Insight Brief

Global Market Access — A Regulatory Affairs Perspective

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KEY TAKEAWAYS:

1. Global Medical Device and In-Vitro Diagnostic product launches are complex and need to consider requirements beyond the US and EU
2. To optimize product launches, companies must consider global clinical, technical and toxicological requirements and identify the impact of local country standards during product design
3. IQVIA's Quality Management and Regulatory Suite provides industry connected, intelligence driven, and AI enabled QMS and RIM modules that support a dual focus on patient safety and commercial performance

Overview

IQVIA's Quality Management and Regulatory Suite empowers Quality Assurance and Regulatory Affairs (QA/RA) professionals with an AI-enabled, intelligence-driven QMS/RIM solution. This integrated platform allows global teams to efficiently capture design requirements based on country-specific regulations, author essential source content and technical documentation for global submissions and leverage digital connectivity to streamline the compilation of registration dossiers. Additionally, it automates the detection and flagging of global regulatory changes, accelerating compliance, and reducing risk across markets.

By eliminating the need to manually connect disparate, legacy systems, this connected ecosystem significantly reduces the risk of human error. The result is improved global regulatory compliance, increased right-first-time execution, and the ability for QA/RA professionals to focus more on strategic, customer-centric, and regulatory-facing initiatives.

Context

Anusha Gangadhara and Michael King discussed common go-to-market challenges faced by Medical Device and In-Vitro Diagnostic organizations, how global product launches can benefit from a purposeful design-driven approach, and how a connected intelligence driven Quality Management and Regulatory Suite can address those challenges and accelerate global registration processes. They specifically outlined five key principles to make the global launch process more predictable by streamlining the design of the registration pathway.

Global medical device and in-vitro diagnostic product launches are complex and often unpredictable

Compliance with ever-changing global and local regulations is a key obstacle to MedTech operators' ability to predict and plan flawless product launches. As well as the changing vertical regulations that specifically target the medical device and in-vitro diagnostic sectors, companies must also address horizontal regulations that can span many industries, for example in areas such as data protection, cyber security, artificial intelligence, environmental and many more.

Specifically, there are five key market access areas that, when addressed by QA/RA professionals, can greatly accelerate their company's global market access activities:

- **Global drivers to regulation** These drivers stem mainly from concerns about patient safety but can also be motivated by politics or economics
  - ***Patient safety drivers*** — industry-specific considerations, such as those that led to raising the risk class ("up classification") of orthopedic products used in hip, knee, and shoulder joint replacements, as per European Commission Directive 2005/50/EC. Consequently, approval for such products now requires more robust clinical information and more detailed review from European Notified Bodies
  - ***Political drivers*** — country-specific considerations that change medical device regulations in those countries (e.g., Brexit, Swiss exit) or lead to intentionally slower review times when two countries are having a tumultuous political relationship
  - ***Advancements in technology*** — As the uptake of Artificial Intelligence (AI) technology accelerates, particularly within Medical Device Software (MDSW) or Software as a Medical device (SaMD), many countries are releasing their own, independent regulations on the safe use and governance of the technology
- **Global regulatory variation** There is a tendency to overemphasize regulatory approvals in the United States or the European Union and neglect the fact that they are not universally accepted. Many countries require additional technical and/or toxicological testing, or localised clinical data or trials, resulting in lengthier and costlier launch plans in those countries. Some countries may also have local product standards that vary in content and parameters to those that are generally accepted. by the United States and European Authorities

To optimize global market access, companies must embrace design for registration

To increase their odds of product launch success and improve the predictability of global market access, companies should aim to identify early on the global registration requirements for their product. This approach helps save time, minimize costs, and improve visibility into the regulatory submission pathway. Other strategies for optimizing product launches include attaining improved estimations of timeline, resources, and cost of the launch; assigning dedicated resources for global registration activities; and communicating transparently about the product launch project status.

These factors and all the components and considerations necessary to fuse them together into a cohesive global product launch strategy form part of a concept IQVIA calls “design for registration.” (King noted that other companies may refer to the same concept as “manufacture for compliance” or “design for compliance.”) The main purpose of design for registration is to bring predictability to global processes, given the multiple challenges and “moving targets” caused by evolving regulations.

The five key principles that make up the design for registration concept are outlined in Figure 1.

“The latest Quality Management and Regulatory technologies support global market access activities through accelerating data driven insights and utilizing targeted applications of AI. Learnings from one product launch drive adaptations to the iterative design of new products, and, as an example, the ability to mine product performance data in post market surveillance activities drives improvements in clinical applications and in advancing a product’s risk profile. All of this data is essential to support global product registration activities.“

— Anusha Gangadhara, IQVIA

Figure 1. A bird's-eye view of the five key principles underpinning design for registration

Scope

Begin with the end in mind:

- Target countries
- Launch sequence
- Registration pathway

Global inputs

Identify global requirements:

- Clinical
- Product toxicological testing
- Product technical testing
- Local standards
- Local documentation requirements

Communication

Conscious and transparent decision making:

- Launch scope
- Project changes
- Critical path
- Include global regulatory early in the plan

Embrace reality

Know your customer:

- Regulator
- 3rd party agency
- Dealer
- Commercial
- Operations
- Regulatory & Quality

Raise the vision

Adjust global launch expectations:

- Traditional launch nominally 2-3 years in US/ EU
- Global launch circa 3-5+ years
- Impacts retainment of resources throughout project lifecycle

IQVIA's quality management and regulatory suite brings a range of connected QA/RA modules under one solution

To support Medical Device and In-Vitro Diagnostic companies with the design of more predictable and effective launch cycles that control timelines and limit costs, IQVIA's Quality Management and Regulatory Suite supports a successful regulatory submission process by driving integrations and automations across a range of QMS and RIM modules:

- Local requirements — Identify country specific requirements for both pre-market product registration activities, and post market surveillance obligations, with a database of content for over 89 countries
- Content Submission — Author, review, and approve source content using country-specific templates to create global product registration documentation
- Regulatory Change — Automate the tracking and identification of regulatory change to drive timely impact assessments and global (re)registration activities

The key objective of a connected Quality Management and Regulatory Suite, with intelligence driven automation and pragmatic AI applications, is to capture product launch-relevant data in near real time and derive insights that can be fed back into companies' standard operating procedures and into their quality, regulatory and safety processes that impact product launches.

"The first thing is understanding the market requirements — the challenge that most companies face is that these requirements don't always sit in one piece of legislation. A connected intelligence system ensures that for any given product type you've spread the nets over the different drivers, be it regulations or standards or position papers that governments have written, and then feed these back into applicable company QMS and RIM processes."

— Michael King, IQVIA

Conclusion

In a heterogeneous regulatory environment that is constantly generating new and updated regulatory mandates, Medical Device and In-Vitro Diagnostic companies need a way to capture those changes and act on them quickly. But beyond that, they need an intentional, streamlined approach to planning global registration processes that enables them to go to market in a more predictable and less costly way. IQVIA's Quality Management and Regulatory suite, with its connectivity across over 20 QMS and RIM modules, embeds regulatory intelligence into the global registration process and optimizes product management activities across the end-to-end product lifecycle. Ultimately, this enables QA/RA professionals to enhance their dual focus on patient safety and commercial performance.

About the authors

MICHAEL KING
Senior Director, Product & Strategy, IQVIA

As the Senior Director of Product and Strategy at IQVIA, Mike ensures that healthcare solutions meet the demands of complex and diverse global regulations. He oversees IQVIA's comprehensive solutions, including the award-winning SmartSolve® eQMS and RIM Smart, which streamline quality and regulatory compliance processes.

With 20 years of commercial experience, Mike focuses on optimizing business workflows through intelligence-driven simplification and automation across quality, regulatory, and safety functions. He is passionate about improving patient outcomes and is an expert in AI applications within the quality and regulatory space. Mike leverages his extensive knowledge and skills to develop innovative solutions that advance the quality agenda in healthcare.

Mike is dedicated to empowering regulatory and quality professionals, helping them recognize their direct impact on patient safety and organizational performance. His goal is to enable these professionals to enhance patient outcomes and drive commercial success.

ANUSHA GANGADHARA
Associate Director, Product Owner, QARA Solutions, IQVIA

With over 12+ years of technology experience in Healthcare Platform and Medical Device Technology, Anusha is part of the Product Management team, QARA Solutions, IQVIA — defining and mapping business needs to technical requirements and leading business critical engagements for Medical Device Technology.

In her previous experience she drove quality processes and regulation requirements for Health Suite Platforms (HSP) development at ***Philips Healthcare*** and spearheaded global product launches and regulatory market approvals across India, USA, and European markets for two novel MedTech devices developed under ***Consure Medical*** and ***Sohum Innovation Labs*** - both incubated from the coveted ***Stanford Biodesign program, Stanford University*** for Medical Technology.

Anusha holds a master's in electrical engineering from ***National University of Singapore*** (NUS) with rigorous hands-on experience in the medical device and technology development process from Stanford-***Singapore Biodesign*** program.

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