



Congenius Whitepaper

# Overcoming the regulatory challenges for global market access

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## Introduction

**Global regulatory requirements for medical devices differ widely in scope and interpretation. These disparities can delay product launches, elevate compliance costs, and deter cross border innovation.**

As healthcare becomes increasingly globalised, harmonising and simplifying market access is becoming both a policy priority and a competitive necessity for medical device manufacturers.

This whitepaper contextualises the current global regulatory landscape, analyses the major challenges with achieving international market access, and outlines practical strategies for manufacturers looking to overcome these hurdles.





**Contextualising the  
global regulatory landscape**

# Contextualising the global regulatory landscape

## Who are the prominent players?

Regulatory authorities around the world have distinct data expectations and approval pathways:



**The EU** | In the European Union, medical devices are regulated under the [MDR](#) and [IVDR](#) framework, with conformity assessment involving Notified Bodies where required and oversight by national competent authorities. The framework emphasises lifecycle management, clinical evidence, post-market surveillance, and device traceability through UDI.



**Switzerland** | Switzerland maintains a closely aligned but distinct regulatory framework for medical devices, largely reflecting EU MDR and IVDR principles while operating under Swiss-specific requirements. Manufacturers placing devices on the Swiss market must consider obligations related to Swiss authorised representation, economic operator responsibilities, vigilance, and device registration requirements through Swissmedic/swissdamed. For companies based in or targeting Switzerland, early alignment with both EU and Swiss requirements can reduce duplication and avoid market-entry delays.



**The UK** | Following Brexit, the UK has established its own medical device regulatory framework under MHRA oversight. Manufacturers must assess UKCA marking requirements, transitional recognition of CE-marked devices, UK Responsible Person obligations, and evolving UK-specific regulatory reforms. The UK remains a strategically important market, particularly because manufacturers may need to manage parallel EU and UK compliance pathways.

# Contextualising the global regulatory landscape

## Who are the prominent players?



**The US** | The FDA oversees the classification, premarket approval ([PMA](#)), and [510\(k\)](#) clearance processes. The FDA framework emphasises risk-based classification and supports both premarket reviews and post-market performance monitoring.



**Canada** | Canada is a highly relevant market for global regulatory planning, particularly due to Health Canada's medical device licensing framework and its mandatory use of the Medical Device Single Audit Program (MDSAP) for applicable manufacturers. Canada's participation in MDSAP allows manufacturers to leverage a single quality management system audit across multiple jurisdictions, making it an important consideration when designing a global compliance and audit strategy.



**China** | China's NMPA requires local testing data and manufacturing audits. It has modernised rapidly, partially aligning with international frameworks but maintaining distinct local requirements.



**Japan** | Japan's PMDA applies a risk-graded classification and emphasises conformity to the Japanese Quality Management System Ordinance.



**Fast-growing markets** | Nations like [Brazil](#) (ANVISA), [Mexico](#) (COFEPRIS), [India](#) (CDSCO), and [South Africa](#) (SAHPRA) have made major strides toward structured regulatory oversight, but still differ in dossier formats, documentation languages, and inspection standards.

# Contextualising the global regulatory landscape

## How has the landscape evolved?

Historically, medical device regulations developed in response to domestic safety incidents or policy reforms. The lack of alignment between systems created barriers for manufacturers expanding internationally. Recognising these inefficiencies, the Global Harmonization Task Force (GHTF) - succeeded by the International Medical Device Regulators Forum (IMDRF), was established to promote convergence in technical documentation, risk classification, and quality management systems.

While IMDRF guidance supports a movement toward mutual recognition, the reality remains uneven. Many jurisdictions adopt its principles adapted to their local legal and cultural context. For example, while the EU has incorporated elements of the IMDRF's clinical evaluation model, others maintain unique evidence standards. This semi-harmonised ecosystem creates partial efficiencies but fails to eliminate redundancy.



# Contextualising the global regulatory landscape

## What are the main factors currently shaping regulations?

Four macro trends dominate the evolution of device regulation worldwide:

### Digital health & SaMD

Regulatory bodies are creating risk-based frameworks for standalone software intended for diagnostic or therapeutic purposes. The FDA and EU MDR both address software differently, creating interpretation challenges.

### AI & Machine Learning

Regulators face the challenge of dynamic, self-learning algorithms. As of 2025, guidance is emerging toward predetermined change control plans (PCCPs) that balance innovation with patient safety.

### Post-Market Surveillance (PMS) & Real-World Evidence (RWE)

Many authorities now require continuous safety monitoring and evidence collection post launch. The EU's Periodic Safety Update Reports (PSURs) typify this shift.

### Cybersecurity, Data Privacy, & Sustainability

Devices increasingly connect to networks, triggering oversight from not only health authorities but also data protection regulators. Environmental regulations are also becoming intertwined with device compliance, reflecting global commitments to sustainable manufacturing.

A teal-tinted photograph of an operating room. In the foreground, a large, circular surgical light fixture is prominent, with its mesh-like interior visible. Below it, another similar light fixture is partially seen. The background shows various pieces of medical equipment, including what appears to be an anesthesia machine with multiple dials and screens, and other instruments on stands. The overall scene is brightly lit, typical of a surgical environment.

**Identifying the challenges  
with global market access**

# Identifying the challenges with global market access

## Regulatory fragmentation & complexity

Medical device manufacturers often encounter inconsistent device classifications and dossier structures across markets. For example, an implantable cardiac device may be classified as Class III in both the US and EU, while China may apply its own Class III pathway, each requiring market-specific evidence, testing, and submission documentation.

Duplicative testing and documentation efforts drain resources, and submission formats often differ (e.g., 510(k) format in the US vs. technical documentation under EU MDR). Companies must balance the need for global consistency with local customisation - a challenge magnified for SMEs without global regulatory departments.

## Market-specific barriers

Beyond registration, manufacturers also face downstream challenges. Some authorities mandate locally generated clinical data, even when international evidence exists - which can delay access and increase costs.

Comprehensive language localisation and compliance with regional labelling formats require careful management to avoid errors that could trigger costly recalls.

And jurisdictions vary in their expectations for reporting adverse events or conducting vigilance studies - with the absence of uniform timelines complicating global monitoring networks.

## Identifying the challenges with global market access

### Compliance costs & resource constraints

The cost of regulatory compliance has risen significantly due to more rigorous quality and evidence standards. The EU MDR, for example, has imposed higher levels of clinical evaluation and post-market follow-up, causing product withdrawal from many smaller firms. Establishing or maintaining [ISO 13485](#) certification, managing audits, and preparing for unannounced inspections all require dedicated resources.

For start-ups, investment in regulatory planning often competes with R&D budgets. Underestimated timelines and costs can lead to missed market opportunities - a critical issue for innovators reliant on venture funding.

### Emerging technologies & regulatory uncertainty

While digital transformation drives healthcare progress, it also creates uncertainty. Definitions for [AI-enabled devices](#), SaMD, and digital therapeutic tools differ widely between jurisdictions. The lack of consistent terminology hinders comparative evaluation and slows multi market approval.

Moreover, cloud-based data management and adaptive algorithms challenge traditional static certification models. Regulators must now monitor continuous learning systems, leaving manufacturers in limbo as rules evolve.

# Identifying the challenges with global market access

## Supply chain & trade barriers

Market access extends beyond regulatory filings. Diverse labelling requirements, tariffs, and geopolitical tensions such as export restrictions on sensitive technologies, create additional layers of complexity. Assembly and component sourcing across borders may trigger multi-jurisdictional inspections, further delaying commercialisation.

The COVID-19 pandemic exposed the fragility of global supply chains, prompting some authorities to impose local manufacturing or stockpiling obligations. As such, for many medical device manufacturers, balancing compliance with global cost efficiency remains a strategic dilemma.



**Overcoming the  
regulatory challenges**

# Overcoming the regulatory challenges

## Implement your regulatory planning early

Manufacturers should integrate regulatory strategy early in product design rather than retrofitting it once development is complete. A global regulatory roadmap aligned with design and clinical strategy will enable efficient data generation and minimise later duplication.

Early engagement with authorities such as FDA's [Q-Submission](#) meetings or EU Notified Body consultations can help to clarify expectations and reduce uncertainty. Companies operating across multiple markets should adopt [master technical documentation](#) frameworks that allow shared data modules adaptable to local requirements.

### Case example | US / EU Dual Approval

A mid-sized cardiovascular device manufacturer harmonised its clinical evidence plan across both FDA and EU MDR frameworks. By conducting a single pivotal study designed to meet both sets of requirements, the company reduced overall time-to-market by 30% and avoided redundant testing.

# Overcoming the regulatory challenges

## Develop a robust global compliance system

Embedding compliance throughout your product's lifecycle will foster uniform standards across regions and implementing ISO 13485 serves as a universal baseline by facilitating recognition in multiple jurisdictions.

Developing centralised regulatory intelligence functions capable of tracking evolving requirements in real time is fundamental for a proactive approach - by utilising advanced databases and AI-driven alerts, your team will be able to anticipate regulatory changes rather than react to them.

And integrating your compliance data across R&D, manufacturing, and post-market divisions will help to ensure transparency and audit readiness.

### Case example | Digital compliance dashboard

A start-up developing AI-driven ophthalmic diagnostics deployed a cloud-based regulatory dashboard integrating version control, task tracking, and jurisdictional checklists. Automated alerts enabled proactive updates to documentation in response to regulatory changes, avoiding costly delays during EU MDR transition.

# Overcoming the regulatory challenges

## Leverage international standards & mutual recognition

International standards are a cornerstone of global harmonisation. Adoption of ISO/IEC and IMDRF common documents can simplify your technical submissions. Participation in Mutual Recognition Agreements (MRAs) or the [Medical Device Single Audit Program \(MDSAP\)](#) enables one audit to satisfy requirements for multiple jurisdictions including the US, Canada, Australia, Japan, and Brazil.

Emphasising conformity with these frameworks accelerates approval and strengthens credibility with regulators. Manufacturers that contribute to regulatory working groups or standards committees also gain early insights into pending policy changes.

### Case example | Leveraging MDSAP

A global diagnostics company participating in MDSAP used a unified quality management audit to satisfy five regulatory bodies simultaneously. This cut its annual audit budget by 40% and improved consistency in documentation.

# Overcoming the regulatory challenges

## Utilise digital & data-driven approaches

Digitisation offers powerful tools to alleviate regulatory burdens:

- **Document automation** | Centralised systems allow teams to version-control and update technical documentation efficiently.
- **Regulatory data analytics** | Predictive models can estimate review timelines and flag potential deficiencies before submission.
- **AI compliance assistants** | Machine learning tools can map local requirements, track evolving nomenclature, and generate cross-referenced compliance matrices.
- **Digital submissions** | Electronic Common Technical Document (eCTD) and online submission portals streamline review processes and enable faster communication with authorities.

These innovations support transparency and speed, but they also demand strong data governance and cybersecurity protocols to safeguard proprietary and patient data.

## Build capacity & partnerships

Expanding global market access often exceeds the capabilities of a single manufacturer. Building partnerships with local regulatory consultants, authorised representatives, and distributors provides localised intelligence and accelerates country-specific filings.

Internally, manufacturers should invest in ongoing training for regulatory affairs professionals, ensuring familiarity with diverse jurisdictions and new technologies. Cross-functional regulatory “steering committees” that link compliance, R&D, marketing, and supply chain functions can facilitate consistent decision-making and timely alignment.



**In conclusion...**

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**Global market access for medical device manufacturers is both an opportunity and a challenge.**

While technological innovation opens new therapeutic frontiers, regulatory complexity threatens to slow progress. Divergent frameworks, escalating evidence demands, and evolving expectations for digital health create a fragmented environment that favours well resourced organisations.

However, the path forward is clear. Adoption of international standards, digital compliance tools, and proactive capacity building will be central to success in the coming decade. And manufacturers who approach regulatory compliance strategically - by harmonising documentation, engaging regulators early, and embedding quality systems across their operations - can turn compliance excellence into a competitive differentiator.



**Should you have a market access challenge related to your medical device, get in touch to find out how our team of experts could help.**