Fact Sheet

SmartSolve® Change Management

Visibility, control, and compliance. every change, every time

Automated change management is essential for regulated industries. It enables organizations to systematically control and document changes, and drive end-to-end change plans ensuring compliance with FDA and ISO requirements. This approach minimizes compliance risks, maintains product quality, and supports efficient, safe operations.

Situation

Organizations in regulated industries such as those governed by global regulators such as the US FDA and EMEA and with the need to follow ISO standards applicable to healthcare products must maintain strict control over changes to facilities, processes, documents, materials, designs, computer systems, laboratory operations, validation procedures, packaging, and labeling. Managing these changes is complex, especially when different types require unique policies and workflows.

Common challenges include:

- Documenting and tracking a wide variety of changes
- Capturing all aspects and impacts of each change
- Maintaining compliance with regulatory requirements
- Coordinating cross-departmental collaboration
- Keeping team members informed and accountable
- Securing change records and electronic signatures

Our Solution

SmartSolve Change Management centralizes and automates change processes, helping regulated organizations maintain compliance, improve efficiency, and ensure secure, audit-ready records. With real-time visibility, robust security, and seamless integration across teams, SmartSolve minimizes compliance risks and supports operational excellence.

Capture every aspect of every change

User-friendly change requests make it easy to quickly capture all elements of a change, allowing documentation of details such as category, type, description, rationale, and due date for each change. Areas of the business affected — including sites, documents, products, processes, equipment, and suppliers — can also be recorded. Once change requests are approved, the system generates change plans so you can administer the necessary actions to carry out each change.

Manage change effectively

Managing various types of changes often requires distinct processes and policies. The flexibility to associate each change type with its own policy helps maintain consistent, repeatable workflows. Changes are automatically guided through all required steps, which may include administering the change, conducting impact assessments, recording multiple levels of approval, and overseeing implementation activities. This approach ensures that every change is reviewed and approved by an expert, and that all necessary steps are completed to uphold a compliant change control process.

Implement temporary changes and planned deviations

Change Management provides the ability to implement temporary changes and/or planned deviations to processes, products, procedures, work instructions, etc., to accommodate necessary departures from the norm. You can categorize the criticality of temporary changes and document their respective process action plans, verification, and start and end dates.

Integrate change throughout your quality system

Integration capabilities ensure control over changes throughout the quality system, providing high visibility into documents impacted by updates. When document revisions are required, tasks are streamlined and activities related to SOPs and document updates are efficiently coordinated. Team members receive timely alerts when changes affect document-related training requirements. Additionally, integration across the SmartSolve platform enables consistent and compliant workflows for addressing audit findings, defects, customer complaints, and other issues.

Make change visible

Configurable reports provide valuable insights to address current challenges and prevent future issues. Automated distribution of reports ensures that change results, aging, and trends are shared across the organization. Additionally, email alerts and dashboards keep teams informed about critical or overdue tasks, equipping you with the information needed to maintain control over the change management process and make compliance-driven decisions.

Complete oversight of quality and regulatory impacted changes

IQVIA SmartSolve® RIM resides in the same, single platform as SmartSolve® QMS to provide a suite of over 20 connected modules dedicated to healthcare Quality Assurance and Regulatory Affairs professionals. For RIM activities, the platform level connectivity allows end to end change plans conducted by quality teams to directly link into RIM event management and lifecycle management activities of global regulatory teams to drive collaboration and ensure transparent line of sight to the impact that change plans have on global product registrations. This drives compliance, supports sustained market access and reduces the burden on teams that would navigate such changes with analogue systems needing manual connectivity.

Secure change records and data

Automating your change management process becomes seamless and secure with features such as role-based security, robust password authentication, and a complete audit trail. These capabilities support IT and industry compliance with requirements for electronic signatures and electronic records, including FDA 21 CFR Part 11 and EU Annex 11.

FEAUTURES	BENEFITS
Best-practice workflows and forms	Create a consistent process for each type of change.
Policy management	Automate required change steps and automatically assign the right team members to complete them.
Impact assessment	Allow experts to document change impacts using a configurable checklist.
Affected items	Document affected site, product, process, equipment, supplier, or document for each change.
Change approval	Record sign-offs by quality assurance and other approvers.
Change plans	Document and approve required actions and implement them in the correct sequence. This can include formal rollback plans when needed.
Reports, dashboards, and email alerts	Stay up to date on critical or overdue change tasks.
SmartSolve integration	Keep control of changes throughout your quality system, including tight, seamless integration with SmartSolve® Document Management.
Consumer-grade UI/UX	Increase user adoption, simplify tasks, and reduce errors and training needs through an intuitive user interface and user experience.
Change request	Change initiation with approval and deferment options.

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/smartsolve