Fact Sheet

SmartSolve® eQMS

IQVIA SmartSolve eQMS is an intelligently connected, enterprise Quality Management System (eQMS) designed to simplify and automate quality, regulatory, and safety processes for MedTech and Pharma companies — all in one platform. It replaces fragmented tools with a single, integrated solution that accelerates compliance and quality processes across the entire product lifecycle — from design and manufacturing to distribution and post-market.

Key features and capabilities

SmartSolve is a unified platform for life sciences organizations to streamline quality and regulatory compliance. Built for scalability and security, SmartSolve centralizes your processes, connects teams and data, and empowers innovation so you can achieve global compliance, drive continuous improvement, and accelerate commercialization with confidence.

- Document and training management.
- Change management and CAPA.
- Non-conformance, deviation, and audit management.
- Risk management and design control.
- Complaint handling and post-market surveillance.
- Supplier quality and inspection management.
- Regulatory impact assessment and automated validation.
- Quality intelligence and quality portal.

SmartSolve eQMS replaces fragmented tools with a single, integrated solution.

Benefits and value proposition

- **Stay ahead of change:** Detect regulatory updates and plan global impact with confidence.
- **Boost efficiency:** Reduce manual work, speed up compliance, and improve resource utilization.
- **Improve collaboration:** Increase transparency across teams and functions.
- **Manage risk proactively:** Turn compliance into a competitive advantage.
- **Drive continuous improvement:** Optimize quality processes across the entire product lifecycle.

Differentiators

- **Purpose-built for life sciences:** The most complete eQMS with a full suite of integrated solutions.
- **Modular and scalable:** Start where you need — expand as you grow by leveraging a single platform for MedTech and Pharma.
- **AI-enabled automation:** Use AI to draft summaries, leverage precedent information, and improve consistency.
- **Analytics and oversight:** Access reporting, trend analysis, and charts to drive improvement.

Compliance and certifications

Supports ISO 13485 and FDA 21 CFR Part 820 requirements:

- Validation-ready, hosted on Microsoft Azure for security and scalability.
- Integrates AI-enabled insights to streamline regulatory processes and improve product safety.
- ISO 9001 and ISO 27001 certified solution.

Business impact

- Accelerates time to market and commercial performance.
- Reduces business risk and improves resource utilization.
- Drives patient safety, product quality, process efficiency, and commercial performance with scalable, modular architecture.

"IQVIA considers that a commercial focus on quality management systems must align with delivering better and safer patient care."

— Sankara Narayanan, Industry Director, Frost & Sullivan

To learn more, request a demo, or contact sales/support, visit: iqvia.com/smartsolve.

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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