Fact Sheet

IQVIA RIM Smart for MedTech

In the rapidly evolving landscape of the MedTech industry, life sciences companies find themselves at a crossroads of navigating the complex web of global regulatory changes and challenges. The transformative technologies of artificial intelligence (AI) and automation have ushered in an era of exponential regulatory complexity. As technology surges forward at a breakneck pace, regulatory frameworks must play a continuous game of catch-up. The need to adapt and respond swiftly is evident in the ever-increasing adjustments to regulations, guidelines and technical standards tailored to specific country requirements.

To bring groundbreaking medical devices to the international market, companies must provide rigorous evidence of patient safety and product efficacy, which, in turn, necessitates more intricate legislation and guidance for the development and commercialization of new healthcare solutions.

The industry is now focusing on strategies that enable early consideration of global registration requirements and harnessing intelligent regulatory technologies for robust traceability, while simultaneously reducing the resource, financial, and time burdens on a global scale.

In the midst of this evolving MedTech ecosystem, companies are also contending with the realities of slimmer budgets and tighter timelines. The confluence of rising regulatory complexity and the expanding global market underscores the need for efficient and cost-effective systems. Consequently, optimizing expenditure has ascended to a prime objective for MedTech companies, with the automation of workflows emerging as a promising solution.

The RIM Smart advantage

RIM SMART ENABLES YOU TO:

- Safeguard data accuracy and compliance with a single integrated system for product registration activities.
- Access and disseminate critical global regulatory data in a transparent way across the organization.
- Automate change control impact assessments on global registrations.
- Reduce resource efforts, save time, and cut maintenance activity spend.

RIM SMART OFFERS:

- A complete, end-to-end regulatory solution that supports organizations of all sizes.
- Intuitive submission management, publishing, and product lifecycle management.
- A single source of truth for all regulatory data and activities.
- Integration with quality management systems including IQVIA SmartSolve® eQMS.
- Integration to IQVIA Regulatory Intelligence to provide insights across the product lifecycle.

A global registration management

RIM Smart offers significant benefits in the efficiency and effectiveness of professional activities and brings transparency to global product registration activities. It consolidates global registration activities and registration data management into a single application.

A single solution, optimized for MedTech

RIM Smart is a single, customer-focused product built to deliver a complete regulatory solution for all product submission, publishing, and variation activities across global healthcare organizations. RIM Smart offers an integrated, automated, and intelligent way of managing the complete regulatory lifecycle of pharmaceutical, medical device, and combination products for companies that manufacture one or many of these product types.

Key capabilities

- **Enables easy tracking and reporting** capabilities through structured and linked data sets in a single eco-system.
- **Supports reuse of prior content, data handling, and automation** in global events triggers for regulatory changes across multiple countries.
- **Reduces redundancy and expensive management** of data across multiple systems.

RIM Smart capabilities for MedTech

EFFECTIVE CONTENT AND CERTIFICATE MANAGEMENT

RIM Smart smooths change control and resubmission processes by recording submission content, and can also make MDSAP and ISO 13485 audits and inspections easier to manage with approval certificate storage and translation using a built-in tool.

STREAMLINING QUERY PROCESSING

To ensure ease of activity monitoring and management, enquiries from healthcare agencies, notified bodies, dealers and other third parties can be linked into registration submissions.

INTEGRATED DOCUMENT HANDLING

Global submission builds can be handled quickly and simply with source documents that can be dragged and dropped from repositories into country-specific templates, with the option to integrate directly into IQVIA's SmartSolve eQMS.

GLOBAL REGISTRATION VISIBILITY AND TRACKING

RIM Smart provides item country-level registration visibility across the globe, with registration status activity tracking at a country-submission level.

INTELLIGENT WORKFLOW

Easily manage tasks and commitments associated with global registration activity within RIM Smart, by simply using a list or calendar format.

COMPLETE EXPIRATIONS OVERSIGHT

RIM Smart helps maintain business continuity with a complete view of global registration and third-party license expirations.

Benefits of a connected ecosystem

A key benefit of working with IQVIA is that connected ecosystem solutions that span across a company's Regulatory and Quality management technologies can be deployed and scaled over time as that company evolves. The connected systems are designed to offer a closed loop by ensuring the changes to product, documents, and data reflects across the ecosystem. The harmonization between data, documents, and integrated process across the connected systems importantly offer a seamless user experience across the systems, reducing redundant data replication between systems.

RIM Smart as a primary key to a connected ecosystem

Customers can leverage the IQVIA Regulatory Intelligence database seamlessly integrated with IQVIA RIM Smart, enabling regulatory intelligence-driven automation within their product registration workflows. Regulatory intelligence can be harnessed at various stages of the registration process to facilitate content verification, assess change event duration and impact, and provide guidance on country-specific submission requirements. This integrated platform allows users to efficiently map regulatory tasks and dependencies across countries, simplifying impact assessments and ensuring timely execution.

Through eQMS Integration with RIM Smart, a comprehensive end-to-end solution is offered for global regulatory impact assessment and change management, enabling the mapping of affected products, assessment of regulatory impact, and creation of regulatory activities across different registration stages. This system seamlessly supports the transfer of document content from eQMS to market-specific, country-specific templates within RIM Smart for streamlined regulatory submission activities.

Our Vision

IQVIA's vision is to empower your organization to focus its resources on what's important: bringing valuable products to market and keeping them there.

Our vision is built on three core foundations:

CONNECTED INTELLIGENCE	Immersing users within an environment to provide complete awareness with actionable insights that are never more than one click away.
ROBOTIC AUTOMATION	With its intuitive automation, simplification, and integration, RIM Smart streamlines processes, improves data accuracy, and delivers exponential increases in productivity.
REGULATORY INSIGHT	Uncovering strategic, regulatory, and compliance updates in real time, actively monitoring and alerting users to changes or emerging trends.

Our vision is built on three core foundations: IQVIA's vision goes beyond just optimizing diverse quality, regulatory, and safety systems: it pioneers the transformation of compliance from a burden to a competitive advantage.

IQVIA TECHNOLOGIES

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