



Global Regulatory Submissions for Medical Devices – A Strategic Guide for MedTech Companies

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When a high-risk medical device reaches the final stages of product development, success hinges on one question: *Can we get it approved, globally, efficiently, and without regulatory delays?*

Navigating global submissions for medical devices has become a high-stakes balancing act for MedTech companies, especially when juggling regulatory, clinical, and design complexities. Between tightening regulations, region-specific requirements, and increased clinical scrutiny, the path medical device approval process has never been more complex, or more critical to get right.

This article explores the evolving medical device global regulatory landscape, including major markets like the US, EU, APAC, and more. It further outlines where regulatory strategy often breaks down and offers practical ways to streamline submission readiness without compromising compliance.

Evolving Regulatory Landscapes Pose a Core Business Risk

Over the past decade, global medical device regulations have significantly evolved. Driven by increasing concern for patient safety, market transparency, and rapid technological advancement, regulators in major markets have modernized their expectations, raising the bar for evidence, risk management, and quality systems. As a result, companies must now adapt to region-specific requirements while keeping submissions globally harmonized.

Here are some major shifts in the recent years that have transformed the roadmap of global submissions:

- The **U.S. FDA** is phasing in the **Quality Management System Regulation (QMSR)** to align with ISO 13485:2016, modernizing its compliance approach. The final rule was published on February 2, 2024, and manufacturers must comply by February 2, 2026. This two-year transition aims to harmonize FDA quality system requirements with the international standard, reducing redundancy for companies operating globally [\[1\]](#).
- The **EU MDR and IVDR** have replaced older directives, drastically increasing the bar for clinical evidence, post-market surveillance, and technical documentation. According to a 2024 survey by MedTech Europe, medical technology companies reported increased costs and longer timeframes for certification and compliance under MDR and IVDR [\[2\]](#).
- In **APAC**, countries like India have mandated device licensing across all risk classes. As per the Medical Device Rules, 2017, all Class A and B medical devices came under the licensing regime effective October 1, 2022 [\[3\]](#).

- **China's NMPA** requires local type testing and submission in Mandarin, regardless of prior global approvals, as stipulated in the revised Regulations for the Supervision and Administration of Medical Devices (State Council Order No. 739) implemented on June 1, 2021 [4].

In short, every region has its own playbook, and each update adds more complexity.

This rising complexity is reflected in the global medical device regulatory affairs market size.

- The **medical device regulatory affairs market** was valued at **USD 6.75 billion in 2024** and is projected to reach **USD 11.66 billion by 2030**, growing at a CAGR of 9.55% [5].
- Medical device companies are increasingly relying on outsourced QARA expertise. As a result, regulatory outsourcing is booming—from **USD 6.53 billion in 2023** to an expected **USD 17.12 billion by 2031**, at a CAGR of 12.8% [6].

Key Medical Device Regulatory Pathways Across Global Markets

U.S. FDA Regulatory Pathways

The FDA offers three main routes:

- **510(k)**: For moderate-risk devices demonstrating substantial equivalence to existing products
- **De Novo**: For novel moderate-risk devices with no predicate
- **PMA**: Required for high-risk Class III devices; demands full clinical and design evidence

What is changing: The FDA **QMSR**, effective in 2026, will harmonize its quality system expectations with **ISO 13485**, reducing redundancy for companies operating globally (FDA, 2024). This presents an opportunity, but only for companies that proactively align their quality and design systems [1].

EU MDR and IVDR Compliance Requirements

The European MDR and IVDR regulations have raised expectations across the board:

- Increased clinical evaluation requirements (Annex XIV, MDR)
- Post-market surveillance obligations and PMCF plans

- UDI implementation and EUDAMED registration

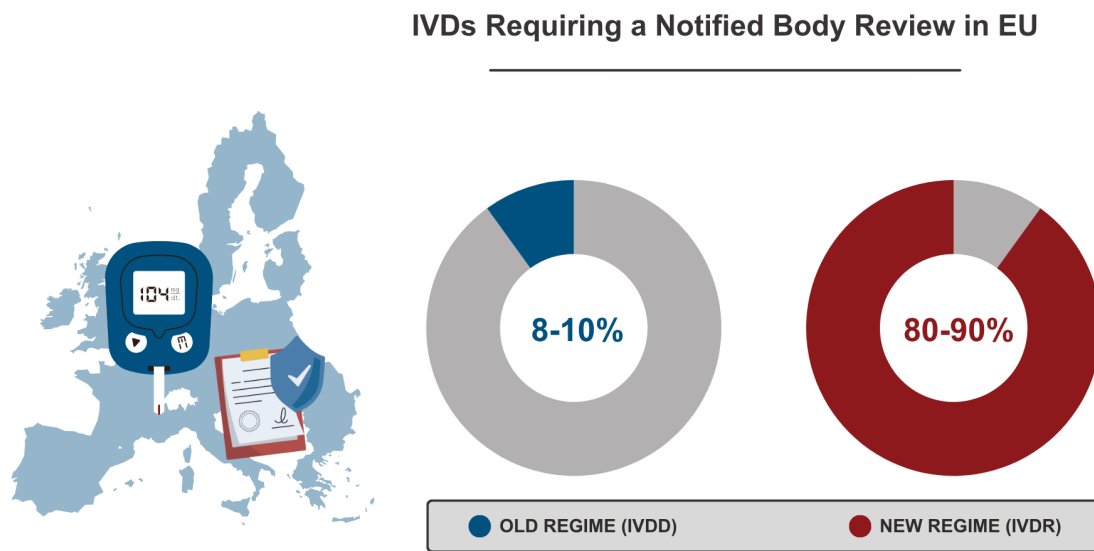


Fig. 1: IVDs Requiring a Notified Body Review in EU: Old (IVDD) vs. New (IVDR) Regime

The IVDR has been especially disruptive. Under the old IVDD, only 8–10% of IVDs needed a Notified Body review. Today, that proportion ranges from is 80–90% [2].

Notified Body capacity has not kept up, leading to significant certification delays, particularly for Class III and novel devices.

This means companies must begin CE planning well in advance, often 18–24 months before launch.

United Kingdom (UKCA Marking)

Although the original deadline for CE mark recognition in Great Britain was 30 June 2025, **CE-marked medical devices can still be placed on the GB market beyond this date** under [updated UK regulations](#):

- **Legacy devices under the EU MDD or AIMDD** can continue to be placed on the market until **30 June 2028** or until their CE certificate expires, whichever comes first.
- **Devices under the EU MDR and IVDs under the IVDD or IVDR** are accepted in Great Britain until **30 June 2030**, again subject to certificate validity.

Despite this extension, manufacturers are strongly advised to **begin transitioning to UKCA** to avoid future disruption. This includes:

- Engaging with a UK Approved Body early if third-party conformity assessment is required.

- Updating technical documentation and product labeling in accordance with UK MDR 2002 (as amended).
- Implementing a **dual compliance strategy** where appropriate, ensuring parallel CE and UKCA certification to maintain uninterrupted access to both EU and UK markets.

Canada (Health Canada)

- Class II–IV devices require Medical Device Licences (MDL).
- Mandatory ISO 13485:2016 certification *via* MDSAP for market access.
- Health Canada recognizes FDA and EU data, but the submission format is unique.

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- Brazil (ANVISA): Stringent dossier review and local clinical data may be required, particularly for high-risk devices.
- Mexico (COFEPRIS): Registration may rely on recognized reference countries (e.g., FDA), depending on device class. High-risk Class III devices without prior approval may require full review.
- Local representation and certified translations are mandatory in most LATAM countries. Furthermore, regulators often require local testing or certification to ensure compliance with national standards (for instance, the Brazilian INMETRO testing requirement for certain devices mandates laboratory tests and inspections). Companies should plan for in-country evaluations and not assume that a CE mark or FDA approval alone will suffice.

APAC Markets

India (CDSCO)

- All device classes (A to D) require registration or licensing.
- Abridged review available for globally approved products.
- IAA is required for foreign manufacturers.

China (NMPA)

- Requires **in-country type testing**, even for previously approved devices.
- Local clinical trials are often needed for Class III products.
- The entire dossier must be translated and localized (NMPA, State Council Order No. 739, 2021).

Japan (PMDA)

- Class III/IV devices require **Pre-Market Approval**
- Foreign companies must appoint a **Designated MAH**.
- JIS (Japanese Industrial Standards) compliance is essential (PMDA, Pharmaceuticals and Medical Devices Act, 2023).

ASEAN

- Follows the ASEAN Medical Device Directive (AMDD) for regulatory harmonization.
- Submissions must follow the Common Submission Dossier Template (CSDT).
- Requirements and enforcement vary by country; local representation is mandatory.

Australia (TGA)

- Classifies devices according to risk (Class I–III and AIMD).
- Conformity assessment often recognizes EU CE certificates.
- The Essential Principles framework governs safety and performance.

To summarize, each of these markets expects regulatory submissions that go beyond documentation. They demand cultural fluency, process discipline, and local regulatory relationships. All of these should form essential components of global submissions planning.

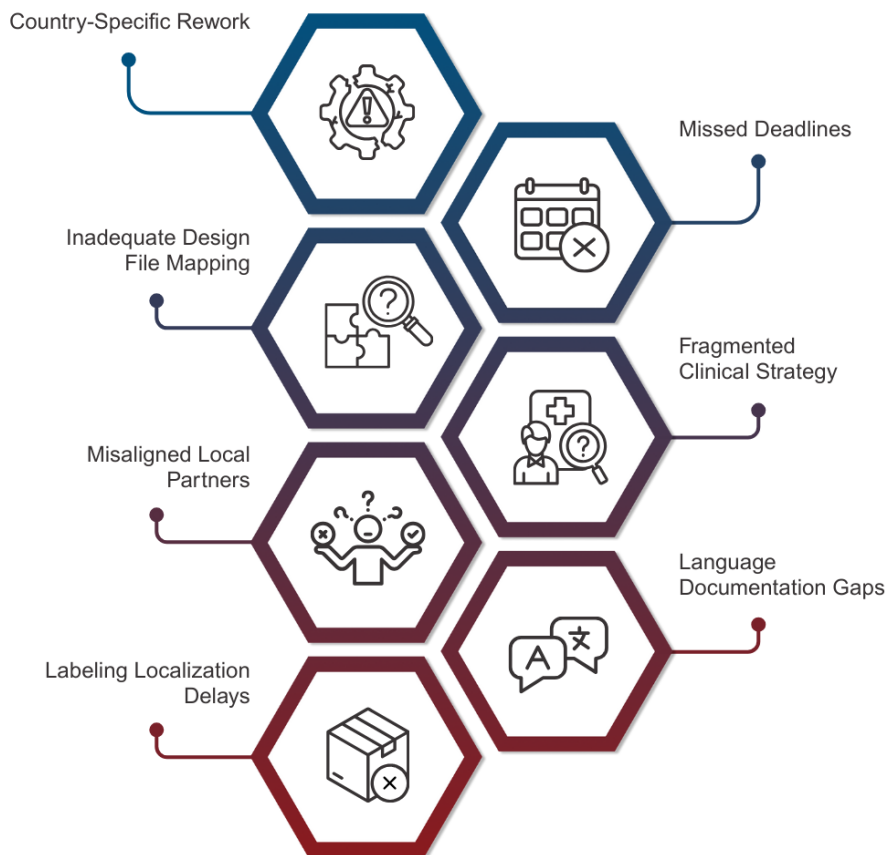


Fig. 2: Risks of poor submission planning

Risks of Poor Global Regulatory Submission Planning

Poor regulatory submission planning slows down medical device approvals and actively undermines your product's success. Companies that fail to coordinate global submissions face:

- **Country-specific Rework Delays:** Inconsistent documentation structures trigger regulator-specific feedback, requiring repeated customization. Multiple iterations of documentation, labeling, and clinical justifications lead to spiraling regulatory overhead.
- **Missed Deadlines Due to Capacity Bottlenecks:** Delays with, say, the Notified Bodies in the EU or the CDSCO queues in India can derail tightly scheduled launches.
- **Inadequate Design File Mapping Across Markets:** Poor technical file alignment leads to fragmented submissions and inconsistent interpretations.

- **Siloed Clinical Strategy:** When trials are planned independently for each region, companies may face multiple study timelines and higher costs.
- **Misalignment with Local Agents or MAH Partners:** Poor communication or lack of regulatory experience can result in submission errors or lost follow-up.
- **Language-specific Documentation Gaps:** Missing certified translations, or improperly localized dossiers often lead to rejections.
- **Delayed Labeling Localization:** Post-approval launch delays due to packaging and IFU adaptations not planned upfront.

These risks amount to a larger cost for MedTech companies:

- **Reputation Damage:** Rejections or recalls due to compliance oversights reflect poorly on quality systems and leadership oversight.
- **Lost Investment & Opportunity:** Regulatory delays can trigger investor concerns, market withdrawal, or product obsolescence.



Fig. 3: Smart global regulatory submission strategy for MedTech companies

A Smarter Global Submission Strategy for Medical Device Companies

To avoid the risks and costs, regulatory leaders should:

1. Develop a Global Submission Roadmap

Start with a unified roadmap identifying your key target markets and submission order. Harmonize documentation such as Clinical Evaluation Reports (CERs), Risk Management Files, and Verification & Validation (V&V) data to create a globally adaptable core dossier. Strategically sequence submissions, launching first in regions with shorter timelines or where market entry will accelerate funding and credibility (e.g., FDA before EU, or *vice versa*).

2. Local Partner Due Diligence

Success in global submissions often hinges on the reliability of local representatives. Conduct early due diligence across markets, such as Notified Bodies in the EU, Authorized Agents for India (CDSCO), Marketing Authorization Holders (MAHs) in Japan, and Legal Agents in China. Look for proven approval histories, transparent communication practices, and familiarity with your device class.

3. Align Clinical Trials Upfront

Design clinical protocols that meet the expectations of all major regulators. This reduces the need for multiple trials and ensures that clinical data can be leveraged across submissions. For example, integrating endpoints relevant to both, MDR and FDA can avoid costly rework and duplicated study timelines.

4. Leverage International Standards

Anchor your submission around globally recognized standards, ISO 13485:2016 for QMS, ISO 14971:2019 for risk management, and IEC 60601 for electrical safety (if applicable). Use the IMDRF Table of Contents to structure your technical documentation in a format recognized across multiple jurisdictions, improving efficiency and review clarity.

5. Pre-submission Engagements

Initiate early dialogue with regulators through formal engagement channels. For example, use the FDA Q-Sub program, PMDA pre-submission consultations, or Notified Body advisory meetings in the EU to clarify expectations, reduce ambiguity, and align on requirements. These touchpoints can pre-empt costly delays and de-risk submissions.

6. Smart Outsourcing

Instead of managing everything internally, leading MedTech companies increasingly rely on external QARA experts to streamline execution. Engage regulatory vendors with experience in your target markets to execute submissions, prepare region-specific documentation, and manage local regulatory interactions. Smart outsourcing lets you stay lean, reduce internal workload, and gain access to region-specific expertise, especially when managing submissions in parallel.

Case Study: Streamlining FDA and APAC Submissions Through Global Dossier Harmonization

A U.S.-based medical device company was developing a Class III orthopaedic implant. With FDA approval in sight, they plan a rapid multi-region expansion across the EU and APAC. However, internal audits reveal that their technical documentation, though FDA-ready, will not meet MDR or NMPA expectations without significant restructuring.

They face two options:

Option 1: Submit to FDA first, then rebuild documentation for MDR and NMPA in phases. This could result in fragmented submission cycles, three separate rounds of evidence reviews, and over 24 months of cumulative approval delays.

Option 2: Develop a harmonized global technical file upfront, structured using IMDRF Table of Contents and ISO 13485:2016. They also align clinical endpoints to meet both FDA and MDR expectations while preparing Chinese translations and PTR documentation in parallel.

By choosing Option 2, they:

- Submit FDA eSTAR and EU MDR applications within **two months** of each other.
- Complete NMPA type testing while EU submissions are under Notified Body review.
- Receive all three approvals in **under 16 months**.

Strategic Gains:

- **Global Readiness:** Eliminated regional gaps early.
- **Time Efficiency:** Saved 8–10 months by overlapping submission preparation.
- **Lower Risk:** Reduced likelihood of rework and regulator rejections.
- **Stronger ROI:** Enabled synchronized launch in multiple revenue regions.

This harmonized strategy gave the MedTech company a unified market entry plan and a head start in APAC without derailing their FDA or EU goals.

Tools and Technologies That Streamline Global Regulatory Submissions for Medical Devices

To manage complexity and accelerate approvals across multiple regions, medical device companies increasingly rely on digital tools that support regulatory planning, documentation,

and execution. These help to manage complexity and accelerate approvals across multiple regions.

Table 1: Digital Tools Supporting Regulatory Submissions for Medical Devices

Tool / Platform	Function / Benefit
Regulatory Intelligence Platforms	Monitor evolving requirements across global authorities (e.g., FDA, CDSCO, NMPA) to ensure submissions reflect the latest regulatory changes.
Centralized Document Repositories	Secure and organize risk files, CERs, and technical documentation with version control; crucial for managing multiple submissions in parallel.
Clinical Trial Platforms with Multi-Region Tracking	Enable real-time monitoring of endpoints, patient recruitment, and data collection, tailored to regional requirements.
E-submission Systems	Format and validate submission packages through tools like FDA eSTAR or IMDRF-compliant portals, improving accuracy and regulatory responsiveness.

Global Success Relies on a Smart Regulatory Strategy

For MedTech companies, the cost of non-compliant regulatory misalignment is a missed market window, a damaged brand, and millions in lost revenue.

By integrating regulatory planning into early design, harmonizing technical documentation, and aligning global submissions with local nuances, companies can not only accelerate market entry but also build a reputation for reliability across borders.

At **Syrma Johari MedTech**, we develop [global regulatory submission strategies](#) that align with your product and market priorities. We help MedTech companies streamline submissions, from documentation to dossier development, clinical integration, and region-specific strategy across all medical device classes. We are your trusted QARA partner for global success!

Partner with Syрма Johari MedTech for Medical Device Regulatory Success!

Get in touch to explore how we can accelerate your device approvals—without compromising compliance.

[Contact Us](#)

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Meta Description

Global regulatory submissions for medical devices explained. Strategies for FDA, EU MDR, CDSCO India, NMPA China, PMDA Japan & more—accelerate approvals with compliance