FACT SHEET

IQVIA™ SmartSolve® Fundamentals for Pharma

Simplify the management of quality compliance for small businesses.

IQVIA™ SmartSolve® Fundamentals is an out-of-the-box, simple, yet powerful digital QMS that enables small to medium-sized organizations to be compliant against regulations in the pharmaceutical industry. Purpose-built for life sciences, it helps to simplify the management of quality compliance for small businesses.

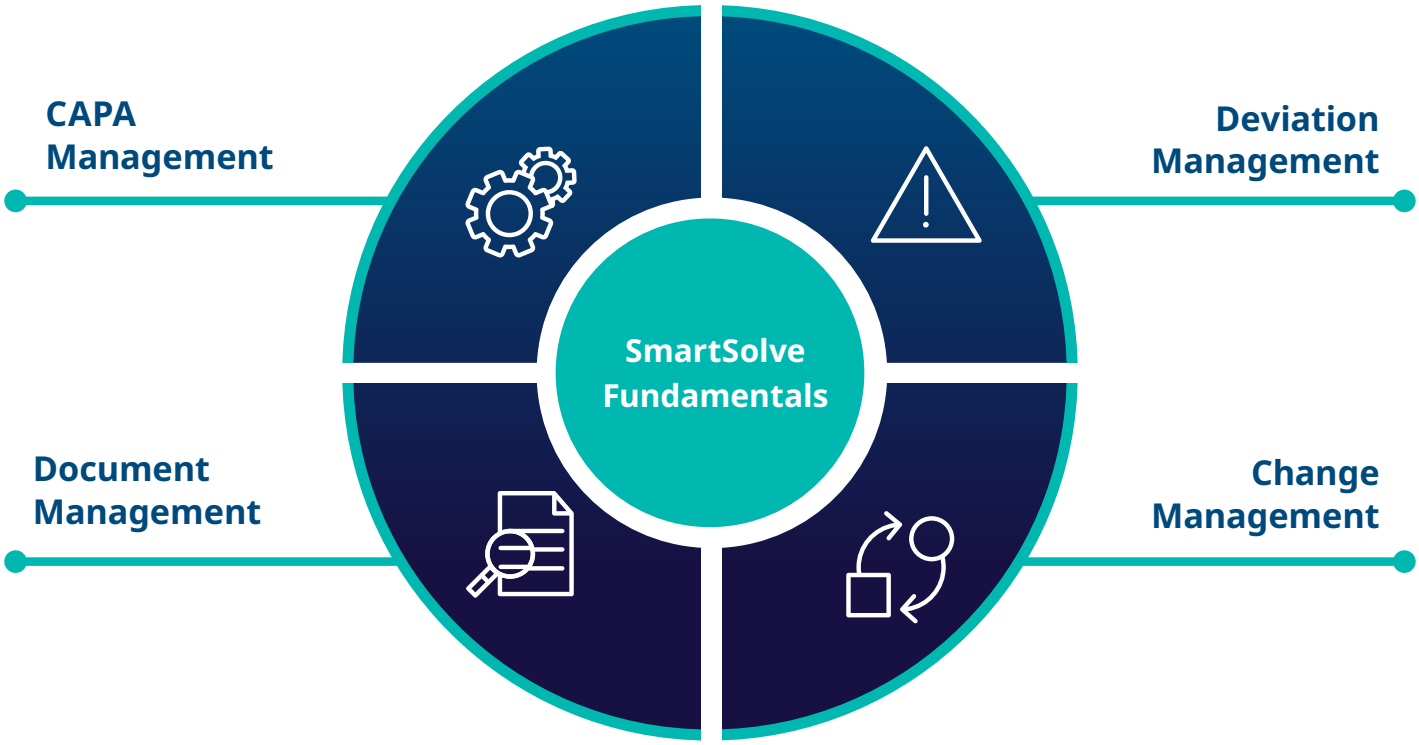
The powerful workflow-driven, pre-built solutions are based on industry best practices and proven business solutions, designed to help manage risk, eliminate variance and facilitate compliance.

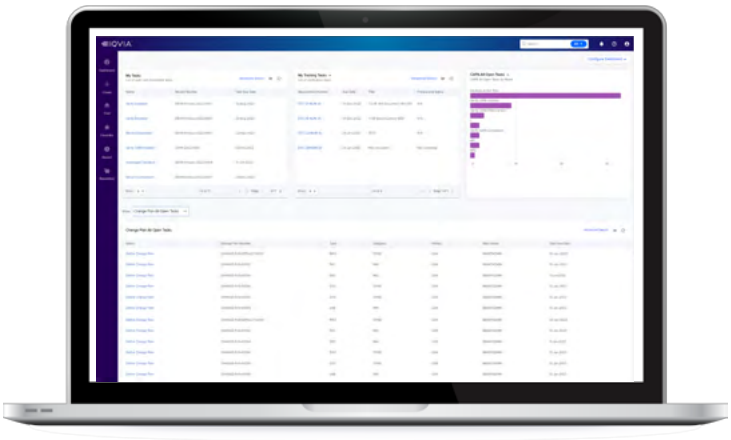
Built on top of the SmartSolve platform, it is one of the most powerful platforms designed specifically for quality and regulatory compliance. As a starting point, SmartSolve Fundamentals will provide organizations with core quality processes to manage controlled documents, changes, deviations and CAPAs.

Users can document CAPAs, Deviations, Change Plans, and manage documents, as well as provide read and sign-off training capabilities.

- **Simple and powerful digital QMS engineered for small businesses in pharma** that includes: CAPA Management, Deviation Management, Document Management and Change Management, including electronic signatures, reports, and audit trails
- **Workflow-driven solutions** based on industry best practices to manage risk, eliminate variance, and facilitate compliance
- **Designed with best practices**
- **Easy to learn, easy to use, and easy setup process**
- **Closed-loop process integration**
- **Scalable** to easily transition to SmartSolve Enterprise as your business grows
- **Affordable** for emerging businesses

SMARTSOLVE FUNDAMENTALS





Our easy setup process allows organizations to personalize master data like Product Information, Failure Modes, Root Causes, and more. User setup is seamless, which uses out-of-the-box roles assigned to each user.

SmartSolve improves your quality processes and gives organizations control of their quality processes. All SmartSolve quality management software (QMS) solutions are:

- Based upon ISO 9001 standards for quality management systems
- Closed-loop with deep, rich functionality and integration across quality processes
- Built to support regulatory requirements for electronic signatures
- Secure and scalable
- Extensible to automate business-specific quality management processes

SMARTSOLVE FUNDAMENTALS INCLUDES THE FOLLOWING MODULE SOLUTIONS

CAPA MANAGEMENT

CAPA Management allows organizations to record a problem, establish and monitor corrective and preventive actions and review the effectiveness of each CAPA. By facilitating an effective CAPA process, CAPA Management helps shorten cycle times, resolve issues quickly and prevent recurrence – ensuring your organization's future well-being and compliance with industry, quality, and regulatory requirements. CAPAs are integrated into the Deviation Management module or may be created as standalone CAPAs.

The CAPA Management module follows a workflow with the following steps:

Initiate CAPA → **Verify CAPA initiation** *(when created from a deviation)* → **Develop action plan** → **Implement action plan** → **Verify CAPA completion** → **Verify CAPA effectiveness**

DEVIATION MANAGEMENT

A deviation is a departure from a documented standard, procedure, approved instruction, or specification that can occur during manufacturing, sampling and testing, and finished product acceptance. Deviation management provides the ability to log deviations and determine root cause through investigations. Action Plan Items may be created to remediate the problem or deviations may be escalated to CAPA for a more in-depth process.

The Deviation Management application fulfills the most current Pharmaceutical Quality System requirements by:

- Properly documenting and explaining product and process deviations
- Reporting deviations in real time
- Performing investigations within 30 days
- Providing the ability to propose, initiate, and complete corrective actions
- Releasing or rejecting implicated batches
- Performing preventive actions, if appropriate

The Deviation Management module follows a workflow with the following steps:

Initiate deviation → **Record containment** → **Investigate deviation** → **Approve deviation investigation** → **Record disposition** → **Implement action plan** → **Verify deviation closure**

DOCUMENT MANAGEMENT

Document Management provides the ability to securely store documents, manage revision control and route documents for review and approval. Integrated training launches training tasks for affected employees so they may perform read and sign-off training. Document Management allows organizations to organize document lifecycles, accelerate reviews, and enforce document training.

The Document Management module follows a workflow with the following steps:

Create document → **Prepare document profile** → **Define training requirements** → **Approve document** → **Finalize document** → **Finalize periodic review**

CHANGE MANAGEMENT

Change Management ensures consistent and compliant change control within an organization and its operations. Change Management provides the ability to define and assess change plans, implement individual action plan items, as well as review effectiveness for those changes that may be the result of a CAPA. Change Management gives organizations the tools to:

- Manage a wide variety of changes
- Harmonize change control procedures
- Maintain well-documented, transparent changes

The Change Management module follows a workflow with the following steps:

Initiate change plan › **Define change plan** › **Assess change plan** › **Approve change plan** › **Implement action plan** › **Close change plan** › **Review change plan effectiveness**

SIMPLE AND POWERFUL DIGITAL QMS ENGINEERED FOR LIFE SCIENCES

- CAPA Management
- Deviation Management
- Document Management (+ read and sign-off training capabilities)
- Change Management

WORKFLOW-DRIVEN SOLUTIONS BASED ON INDUSTRY BEST PRACTICES

- Manage risk
- Eliminate variance
- Facilitate compliance

Find the solution with IQVIA SmartSolve Fundamentals for Pharma

SmartSolve is a powerful suite of quality management software solutions, specifically engineered for life sciences. Delivered on a compliance-ready platform, SmartSolve Fundamentals:

- Is easy to learn, easy to use, and easy to set up
- Provides closed-loop process integration
- Includes electronic signatures, reports, and audit trails

SmartSolve Fundamentals is scalable and can easily transition to SmartSolve Enterprise as your business grows. SmartSolve Enterprise can enable the automation of a single process or optimization of the entire quality management system.

With over one million users, SmartSolve Enterprise helps streamline quality processes, ensure the highest quality standards, and deliver real business impact.

IQVIA TECHNOLOGIES

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