers more flexibility especially in clinical investigation waivers, documentation acceptance, and transition timelines. For global market entry, manufacturers of surgical robots should design documentation to meet FDA and EU requirements first, as this will make compliance in India and Japan faster.

3.1 IDENTIFIED REGULATORY GAPS IN INDIA

Surgical robotic systems are classified globally as high-risk devices, requiring robust regulatory oversight. While India’s Medical Device Rules (MDR) 2017 has strengthened the regulatory framework for high-risk medical technologies, several critical gaps persist compared to advanced jurisdictions.[39]

A. Lack of Device-Specific Guidance

India currently does not have dedicated, detailed guidelines addressing the unique risks of surgical robots, in contrast to the device-specific frameworks available in the US FDA and EU MDR.[18]

B. Insufficient AI and Software Oversight

Software validation, AI governance, cyber security, and machine-learning update controls are only partially addressed in recent CDSCO guidance. Oversight of adaptive or algorithm-driven robotic functions remains limited.[8]

The FDA's review of da Vinci Xi and Johnson and Johnson's Ottava.[40] required extensive documentation such as AI control systems, human- robot interaction safety and software lifecycle validation (IEC 62304).[41] Meanwhile, India did not require similar AI documentation for early review submission for imported robotic systems.

C. Underdeveloped Post-Market Surveillance (PMS)

India's PMS structure including UDIs, real-time vigilance reporting, and digital traceability is still evolving, whereas the EU and Japan have long-established, systematic surveillance systems.[17]

In the USA, adverse events involving da Vinci Surgical System were systematically captured in MAUDE (FDA's public adverse-event database). These reports prompted post-market design corrections.[42]

In India, no equivalent system existed when robotic systems were introduced. Adverse events in private hospitals using imported da Vinci robots were not publicly traceable, limiting transparency and system-wide learning.

D. Limited Clinical Data Requirements

India allows greater flexibility in accepting foreign clinical evidence or waivers, resulting in less structured and uniform clinical data compared to FDA PMA or EU MDR CER requirements.[43]

For FDA PMA approval of robotic platforms (Mazor X),[44] companies submitted such as multicenter clinical trials, long-term follow-up and human factors engineering reports. In India, several imported surgical robotics systems obtained approval using foreign clinical data only, with CDSCO not mandating India-specific clinical trials. This reduces the ability to evaluate performance in Indian populations.

The comparative analysis reveals substantial heterogeneity in regulatory approaches, implementation maturity, and governance mechanisms across the regions. These findings underscore the absence of a unified regulatory paradigm and highlight critical gaps as well as best-practice models that inform future harmonization efforts and policy evolution. Such findings are:

a. **Uniform High-Risk Classification**: All the regulatory bodies classify surgical robots as high-risk medical devices (Class C/D in India, Class II/III or PMA in the USA, Class IIb/III under EU MDR, and Class III/IV under the PMD Act).
b. **India's Regulatory Maturity Is Increasing but Still Behind:** India aligns with IMDRF principles and ISO 13485 for medical devices but remains less stringent and less structured in evidence requirements, conformity assessment, and lifecycle oversight.
c. **Advanced Regulatory bodies have more comprehensive frameworks:** The advanced regulatory bodies such as USA, EU, and Japan have stronger clinical evaluation standards, software and cybersecurity validation, and post-market performance monitoring.
d. **Greater Flexibility in India's Approval Pathways:** While flexibility reduces regulatory burden for manufacturers, it raises concerns regarding inconsistency in technical documentation, limited safety datasets and slower global harmonization.

3. CHALLENGES IN REGULATORY APPROVAL OF SURGICAL ROBOTS IN INDIA

a. Incomplete Framework for Robotics and AI

CDSCO lacks comprehensive protocols for autonomous systems, adaptive AI, cybersecurity validation, and software lifecycle standards comparable to IEC 62304 or FDA AI/ML guidance documents.

b. Evolving Post-Market Surveillance Capabilities

PMS systems such as periodic safety update reporting, adverse event analysis and UDI traceability are not yet as mature, or enforcement driven as FDA's MAUDE or EU's EUDAMED systems.

In 2023–2024, several tertiary centers in India installed new robotic systems, but no centralized PMS database captured intra operative errors, equipment failures and network or software glitches. In contrast, the EU's EUDAMED database requires mandatory reporting for all high-risk devices.[45] India's evolving PMS system makes monitoring of robotic complications less efficient.

c. Limited Domestic Experience and Technical Expertise

India has fewer regulatory reviewers trained in robotics/AI, precedent-based approvals and national clinical databases for robotic procedures which lead to limited domestic experience as well as expertise.

d. Transition from Drug-Focused to Device-Focused Oversight

The regulatory ecosystem is still shifting from pharmaceutical-centric processes to risk-based device evaluation. This results in slower decision cycles, variable documentation requirements and constrained readiness for assessing next-generation surgical robots.

Before 2020, many device reviews in India were conducted by committees oriented toward pharmaceuticals. Early robotic submissions faced delays because dossiers were evaluated using frameworks not optimized for complex electromechanical software systems.[15,46]

e. Variability in Clinical Investigation Requirements

India's acceptance of external clinical evidence and occasional waivers leads to uncertainty in evaluating novel robotic systems, delaying approvals compared to FDA PMA or EU MDR pathways.

A foreign manufacturer importing a mid-range robotic-assisted laparoscopy system was granted approval by CDSCO using a technical dossier, Bench testing, CE certificate without requiring fresh Indian clinical investigation (Form MD-23).

Meanwhile, the same system required substantial clinical justification during CE marking under EU MDR. This variability creates unpredictability in India's approval process.

4. CONCLUSION

The comparative analysis of regulatory frameworks for surgical robotic systems in India, the United States, the European Union, and Japan reveals both growing trends and permanent differences. While all major jurisdictions uniformly classify surgical robots as high-risk medical devices requiring stringent scrutiny, the depth, structure, and enforcement of regulatory requirements vary substantially. India's Medical Device Rules (MDR 2017) represent a

major step toward a modern, risk-based regulatory ecosystem; however, the nation continues to lag behind global regulatory leaders in several critical domains, including device-specific guidance, AI and software governance, harmonized clinical evidence requirements, and robust post-market surveillance infrastructure.

The FDA, EU MDR, and PMDA are examples of advanced authorities that have set up better frameworks that make it easier to assess compliance, validate clinical data, control cybersecurity, and monitor the lifecycle of high-precision, software-intensive technologies like surgical robots. India's comparatively flexible approval mechanisms, though advantageous for promoting innovation and market entry, may compromise uniformity in safety and performance evaluation.

To ensure patient safety, regulatory credibility, and global competitiveness of indigenous surgical robotic technologies, India has to make its rules stringent by using standardized rules, hiring more experienced reviewers, and setting up strong AI-specific monitoring and digital vigilance systems, and transparent clinical investigation pathways. Bridging these gaps will enable India not only to keep pace with rapid global advancements in robotic surgery but also to foster innovation while ensuring the highest levels of quality, reliability, and patient welfare.

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