Fact Sheet

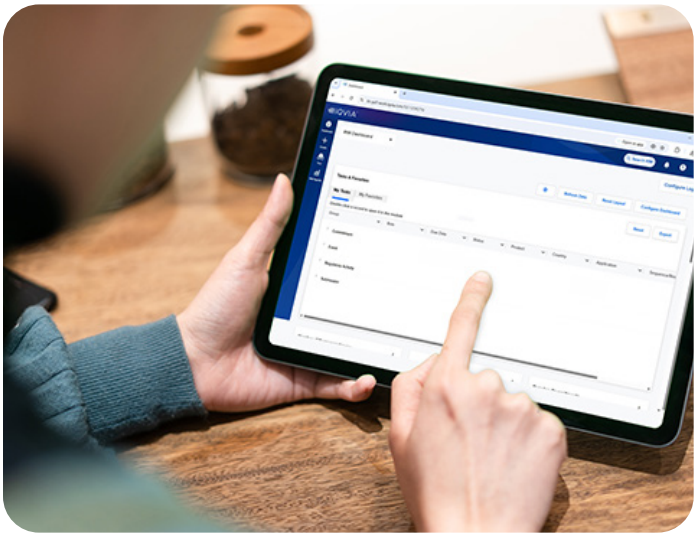
IQVIA SmartSolve® RIM

Drive global market access with AI-enabled regulatory management

Bringing healthcare products to market, such as medical devices, diagnostics, and pharmaceuticals, requires navigating complex global regulations. Rapid advances in AI and technology often outpace regulatory frameworks, leaving life sciences organizations with fragmented data, manual processes, and limited visibility. Disconnected systems make it difficult to reuse approved materials, turning potential efficiencies into bottlenecks that slow progress.

The IQVIA SmartSolve RIM advantage

SmartSolve RIM manages the complete regulatory lifecycle for lifescience companies. One platform handles everything from initial submissions through to approvals, variations, renewals, and withdrawals. SmartSolve RIM is built on the same platform as SmartSolve® eQMS, ensuring full traceability between quality and regulatory operations. A direct connection to IQVIA Regulatory Intelligence provides global regulatory insights and early warnings on the impact of regulatory and product changes across the product lifecycle.



SmartSolve RIM delivers:

- **Complete lifecycle management across medical devices, IVDs, and pharma**
- **Accelerated and predictable market access**
- **Single source of truth for global data and documents**
- **AI-enabled workflows, translation capabilities and business analytics**
- **Compliance by design, by process and by culture**

SmartSolve RIM key capabilities

LIFECYCLE MANAGEMENT AND CERTIFICATE STORAGE

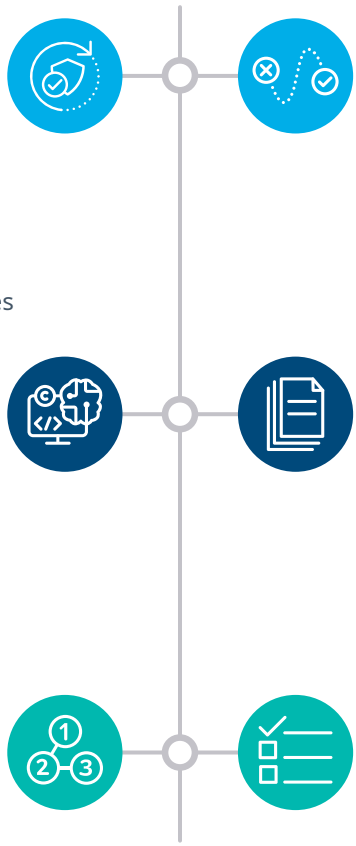
- Manage full regulatory lifecycle for medical devices, in-vitro diagnostics and pharmaceuticals in a single system
- 21 CFR and ISO 13485 certified platform
- xEVMPD/ IDMP compliant (Pharma) and UDI DI compliant (MedTech)
- Central storage of global approval certificates

AI, ANALYTICS & INTELLIGENCE

- Automate workflows and translate/ analyze content with Microsoft powered AI, translation capabilities and analytics
- Optimize performance with the resuse of existing content, mining of health authority responses, and data driven builds

STREAMLINED QUERY PROCESSING

- Route health authority questions to the correct record; track correspondence and commitments
- Generate complete audit trails instantly



GLOBAL REGISTRATION VISIBILITY AND TRACKING

- Real time status for global healthcare approvals including:
  - » US 510(k)/US PMA/EU CE (MedTech)
  - » INDs/NDAs/MAAs (Pharma)
- Portfolio view across all markets; planning tools flag risks early to drive remediations to accelerate market access

REGULATORY CONTENT MANAGEMENT

- Drag and drop content into country templates; review/approve without switching platforms
- Publish global eCTD and NeeS formats
- Assembled MedTech dossiers and global technical documentation

COMPLETE EXPIRATIONS OVERSIGHT

- Track CE marks, authorizations, and third party licenses
- Early alerts and 3rd party ERP/ MDM integration supports global importation compliance

Integrated Ecosystem — SmartSolve unifies regulatory and quality operations within a single, data-driven solution. With SmartSolve RIM and SmartSolve eQMS in a single instance, end-to-end connectivity across processes such as design control, CAPAs, Supplier Control and post-market surveillance ensures line of sight to the impact on global product registrations and supports conscious decision making of change management activities. IQVIA Regulatory Intelligence delivers early warnings and actionable guidance as requirements evolve across global markets to support companies maintain global market access.

About SmartSolve®: SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. **SmartSolve® eQMS** centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while **SmartSolve® RIM** manages regulatory submissions, product registrations, and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality, and commercial performance.

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