WEBINAR SUMMARY

September 28, 2022

Medtech Insight

Pharma Intelligence

MedTech Market Access Trends in 2022: Design for Registration – Principles of a Global Approach

Michael King, Senior Director, Product & Strategy, IQVIA
Anusha Gangadhara, Business System Analyst, IQVIA

KEY TAKEAWAYS

- Global MedTech product launches are complex and often unpredictable.
- To optimize global product launches, companies must embrace design for registration.
- IQVIA's connected intelligence approach unites design for registration elements under one roof.

in partnership with

IQVIA TECHNOLOGIES

OVERVIEW

The success of global MedTech product launches is determined not just by the speed of registration, but also by the predictability of process cycles, the consistent delivery of right first-time submissions, and the cost- and time-efficient design of parallel country submissions. This conglomeration of factors requires a system with built-in market intelligence that is capable of assimilating information that captures global variations and requirements per product and country types and communicating that information across a company's global teams to streamline decision making.

IQVIA's design for registration framework and connected intelligence system responds to that need by harvesting relevant country-specific regulatory information, automating the transactional part of insight generation, and enhancing professional regulatory activities—and in doing so bringing much needed clarity to the global launch process.

CONTEXT

Anusha Gangadhara and Michael King discussed common go-to-market challenges faced by MedTech organizations, how global product launches can benefit from a purposeful design-driven approach, and how a connected regulatory intelligence system can address those challenges and accelerate global registration processes. The panelists specifically outlined five key principles to make the global launch process more predictable by streamlining the design of the registration pathway.

KEY TAKEAWAYS

Global MedTech 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. Specifically, there are five key go-to-market challenges for regulatory professionals within the MedTech industry:

- **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.

  "We need to look beyond regulations on patient safety and recognize that politics and economics quite often drive some of the regulatory changes," said King.
- **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.

- **Product-specific requirements.** Because local standards can vary from globally accepted standards (e.g., a medical device in one country may be considered a non-medical device or a pharmaceutical product in another), and because software, chemical, mechanical, and combination products may be governed by different types of legislation, different considerations may need to be applied in the design phase of any product.
- **Regulatory submission variation.** Choosing the right submission strategy affects the registration pathway. Considerations such as which legal entity will hold the registration, whether the registration is submitted as a new registration or a re-registration, and whether the registration submission is at a product solution or product type level can affect the in-country pathway. "Choosing the optimised submission strategy requires considering the impact of different inputs affecting the submission. That's where local in-country experts are often key in helping to navigate the most effective submission pathway," said King.
- **Global registration approval timelines.** A global product launch often requires that a stable product is launched in the finished goods country of manufacture before other countries' submission and registration processes begin. King noted that receipt of a 510k clearance or a CE mark often marks the start for global activities, due to the design freeze of a new product occurring around this time but added that it may be more advantageous for companies to design registration strategies that would work in the US, Canada, the EU, Brazil, China, Russia, and Japan as a group rather than in the US and the EU alone.

To optimize global product launches, companies must embrace design for registration.

To increase their odds of product launch success, 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.

> I think there should be a base layer as the sixth element, which is bidirectional. It takes in the experience and the learnings at each stage, builds on it, understands it, and feeds it back to newer launch cycles. This is a key output of where Regulatory Intelligence supports global launch processes.
>
> *Anusha Gangadhara, IQVIA*

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

IQVIA's connected intelligence approach unites design for registration elements under one roof.

To support MedTech companies with the design of more predictable and effective launch cycles that control timelines and limit costs, IQVIA's connected intelligence approach illustrates how three essential Regulatory Intelligence elements support a successful regulatory submission process. Those elements are:

- **Local health authority requirements:** product type-specific, by regulatory activity, and made available in a machine-readable format.
- **MedTech client's insights:** user edits incorporating "tribal knowledge," quality checked by data steward and ready for analytics and re-use.
- **MedTech client's precedence:** operational history and audit trail, ready for analytics and re-use.

The key objective of this connected intelligence approach is to capture product launch-relevant data in near real time and derive from its insights that can be fed back into companies' standard operating procedures and into their safety, regulatory, and quality 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 processes.
>
> *Michael King, IQVIA*

CONCLUSION

In a heterogeneous regulatory environment that is constantly generating new and updated regulatory mandates, MedTech 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 connected intelligence approach, which is to embed regulatory intelligence in the global registration process, helps companies deliver that goal into reality.

> If we can reduce the cost of bringing a product to market, we can potentially open more markets where it's affordable to bring the best products in the hands of clinicians to support patient outcomes. New technology that drives efficiencies in [regulatory submission] processes truly does have a direct impact on public health.
>
> *Michael King, IQVIA*

BIOGRAPHIES

Michael King

Senior Director, Product & Strategy, IQVIA

As senior director of product and strategy within the technology solutions business of IQVIA, Michael King is responsible for ensuring that the medical device solutions have the necessary functionality to support the increasingly complex and diverse global regulations. He is particularly focused on optimising business workflows through intelligence driven simplification and automation within and across the safety, regulatory, and quality functions.

Michael has over 15 years of knowledge and experience leading localised and global teams in regulatory affairs and quality assurance and has worked within the medical and surgical, orthopaedic, in vitro diagnostic, diagnostic imaging, dental, and urology sectors. Before joining IQVIA, he was the vice president of international regulatory affairs for a dental technology organisation and had oversight of the international product registration, adverse event reporting, and country-based quality management systems.

Michael holds a degree in physics from Oxford University and briefly worked for a consulting firm in the telecommunications industry prior to beginning his career in the medical industry.

Anusha Gangadhara

Business System Analyst, IQVIA

With close to a decade of technology experience in the healthcare platform and medical device industry, Anusha Gangadhara is part of the RIM Smart Product Management team at IQVIA. She drives the mapping of business needs to technical requirements and leads business critical engagements in defining RIM Smart Solutions for MedTech. Prior to IQVIA, she worked as a regulatory and quality engineer at Philips Healthcare and before that spearheaded global product launches at two start-ups: Consure Medical and Sohum Innovation Lab. Anusha holds a master's in electrical engineering from National University of Singapore with rigorous hands-on experience in the medical device and technology development process from the Stanford-Singapore Biodesign program.