

SmartSolve® Change Management

Meet the challenge of managing change

Whether driven by FDA, EMEA, or ISO regulations, change control is critical to your operations. That's why IQVIA SmartSolve® eQMS Change Management helps you create a standard process to record, review, approve, and implement change.



CHANGE MANAGEMENT PROVIDES USER-FRIENDLY TOOLS

- Record a wide variety of changes
- Capture every aspect of every change
- Manage change effectively
- Implement temporary changes and planned deviations
- Integrate change throughout your quality system
- Make change visible
- Secure change records and data
- Provide complete oversight of quality and regulatory impacted changes



CHANGE MANAGEMENT ALLOWS YOU TO RECORD ALL TYPES OF CHANGES IN A SINGLE SYSTEM

You can easily document changes for:

- | | |
|--------------------------|----------------------------------|
| • Facilities | • Laboratory operations |
| • Processes | • Validation and test procedures |
| • Documents | • Packaging and labeling |
| • Materials | • Business-specific changes |
| • Design or formulations | |
| • Computer systems | |

Capture every aspect of every change

Change Management's user-friendly change requests help you quickly capture all elements of a change. The system allows you to document details such as the category, type, description, rationale, and due date for each change.

You can also capture the areas of your business that will be affected, including sites, documents, products, processes, equipment, and suppliers. Approved change requests generate change plans so you can administer the actions needed to carry out each change.

MANAGE CHANGE EFFECTIVELY

You may have different processes in place to manage different types of change. That's why Change Management gives you the flexibility to associate each type of change with its own policy, helping you maintain consistent, repeatable workflows. Each change is automatically moved through its required steps, which can include administering the change, performing impact assessments, recording different levels of approvals, and managing implementation activities. This ensures that each change is reviewed and approved by an expert, and that you complete all the necessary steps to maintain 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. These temporary changes can be isolated from other change types to allow for quality reporting and regulatory inspection readiness.

INTEGRATE CHANGE THROUGHOUT YOUR QUALITY SYSTEM

Change Management's integration capabilities keep you in control of changes throughout your quality system and give you high visibility into documents affected by changes. When changes require documents to be



updated, Change Management streamlines tasks and coordinates activities related to SOP and document revisions. Change Management also ensures that affected team members are alerted when changes to document-related training requirements need their attention.

In addition, integration across the SmartSolve platform ensures that changes related to audit findings, defects, customer complaints, or other issues are addressed using a consistent and compliant workflow.

MAKE CHANGE VISIBLE

Change Management's configurable reports help you solve problems today and prevent problems in the future. The system automatically distributes reports to share change results, aging, and trends throughout your organization. Plus, email alerts and dashboards help keep your team up to date on critical or overdue tasks. This gives you the information you need to maintain control of your change management process and make compliance-driven decisions.

Complete oversight of quality and regulatory impacted changes

Ensure regulatory and quality oversight with integration to RIM Smart RIM Event. Integration with RIM Event supports business processes to bring quality and regulatory out of their departmental silos, which ensures collaboration, efficiency, and accuracy of information to support faster time to market and reduced maintenance to ensure products stay compliant once in market. Improve cross-departmental collaboration and processes for registration updates with systematic regulatory impact assessment guidance offered with Change Management and RIM Smart Event.

SECURE CHANGE RECORDS AND DATA

Change Management allows you to automate your change management process with the confidence that your data is secure. The system provides role-based security, powerful password authentication, and a complete audit trail. These features help you facilitate IT and industry compliance with requirements for electronic signature and electronic records, such as FDA 21 CFR Part 11 and EU Annex 11.

SmartSolve — the enterprise-quality compliance management platform

IQVIA SmartSolve eQMS is built on life sciences industry best practices. Delivered on a compliance-ready platform, SmartSolve provides closed-loop process integration unmatched in the market. Whether you are ready to automate a single process or optimize your entire quality management system, SmartSolve gives your enterprise a strategic advantage in quality leadership.

Features

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.