Fact Sheet

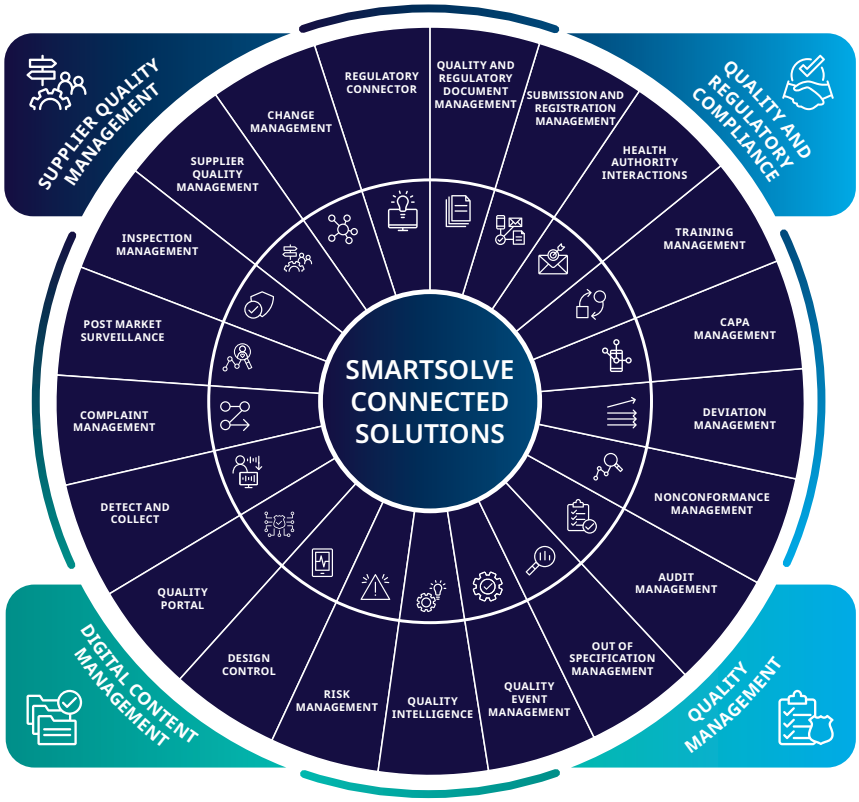
# SmartSolve® eQMS for MedTech

As global regulations become increasingly complex and diverse, and as innovative healthcare solutions integrate multiple product types, MedTech companies face greater challenges in market access and commercial growth. In this environment, Quality Assurance and Regulatory Affairs (QARA) professionals must operate with precision to drive both compliance and business success.

## Situation:

Many MedTech organizations continue to rely on legacy tools and spreadsheets, or outdated point solutions, which create data silos and hinder efficient compliance workflows. Quality Assurance and Regulatory Affairs (QARA) leaders must adapt to evolving global regulations and standards while navigating the complexities of premarket, manufacturing, distribution quality, supplier control, post-market, and change management activities. Operating with constrained resources in a network of disconnected QMS and RIM solutions increases organizational risk, especially as regulatory demands grow. The need for cost-effective compliance is greater than ever, as companies strive to enhance patient safety, product quality, and commercial performance.

## Our solution:

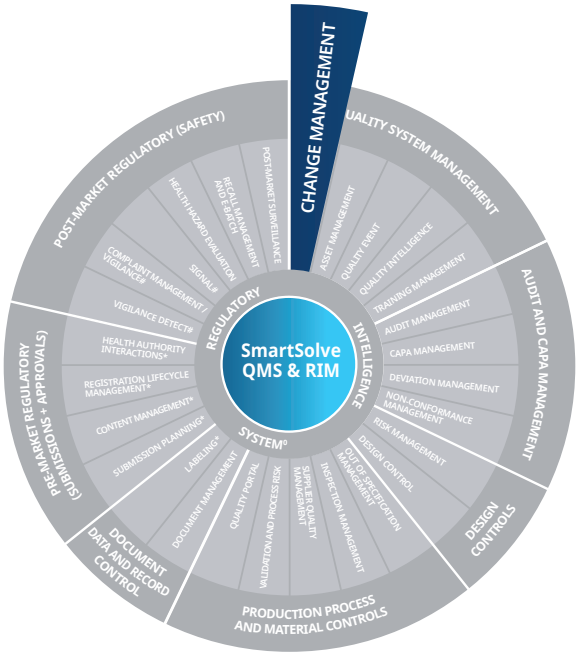



IQVIA's SmartSolve® for MedTech provides a unified, AI-enabled platform that automates and connects quality, regulatory, and post-market processes. With more than 20 dedicated life sciences modules, SmartSolve streamlines compliance, accelerates approvals, and improves patient safety, all on a scalable, validation-ready platform. By eliminating manual tracking and connecting QARA processes in a single platform, SmartSolve empowers MedTech organizations to reduce risk, boost efficiency, and stay ahead of global regulatory change.

# Use cases

## 1. Global change control

A global, end-to-end change management process that supports the gathering of impact assessments to ensure decisions are made with clarity and transparency.

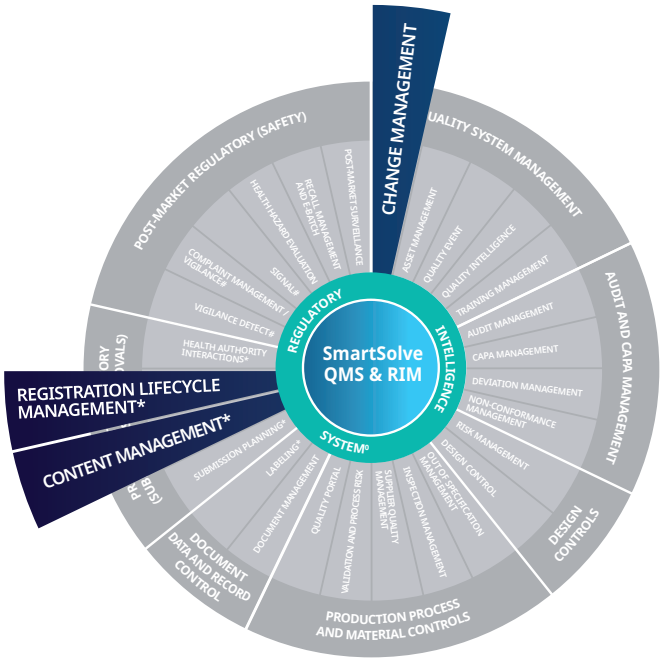



### Essential solution

A single solution to allow the global tracking of change notifications and help drive plans to completion


### Advanced solution

In-system intelligence that supports the identification of the global impact of your change activities.




### Optimal solution

A single source of truth for global registration activities, including impact assessment and workflow changes on regulatory submissions, as well as global tracking of change notifications and in-system intelligence.

## 2. Growing as a small company/start-up

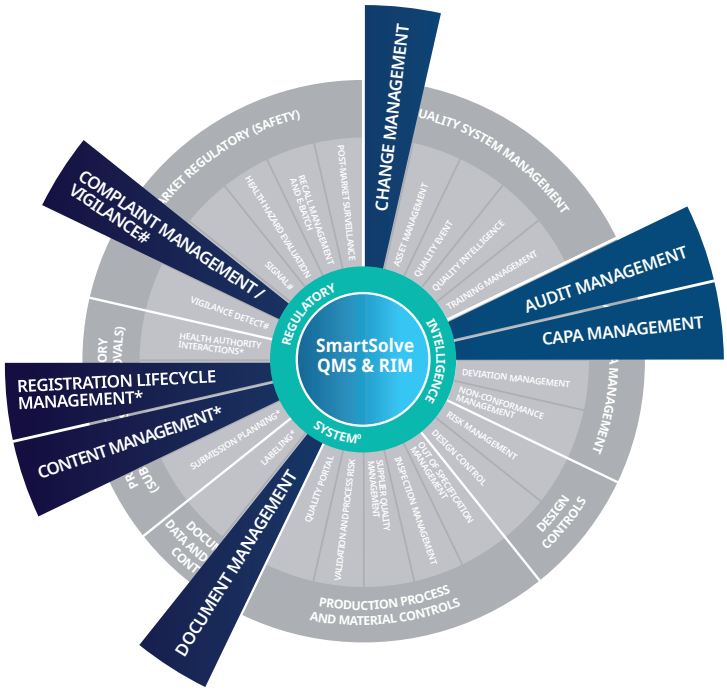
Gain significant operational and compliance efficiencies by implementing end-to-end eQMS modules. Connect workflows and optimize quality, regulatory, and safety processes, and leave paper-based systems and legacy in-house solutions behind.


### Essential solution

A baseline framework for core eQMS modules required when a company transitions to electronic solutions.


### Advanced solution

Provides support for global regulation identification as a company scales its product range or geographic footprint. Deploy a global complaint solution to ensure case capture and Adverse Event Reports (AERs) and meet global and local country requirements.




### Optimal solution

A single source of truth for global registration activities, including team management and inclusive of Health Authority Interactions (HAIs), and the ability to have multi-tenant reviews of core source documentation and the compilation of global registration dossiers.

These use cases represent just a glimpse of the comprehensive solutions IQVIA's end-to-end eQMS offers to enhance the efficiency and effectiveness of quality, regulatory, and safety operations. Additional capabilities include global complaint handling, streamlined product registrations, rapid point fixes, and support for corporate conglomerates aiming to harmonize existing processes and integrate digital QMS and RIM infrastructure.

## 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.

IQVIA TECHNOLOGIES

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