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MEDICAL DEVICE APPROVAL ISSUES IN ICH AND A FEW OTHER COUNTRIES FOR IMPROVED REGULATORY DELIVERY

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Abstract:
To ensure the safety, effectiveness, and high quality of the goods, there are global monitoring systems that cover the medical device sector comprehensively. Gaining entry to every market is difficult due to the vast disparities in how regulatory systems in different countries work. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) processes, additional US, EU, Japanese, and Indian regulatory frameworks, and medical device approval procedures are all part of this study. The absence of post-market surveillance, criteria for clinical reviews, approval procedures, and various pharmaceutical classification systems are only a few of the important subjects covered in this article. Researchers have shown that manufacturers' uneven policies are to blame for the longer wait periods for new technology. The International Conference on Harmonisation (ICH) is one of the organisations that has been trying to speed up the rule-making process by standardising technical documentation, implementing risk-based approaches, and establishing mutual recognition agreements. They are also a participant in the study. Access to medical devices may be enhanced and harmonised across all worldwide markets with a unified regulatory framework that prioritises innovation and safety.

Keywords: *Harmonisation of Regulations, Medical Device Approval, International Conference on Harmonisation of Standards, and worldwide Regulatory Frameworks.*

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INTRODUCTION:

New methods of diagnosis, therapy, and patient management have been made possible by breakthroughs in medical technology, which are essential to modern healthcare. But a strong and consistent regulatory framework is essential for their quality, safety, and effectiveness. The ICH has become more influential on a worldwide scale, despite the fact that it mostly regulates pharmaceuticals. Expectations of medical devices are not immune to this impact, which is most noticeable in the areas of clinical assessment, risk management, and quality systems. It is not possible to provide treatment without medical equipment. In contrast to developed nations, emerging economies have seen a meteoric rise in the need for healthcare technology. According to specialists in the field, the worldwide market is expected to grow in the next years due to factors such an ageing population, increasing disposable money, and a growing awareness of the importance of health in emerging nations. Medical devices are an integral part of many modern healthcare facilities' state-of-the-art patient monitoring, diagnostic, and treatment systems. When it comes to their efficacy, safety, and efficiency, you should take command of them. Although medication supervision is its primary function, the ICH also has an impact on how regulators perceive the safety of medical device safety (1).

Differences Between Drug and Medical Device:

Criteria	Drug	Medical Device
Definition	A substance intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease and that achieves its primary intended effects through chemical action.	An instrument, apparatus, implement, machine, implant, or similar article that does **not achieve its primary intended purpose through chemical action**.
Mode of Action	Acts **pharmacologically**, **metabolically**, or **chemically** on the body.	Acts **mechanically**, **physically**, or **structurally** without altering body chemistry.
Regulatory Authority	Regulated by the **Center for Drug Evaluation and Research (CDER)** under the **FDA**.	Regulated by the **Center for Devices and Radiological Health (CDRH)** under the **FDA**.
Regulatory Submission	Requires **NDA (New Drug Application)** or **ANDA (Abbreviated NDA)**.	Requires **510(k)**, **PMA (Premarket Approval)**, or **De Novo submission**.
Examples	Paracetamol, insulin, antibiotics, antihypertensives, vaccines.	Pacemakers, syringes, catheters, surgical gloves, MRI machines, contact lenses.
Clinical Trials	Extensive trials including **phases I–IV** are mandatory.	Clinical studies may be required (mostly for Class III); lower-risk devices may not require trials.
Approval Timeframe	Often **longer** due to the complexity of clinical trial data.	Can be **shorter**, especially for 510(k) submissions.
Labeling Requirements	Strict labeling, including dosage, warnings, and side effects.	Includes use instructions, indications, precautions; varies by class.
Manufacturing Controls	Subject to **cGMP (current Good Manufacturing Practice)** regulations.	Subject to **QSR (Quality System Regulation)** requirements.

Regardless of these endeavours, the uneven regulation of medical devices by states persists. Even in ICH nations with well-established regulatory systems, like the EU, Japan, and the US, issues with post-market monitoring, licencing delays, and fast technology improvements persist. On the other hand, emerging nations often have difficulties with their regulatory systems, such as uneven enforcement and a failure to follow global standards.

The challenges of medical device approval in ICH areas and a few non-ICH nations are investigated in this research. Furthermore, it looks for prospects for convergence as well as gaps, overlaps, and similarities. International Medical Device Regulators Forum (IMDRF) standards and improved worldwide cooperation and reliance mechanisms are necessary for the simplification of rule transmission. Improving regulations in resource-constrained places should be a primary focus, as does ensuring that everyone has easy and quick access to safe and effective medical equipment.

The ever-growing and innovative medical device sector in the Asia-Pacific region is a magnet for both large corporations and new ventures.

The following table provides definitions of medical devices as provided by regulatory authorities from different nations and regions. Some of these organisations are CDSCO, the EU MDR, and the FDA.

Definition of Medical Devices in Different Countries/Regions:

Region/Country	Regulatory Authority	Definition of Medical Device
United States (USA)	FDA – CDRH (Center for Devices and Radiological Health)	"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease... and which does not achieve its primary intended purposes through chemical action within or on the body."
European Union (EU)	European Commission (under **EU MDR 2017/745**)	"Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for specific medical purposes… and which does not achieve its principal intended action by pharmacological, immunological or metabolic means."
India	CDSCO (Central Drugs Standard Control Organization)	"Any instrument, apparatus, appliance, implant, material or other article including software… intended to be used for human beings or animals for diagnosis, prevention, monitoring, treatment or alleviation of disease or disorder… and which does not achieve its primary intended action in or on human body by pharmacological or immunological or metabolic means." *(Medical Device Rules, 2017)*
Canada	Health Canada (Medical Devices Bureau)	"A device within the meaning of the Food and Drugs Act, including any component, part or accessory, manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease or abnormal physical state."
Japan	PMDA / MHLW (Pharmaceuticals and Medical Devices Agency / Ministry of Health)	"Appliances, instruments, apparatus and materials intended for use in the diagnosis, treatment or prevention of disease in humans or animals, which do not exert their effect through pharmacological, immunological, or metabolic means."
Australia	TGA (Therapeutic Goods Administration)	"A device that is used for human beings to diagnose, prevent, monitor, treat, or alleviate disease or injury, and that does not achieve its principal intended action by pharmacological, immunological, or metabolic means."
China	NMPA (National Medical Products Administration)	"Instruments, apparatus, appliances, materials or other articles used alone or in combination… for the purpose of disease prevention, diagnosis, treatment, monitoring or alleviation… not achieving the intended primary function through pharmacological, immunological or metabolic means."

AIM & OBJECTIVES:

AIM:

Reviewing the current position, potential future developments, regulatory framework, and key obstacles of the Indian market is crucial for improving worldwide competitiveness in the medical device business, expanding local manufacturing, and minimising dependency on imports.

OBJECTIVES:

Look into the country you're thinking about moving to by visiting their official websites.

Here are the goals: Given the current state of affairs, it is imperative that: • Data on medical device regulations and the difficulties encountered by those tasked with approving them be collected.

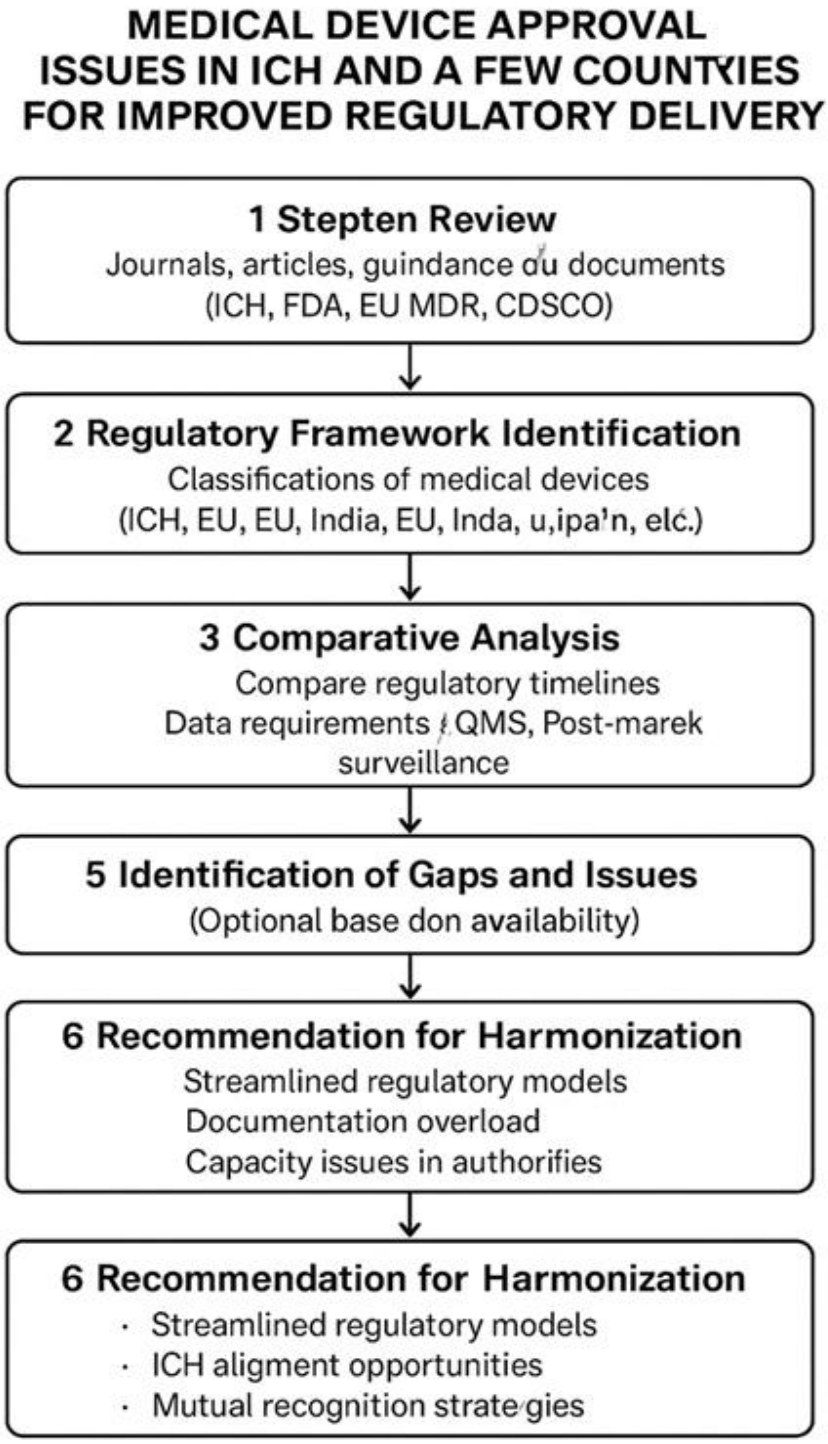
A number of nations' processes for medical product classification and approval have piqued my interest; they include Singapore, South Africa, Brazil, and Saudi Arabia.

Compare and contrast the openness of medical device product laws in the US, Saudi Arabia, the Kingdom of Saudi Arabia, and the Ministry of Health (MOH).

It is important to provide businesses and government agencies with the resources they need to expedite the approval process. Give some recommendations on how the present system for medical device clearance and categorisation in India should be improved.

METHADOLOGY:

Step by Step Description of work medical device approval:



This chapter delves deeply into the methods, tactics, timelines, and goals for data collection. The investigator is presented with a wide array of possibilities, each with its own set of pros and cons, by the study's goals.

Parameters for Survey and Survey Questions

Parameters for Survey

S. No.	PARAMETER	QUESTIONS
1	Transportability of Data	4
2	Conducting clinical investigation	1
3	Harmonization	1
4	Review Process	2
5	Adoptability	2
	Total	10

Survey Questions

1. Harmonization on classification of medical device across the globe is possible?
a.Agree
b.Neither agree Nor disagree
c.Disagree
2. The Regulatory information/Documents required for filling of new Medical devices are available in their respective website (Emerging Market)
a.Agree
b.Neither agree Nor disagree
c.Disagree
3. If clinical trials are conducted as per ISO 14155:2011 standards in emerging market, then the approval process will be faster.
a.Agree
b.Neither agree Nor disagree
c.Disagree
4. It is better to follow international standard than that of regional standard
a.Agree
b.Neither agree Nor disagree
c.Disagree
5. Electronic submission will faster the Approval process than that of the paper submission
a.Agree
b.Neither agree Nor disagree
c.Disagree
6. There is lack of regulators in the emerging market to review the application submitted for the approval process
a.Agree
b.Neither agree Nor disagree
c.Disagree
7. Fees required for submission of the application are clearly defined in emerging market
a.Agree
b.Neither agree Nor disagree
c.Disagree
8. The committee responsible for the Medical device approval process provides an official written report to the applicant on decisions (e.g. accepted and rejected files) taken at key decision points of the application process
Based on your professional experience please rank the 4 countries below on an individual basis from an overall transparency perspective from most to least transparent

a. Brazil b. Singapore

c. Saudi Arabia d. South Africa e. India

9. Regulatory Changes having bigger Impact on Smaller Medical Device Companies
a.Agree
b.Neither agree Nor disagree
c.Disagree

Interview Questions posed to regulatory officer of medical devices

Parameter on Questions posed to regulatory officer

S. No.	PARAMETER	QUESTIONS
1	Organization of the Authority	1
2	Review model(s) currently in place	2
3	Regulatory Review Process	5
4	Good Review Practices	4
	Total	12

Questions

Organization of the Authority

1. What is the current organization of the Authority, Size and resources available

Review model(s) currently in place

2. What are the models that are in place for the product review assessment

3. How many Notified Bodies has been registered under central Licensing authority for carrying out audit of medical devices

Regulatory Review Process

4. What is the queue time that is taken for the approval of medical device application

5. How are the scientific assessment done for the approval of application

6. What is the time allotted for the sponsor to response to the query

7. What is the committee of expert that is in place for the approval of medical device application process?

8. How often do the expert committees meet?

Good Review Practices

9. How many Central medical device testing laboratory are there, name them and what are their activities.

10. What is the Training and professional development programs for the internal and external assessors?

11. What are the roles of Medical Device Testing Officer?

12. What are the preparation going on for Unique device identification of the medical device and its impact

Research Philosophy

Reason, positivism, pragmatism, and perception were the four theoretical ideologies listed by Saunders et al. in 2012. Research methods, findings, and theoretical foundations are all affected by one another (Saunders et al., 2012). These concepts form the basis of this method. In order to tackle the specific analytical challenge, this thesis takes a pragmatic approach by modifying its technique. Despite the success of quantitative and qualitative analysis, pragmatics suggests that academics should diversify their methods. In a recent study, Rosenberg et al. (2014)....

Research Approaches

Positivism, pragmatism, reason, and perception are the four theoretical ideologies that Saunders et al. (2O12) outlined. According to Saunders et al. (2012), the theoretical foundation affects the study methodologies, processes, and results. These principles form the basis of the methodology. To address the specific analytical challenge at hand, this thesis adopts a pragmatic approach by adapting its technique accordingly. Pragmatists believe that academics should broaden their focus beyond the tried-and-true methods of quantitative and qualitative analysis. In a recent research, Rosenberg et al. (2014)....

Research Strategies

In order to wrap up the inquiry, the researcher documents the steps in the thesis. According to

Davis et al. (2012) . Research interventions, case study investigations, interviews, surveys, and systematic literature reviews are some possible approaches. In order to gather data from large populations, surveys are often used in descriptive and exploratory research. Therefore, we take a look at a method that, as of 2012, Saunders et al., suggests might work for studying the challenges encountered by those working in regulatory roles.

Questionnaire Design

"The quality & reliability and response rate of the data you collect rely largely on the nature of the questions, questionnaire design & the rigour of pilot tests" (Saunders in conjunction with others). We need to pay more attention to the survey's structure since it is vital to its purpose. If you're making the survey, keep these lists of categories in mind:

Purpose of the Survey

The International Chemical Health Organisation (ICH) and researchers from countries including Saudi Arabia, Brazil, South Africa, and Singapore have found that developing nations would face challenges when trying to acquire regulatory approval. It seems that there are many concerns: The problems that have been identified are as follows: 4. Clearance requests are reviewed according to an informal process. The potential impact of policy changes on the industry is the subject of the fifth argument. Everyone who works at the firm may see these changes. Having additional things available improves the monitoring of medical devices.

For this reason, we conducted surveys in Saudi Arabia, Brazil, and South Africa to gauge the level of transparency in their respective medical device laws.People who should get its advantages

Since many individuals will be impacted by the regulations that regulate medical devices, we requested politicians, physicians, and patients to participate in our poll. Due of their connections to the intellectual sphere, academic and business directories were deemed reputable sources by the writer. Internal and external commercial exchanges were taken into account, along with regulatory considerations and relationships between different medical device enterprises. The author distributed the question using the Monkey SurveyTM app. The amount of experience our contacts had varied from two years to twenty.

Sample size

If you want reliable findings, you need a big enough sample. Although 180 people were sent the survey, only 90 of them actually filled it out.

Hague, Hague, and Morgan (2O13) state that as the number of survey questions above 30, response variability becomes apparent.

Method of data collection

The survey was first administered to a small group of three people for feedback purposes. On top of that, we gave their suggestions a thorough evaluation.

We were able to design a user-friendly and data-efficient survey using the SurveyMonkeyTM platform. Visit https://www.surveymonkey.com for more information about Surveymonkey, a platform that might be used for your professional and academic research. Survey Monkey makes it simple to share survey links. Participants may easily boost the response rate by sending an email invitation to the appropriate individuals in the relevant businesses.

An email outlining the goals of the research was sent to every participant. Because of this, we are considering referring to the survey as an online self-study. Emails sent as a follow-up had a higher response rate.

Data Analysis

The study's quantitative raw data is useless, according to Saunders et al. (2012). The illustrations in this thesis help you understand the connections between the study's findings and current trends.

Limitations

The study's limitations would be the participants' lack of enthusiasm, forgetfulness, or boredom, which would prevent them from giving completely honest answers. Other than that, there aren't many limits.Getting a sufficient quantity of answers might be even more challenging at times.

Because surveys are widely used, there is a possibility that certain problems may be left unanswered. Stay away from direct, in-person questions since others can misunderstand your issues. Results may be skewed if survey takers have trouble understanding and completing the questionnaire.

Compilation

Throughout the study process, all policies, rules, and survey results are thoroughly evaluated and adhered to.

Conclusion

Included in this part of the research strategy were the study's objectives, time frame, methods of data collecting, participants, and limitations. In this section, the author's selected approach is assessed with supporting evidence.

RESULTS AND DISCUSSION:

1. Regulatory Timeline Variations:
    - USA (FDA): Average approval time for Class III devices is 180–300 days.
    - EU (MDR): CE marking can take 6–24 months depending on Notified Body backlog.
    - Japan (PMDA/MHLW): Approval process averages 9–12 months for high-risk devices.
    - India (CDSCO): Lack of defined fast-track pathways; average time varies between 12–18 months.
2. Differences in Classification Systems:

- ICH member countries follow similar risk-based classification, but terminology and subclass handling vary.
- India's system is transitioning to align with GHTF principles but has inconsistencies in enforcement.

3. Document Requirements:
   - US and EU require full clinical evaluation reports (CER), risk assessments, and PMS plans.
   - India still accepts less stringent data for some categories.
   - Japan requires additional local clinical trial data in some cases.
4. Post-Market Surveillance (PMS) Challenges:
   - EU MDR has strict PMS and vigilance reporting norms.
   - India's PMS is evolving but lacks comprehensive traceability mechanisms.
   - Disparities lead to issues in global recalls and corrective actions.
5. Stakeholder Input (if applicable):
   - Manufacturers cited challenges with redundant documentation.
   - Regulatory consultants emphasized the burden of language translation and local agent requirements.
6. Identified Gaps:
   - Duplication of effort in dossier submission for multiple countries.
   - Lack of unified electronic submission portals.
   - Limited use of reliance or mutual recognition agreements.
7. Harmonization Opportunities:
   - Scope for ICH-based convergence in safety and performance standards.
   - Adoption of UDI (Unique Device Identification) standards globally can reduce regulatory friction.

Factsheet of USA Country profile

- Capital – Washington D.C.
- Currency - United states dollar
- Official language - English
- Drug regulatory authority – U.S. Food and Drug Administration

Medical device Market

1. U.S. Medical Devices Market (Sales & Revenue)
   - In 2024, the market was valued between approximately $188–$190 billion, depending on the source. It's forecast to grow to ~$199 billion in 2025, reaching ~$367–$368 billion by 2034, at a CAGR of 6.8–6.9% grand view research.com +3 fortune business insights.com+3 statifacts.com +3.
   - Another source estimates the 2024 value at $184.5 billion, projecting $311.5 billion by 2033 at a ~5.9% CAGR astuteanalytica.com.

Summary: The U.S. medical devices market currently stands around $185–$190 billion, expected to nearly double over the next decade, with steady CAGR ~6–7%.

2. U.S. Medical Device Manufacturing Segment (NAICS 33451)
   - According to IBISWorld, manufacturing output (domestic production) was $54.7 billion in 2024, rising to $56.4 billion in 2025 (about 3.1% year-over-year growth) ibisworld.com.

3. Market Overview

Metric	2024 Estimate	2025 Forecast	CAGR (2025–2033/34)
Market Size (Revenue)	$184–190 billion	$199 billion	6.8–6.9%
Domestic Manufacturing Output	$54.7 billion	$56.4 billion	~3.1%

4. Market Drivers
   - Aging U.S. population & rise in chronic diseases
   - Technological innovation (wearables, AI diagnostics, minimally invasive systems)
   - Regulatory support and higher healthcare spending

Bottom Line
- The total U.S. medical devices market (sales/revenue) is roughly $185–190 billion in 2024, poised to grow to $200 billion+ in 2025, with potential to exceed $350 billion by mid-2030s.
- The manufacturing output sub-sector is around $55–56 billion annually.

Factsheet of Europe Country profile

- Currency - Euro
- Official language - Russian, German, French, Italian, English , Spanish, Romanian, Dutch
- Drug regulatory authority – European Medicines Agency

Medical device Market –

EU Overall Medical Device Market (Europe)

- The European medical device market was valued at US $142.17 billion in 2024, projected to reach $148.3 billion in 2025, and $207.4 billion by 2032, with a CAGR of ~4.9% from 2025 to 2032 reuters.com+13fortunebusinessinsights.com+13marketdataforecast.com+13.

2. Surgical Equipment & Devices

a. General Surgical Devices Market

- In 2023, the general surgical devices segment (covering instruments, powered & energy-based tools) generated US $4.465 billion, expected to grow to $7.85 billion by 2030 at a CAGR of 8.4% grand View Research, com+1 Mordor Intelligence.com+1.

b. Surgical Equipment Market

- Total revenue was US$5.19 billion in 2024, with forecasts reaching $8.61 billion by 2030 (CAGR ~8.8%) grand view research.com.

c. Europe Minimally Invasive Surgical Instruments

- In 2023 revenue hit US $8.4508 billion, expected to grow to $17.01 billion by 2030 (CAGR 10.5%) fortunebusinessinsights.com+5grandviewresearch.com+5mordorintelligence.com+5.

3. Orthopedic Devices

- Europe's orthopedic devices sector was valued at US$12.89 billion in 2024, projected to reach $13.58 billion in 2025 and $19.92 billion by 2032 (CAGR ~5.6%) fortunebusinessinsights.com.
- Another source aligns, estimating $13.32 billion in 2024, growing to $21.06 billion by 2033 (CAGR 5.22%), market data forecast.com.

4. Key Trends & Market Drivers

- Strong CAGR: Surgical instruments (~8–10% CAGR), orthopedic devices (~5–6%), and overall medical devices (~5%).
- Drivers: Aging population, rising chronic & musculoskeletal conditions, surge in minimally invasive and robotic surgeries, healthcare infrastructure investments reddit.com+2fortunebusinessinsights.com+2en.wikipedia.org+2marketdataforecast.com.
- Regulatory pressures: EU MDR/IVDR compliance increasing time-to-market, favoring larger firms en.wikipedia.org+7mordorintelligence.com+7en.wikipedia.org+7.

Market Snapshot Summary

Segment	2023/24 Value (US$ Bn)	2030–32 Forecast (US$ Bn)	CAGR (%)
Overall Medical Devices (Europe)	142.2 (2024)	207.4 (2032)	4.9%
Surgical Equipment	5.2 (2024)	8.6 (2030)	8.8%
General Surgical Devices	4.47 (2023)	7.85 (2030)	8.4%
Minimally Invasive Instruments	8.45 (2023)	17.01 (2030)	10.5%
Orthopedic Devices	12.9 (2024)	~19–21 (2032–33)	5.5–5.6%

Insights & Implications

- The medical device market is robust but slower-growing (5%) compared to surgical and minimally invasive segments (8–10% CAGR).
- Minimally invasive devices are fastest growing, reflecting a shift toward outpatient care and advanced technologies.
- Regulatory reforms like MDR/IVDR pose hurdles, prompting consolidation and favoring larger industry players.

FACTSHEET OF JAPAN

- Country profile
- Capital – Tokyo
- Currency - Japanese yen
- Official language - Japanese
- Drug regulatory authority – Pharmaceutical and Medical Device Agency
- Medical device Market –

. Total Market Size & Growth

- The combined medical device market in Japan is projected to reach approximately US $30.01 billion in 2025, with a 7.1% YoY growth from the previous year mordorintelligence.com+12statista.com+12fitchsolutions.com+12.
- Forecasts indicate a CAGR of ~5.6% between 2025 and 2030, expected to reach around US $39.44 billion by 2030 .
- Another estimate suggests growth from US $54.5 billion in 2018 to

US $74.7 billion by 2025, reflecting a CAGR of ~4.6% drug-dev.com.

Thus, Japan ranks as the world's 2nd-4th largest medical device market, following the U.S. and China en.wikipedia.org+14fitchsolutions.com+14drug-dev.com+14.

2. Key Segments

• Surgical & General Surgical Devices

- Surgical equipment market was USD 883.3 million in 2023, predicted to USD 1,821.6 million by 2030, at 10.9% CAGR (2024–2030) mordorintelligence.com+4grandviewresearch.com+4grandviewresearch.com+4.
- General surgical instruments were valued at USD 8.3 billion in 2024, growing to USD 12.6 billion by 2033 (4.3% CAGR) imarcgroup.com.
- Diverse forecasts place this segment between USD 0.93–1.0 billion in 2025, rising to USD 1.43 billion by 2030 at ~8.9% CAGR statista.com+4mordorintelligence.com+4imarcgroup.com+4.

• Smart / Digital Devices

- The smart medical devices segment (diagnostics, therapeutic, wearables) stood at USD 3.49 billion in 2024, forecasted to USD 7.33 billion by 2030 (13.3% CAGR) grandviewresearch.com.

• Implantables

- The implantable device market totaled USD 8.36 billion in 2024, projected to USD 15.36 billion by 2033 (7% CAGR) imarcgroup.com.

• Disposable/Sutures Tools

- Disposable surgical devices reached USD 307.2 million in 2024, expected to USD 503.6 million by 2030 (8.8% CAGR) grandviewresearch.com.

3. Drivers & Trends

- Aging population (over 30% aged ≥65), growing demand for chronic-disease and orthopedic solutions, and strong move toward minimally invasive surgery mordorintelligence.com+1fitchsolutions.com+1.
- Digital health & smart devices increasingly popular, supported by policy shifts like Society 5.0 statista.com.
- Regulatory modernization: PMDA's Sakigake designation, new overseas offices (e.g., Washington), alignment with global standards (JIS T 62366-1, ISO 13485) reddit.com+2en.wikipedia.org+2imarcgroup.com+2.
- R&D & innovation partnerships (robotic surgery, regenerative medicine), e.g., Osaka University's surgical plate en.wikipedia.org+8reddit.com+8reddit.com+8.

4. Summary Table

Segment	2024 Value (US$)	2030 Value (US$)	CAGR
Total Market	~$30 bn (2025 est.)	~$39.4 bn (2030 est.)	~5.6% (2025–30)
Smart Devices	$3.49 bn (2024)	$7.33 bn (2030)	13.3%
Implantables	$8.36 bn (2024)	$15.36 bn (2033)	7.0% (2025–33)
Surgical Equipment	$0.88 bn (2023)	$1.82 bn (2030)	10.9% (2024–30)
General Surgical Instruments	$8.3 bn (2024)	$12.6 bn (2033)	4.3% (2025–33)
Disposable Surgical Devices	$0.31 bn (2024)	$0.50 bn (2030)	8.8%

Takeaways

- Japan's market is large and mature, showing steady growth overall (~5–6% CAGR) with faster expansion in digital, surgical, and implantable segments.
- Innovation, driven by demographic needs and digital health uptake, is supported by regulatory modernization and global alignment.
- Smart and implantable devices will likely be the fastest-growing pillars in the coming years.

FACT SHEET OF INDIA

Country profile

- Capital – Delhi
- Currency - Rupee

- *Official language - Hindi*
- Drug regulatory authority – Central Drugs Standard Control Organization

Medical device Market

INDIA Market Size & Growth

- USD 11 billion in 2022, with expectations to reach USD 18 billion by 2024 globenewswire.com+10ibef.org+10indialawoffices.com+10practiceguides.chambers.com.
- Forecasts range from USD 15.35 billion in 2023 to USD 30.6 billion by 2033 (CAGR ~6–6.1%) imarcgroup.com+1exactitudeconsultancy.com+1.
- More ambitious projections aim for USD 50 billion by 2030, reflecting a strong CAGR of ~15–16% imarcgroup.com.

Summary: The market is currently USD 15–18 billion, on a rapid growth trajectory toward USD 30–50 billion over the next decade.

2. Growth Drivers

- Government Push: The Production Linked Incentive (PLI) program (~USD 400 million), National Medical Devices Policy 2023, Make in India, and establishment of MedTech parks (e.g., Andhra Pradesh MedTech Zone) globenewswire.com+3beta.investindia.gov.in+3indialawoffices.com+3.
- Export Expansion: Medical device exports are rising—from USD 2.4 billion in 2022 toward targets of USD 10 billion by 2025 practiceguides.chambers.com.
- Healthcare Infrastructure: Growth in Tier II/III cities, hospital networks, and health-tech projects (diagnostics chains, telemedicine) .
- Tech & Innovation: Surge in AI-enabled wearables, smart devices, frugal innovation at IIT-BETiC labs en.wikipedia.org+1reddit.com+1.

3. Segment Highlights

- Diagnostic Imaging: Growing from USD 4 billion (2023) to USD 6 billion (2027)—CAGR ~16% prnewswire.com+2ibef.org+2practiceguides.chambers.com+2.
- Patient Monitoring Devices: Fastest growing segment (TechSci), spurred by home healthcare and digital health uptake .
- Surgical Instruments & Consumables: Dominated by domestic producers, with improvements through Medical Device Parks prnewswire.com+4indialawoffices.com+4india-briefing.com+4.

4. Key Challenges

- Import Reliance: India imports ~70–80% of devices, especially high-tech equipment, driving cost and supply-chain vulnerability reddit.com+3ibef.org+3marketresearch.com+3.
- Regulatory Delays: CDSCO approval processes can extend up to 2 years, slowing innovation marketresearch.com.
- Infrastructure Gaps: Logistics, cold chain, and distribution deficiencies pose scale-up challenges timesofindia.indiatimes.com+8globenewswire.com+8reddit.com+8.

5. Policy & Ecosystem Support

- Regulatory Strengthening: CDSCO tightening oversight via Med Devices Rules 2017, new marketing codes en.wikipedia.org+5indialawoffices.com+5mordorintelligence.com+5.
- MedTech Infrastructure: Andhra Pradesh, Telangana, Tamil Nadu, Gujarat, and others establishing MedTech parks with labs and certification facilities indialawoffices.com+1en.wikipedia.org+1.
- Innovation Hubs: Initiatives like BETiC at IIT Bombay foster frugal medical device design and commercialization beta.investindia.gov.in+6en.wikipedia.org+6marketresearch.com+6.

Overview Table

Category	Value (USD B)	Forecast
Current Market (2023–24)	15–18	–
2033 Projection	–	~30.6 (6.1% CAGR)
Aggressive Target	–	~50 by 2030 (~15%)

Takeaways

- The Indian medical device market is fast-growing, underpinned by strong policy support and innovation push.
- While import dependence and regulatory delays remain issues, targeted initiatives

and infrastructure are enhancing domestic capacity and exports.
- High-growth niches include diagnostics, patient monitoring, digital devices, and surgical consumables.
- Sustained momentum expected, with a potential to become a USD 50 billion market by 2030.

DISCUSSION:

Indian Medical Devices Market

Rising healthcare demand, changes in the global supply chain, and institutional reforms have all contributed to a dramatic shift in India's medical devices business in recent years. With some of the most promising markets for medical equipment sales and purchases in the world, India's medical technology sector is ripe for expansion.

1. Structural Growth Amid Policy Reforms

India's shift from being a predominantly import-dependent market to building a robust domestic manufacturing ecosystem is largely influenced by supportive government initiatives. The **National Medical Devices Policy (2023)**, **Make in India**, and the **PLI scheme** are laying the foundation for self-reliance by incentivizing local production and reducing import reliance—especially in high-end segments like diagnostic imaging and implants.

The establishment of **Medical Device Parks** in Andhra Pradesh, Tamil Nadu, Telangana, and Himachal Pradesh further reflects the government's commitment to build infrastructure and testing facilities that lower manufacturing costs and speed up regulatory compliance.

2. Innovation & Market Diversification

India is uniquely positioned to lead **frugal innovation** in medical devices. Institutions like **IIT-BETiC** are promoting the development of cost-effective and clinically validated technologies suited for the Indian population. Additionally, rising demand for **wearables**, **remote diagnostics**, and **smart health monitoring tools**—especially post-COVID—has opened new growth avenues for startups and SMEs.

Moreover, the **digitization of healthcare**, integration of AI, and adoption of telemedicine are reshaping device usage models, especially in rural and semi-urban areas.

3. Regulatory and Market Challenges

Despite progress, the Indian medical device industry still faces several challenges:

- **High import dependence** for complex Class C and D devices.
- **Fragmented regulatory oversight**, though improving under CDSCO.
- **Prolonged approval timelines** and lack of clear guidance in certain categories.
- **Price caps** imposed by the NPPA, while aimed at affordability, have discouraged some multinational investments.

These barriers, if not addressed, could delay India's ambitions to become a global medical device export hub.

4. Global Competitiveness and Exports

India's medical device exports are growing rapidly, with aspirations to increase from **USD 2.4 billion (2022)** to **USD 10 billion by 2025**. To achieve this, alignment with global standards (ISO 13485, CE marking, USFDA) is critical. Bilateral trade agreements and mutual recognition of conformity assessments can further facilitate smoother market access abroad.

CONCLUSION:

The Indian medical devices market is on a robust growth trajectory, transforming from a traditionally import-dependent sector into a dynamic and innovation-driven industry. With a current estimated value of **USD 15–18 billion** and aggressive projections to reach **USD 50 billion by 2030**, India is positioning itself as a global hub for affordable and high-quality medical technology.

Key government initiatives such as the **Production Linked Incentive (PLI) Scheme**, **National Medical Devices Policy 2023**, and the creation of **Medical Device Parks** across multiple states are fostering a supportive ecosystem for manufacturing, R&D, and export-oriented growth. Moreover, the rapid expansion of healthcare infrastructure, increased demand for diagnostics and patient monitoring equipment, and rising health awareness are further fueling the market.

Despite significant progress, challenges such as heavy import reliance (70–80%), regulatory bottlenecks, and gaps in standardization and supply chain infrastructure persist. However, strategic policy reforms, regulatory capacity building (via CDSCO), and emerging indigenous innovations (like those from IIT-BETiC) are gradually addressing these concerns.

In conclusion, India's medical devices industry holds immense potential for both domestic fulfillment and international competitiveness. With the right mix of regulatory harmonization, industry-

academia collaboration, and continued investment, India is set to emerge as a global leader in affordable medical technology manufacturing and innovation in the coming decade.

Summary

India's medical device market is at a critical inflection point—where policy push, manufacturing capability, and innovation converge. If current momentum is maintained and regulatory frameworks continue to mature, India can position itself as a global supplier of affordable, innovative, and quality-assured medical technologies over the next decade. However, sustained investment in R&D, capacity building, and harmonization with international standards will be key to realizing this vision.

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