Fact Sheet

SmartSolve® Fundamentals for Pharma and MedTech

Simplify quality and compliance management for small businesses in Emerging Biopharma (EBP) and MedTech SMEs.

For small companies in Pharma and MedTech, maintaining quality and compliance is essential to building customer trust and staying competitive. However, limited resources and reliance on manual, paper-based processes make it challenging to stay ahead of documentation, approvals, training, and evolving regulatory requirements — often resulting in inefficiencies, oversight gaps, and heightened risk across operations and global compliance.

Situation

Small businesses often struggle to manage quality and compliance efficiently. Manual processes slow down operations, increase the risk of errors, and make it harder to meet industry standards and customer expectations.

Our solution

SmartSolve® Fundamentals is a simple, powerful digital QMS built on our award-winning SmartSolve platform. Designed specifically for small to medium-sized organizations, it streamlines quality compliance with workflow-driven modules for CAPA, Deviation (Pharma)/ Event (MedTech), Document, and Change management. Features such as electronic signatures, audit trails, and integrated training help you manage risk, reduce variability, and maintain compliance — so you can focus on delivering safe, high-quality products.

Key features

- Digital QMS engineered for small businesses in Pharma and MedTech
- Electronic signatures, reports, and audit trails
- Workflow-driven solutions based on industry best practices
- Easy to learn, use, and set up
- Closed-loop process integration
- Scalable to support business growth
- Affordable for emerging businesses
- Integrated training and seamless user setup

Module solutions

- **CAPA Management**: Record, monitor, and review corrective and preventive actions.
- **Deviation Management (Pharma)/Event Management (MedTech)**: Log deviations/quality events, investigate root causes, and remediate issues.
- **Document Management**: Secure storage, revision control, and approval workflows.
- **Change Management**: Ensure consistent, compliant change control and clear, transparent procedures.

Why choose SmartSolve Fundamentals?

- Built on ISO 9001 standards and certified to ISO 9001 and ISO 27001.
- Supports regulatory requirements for electronic signatures.
- Secure, scalable, and extensible for business-specific needs.
- Easy setup and personalization.
- Trusted by over one million users.
- Enables a seamless transition to enterprise-level automation as your business grows.

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

CONTACT US
eQMS@iqvia.com
iqvia.com/fundamentals