≡IQVIA
TECHNOLOGIES

IQVIA SmartSolve® Audit Management

Plan, manage, and conduct internal and external audits

IQVIA SmartSolve® eQMS Audit Management supports compliance and controls risk with end-to-end process management of internal and external audits.

AUDIT MANAGEMENT PROVIDES USER-FRIENDLY TOOLS

- Implement best-practice audit planning

- Improve audit efficiency and reduce cost

- Manage audit findings effectively

- Drive continuous improvement

- Enhance visibility of audit results

Effective and timely audits improve product quality and safety while ensuring compliance throughout your value chain.

IMPLEMENT BEST-PRACTICE AUDIT PLANNING

Audit Management enables you to organize and approve audit plans across your organization and supply chain. You can create audit programs to help manage audit schedules and resources – reducing time and labor costs throughout the audit process. You can also copy previous audit programs for easy reuse during your next planning cycle.

KEEP CRITERIA CONSISTENT AND IN CONTROL

WAudit Management enables your auditors to establish distinct evaluation criteria for the various types of audits they perform. Checklists can be created using Microsoft Excel and imported into the solution. This simplifies the process of adding, merging, revising, and approving audit checklists, and ensures that auditors reference up-to-date standards during each audit.

IMPROVE AUDIT EFFICIENCY

Audit Management's policy setup allows you to create, schedule, and perform audits more quickly than ever before. Email notifications, user-friendly dashboards, and Microsoft Outlook calendar integration provide quick access to schedules, open audits, and other pending tasks. When an audit is being planned, you can easily assign the right auditors to work on the entire audit, or assign a specific criteria section of an audit for completion.

ENHANCE AUDIT FLEXIBILITY WITH SMARTSOLVE® MOBILE AUDIT

Audit Management's mobile application simplifies remote audits where a network connection may be limited or unavailable. Your audit team can leverage SmartSolve Mobile Audit and its streamlined mobile interface to download records and capture audit findings wherever your audit takes place. Whether on a manufacturing floor, in a lab, or offsite in a remote supplier facility, you can perform and review audits in an offline mode with no internet connectivity. This gives you the flexibility to easily conduct audits in the field and sync records with the enterprise system when a connection becomes available.

CAPTURE AUDIT RESULTS AND FINDINGS

Audit Management's simple interface helps you quickly record checklist responses, specific findings, and an auditor's summary. The system gives you the flexibility to define an audit scoring system that is meaningful to your organization. Once you define your scoring system, audit results are assigned based on the numeric score from checklist responses or audit findings.

Audit scores are also integrated with SmartSolve's supplier performance rating capabilities to ensure that ongoing performance is a part of each supplier's scorecard.

MANAGE AUDIT FINDINGS EFFECTIVELY

Audit Management enables you to document and categorize audit findings, and to quickly issue findings to the appropriate people, departments, and organizations for prompt resolution. Low-risk findings initiate immediate action plans, while seamless integration with SmartSolve® CAPA Management allows you to investigate and resolve high-risk audit findings.

The system provides a simple workflow to ensure the timely completion of responses and action plans.

MANAGE FOLLOW-UP FOR CONTINUOUS IMPROVEMENT

Audit Management provides a structured environment to manage audit findings and action plans, allowing KPIs to be tracked and trended to drive continuous improvement. Follow-up audits enable you to measure action plan effectiveness and reduce the risk of recurring findings. You also have quick access to past audit results as you carry out CAPAs or plan for future audits.

ENHANCE VISIBILITY OF AUDIT RESULTS

Audit Management's reporting capabilities provide instant visibility into critical audit data to save time and minimize risk. Audit Management allows auditors to quickly generate a final audit summary report to be distributed to all parties involved with the audit.

SECURE AUDIT RECORDS AND DATA

SmartSolve allows you to automate your audit 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 signatures 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
Audit planning	Organize, approve, and reuse audit plans to build a more efficient planning process.
Import/export checklists	Add, merge, or revise checklists in Microsoft Excel and easily import them into the system.
Audit criteria maintenance	Create, approve, and control audit criteria to maintain regulatory compliance.
Audit lifecycle workflow	Create, schedule, and perform internal and external audits.
Microsoft Outlook integration	Improve schedule visibility with email notifications and calendar integration.
Offline audits	Simplify offsite audits by performing and reviewing audits within the streamlined mobile application without the need for an internet connection.
Mobile device traceability	Manage mobile devices within Audit Management to block unauthorized device usage and keep audit data secure.
Capture meetings	Record attendance, date, time, and decisions for audit kickoff, ad hoc, and closure meetings.
Attach evidence	Store evidence and audit results in a single record.
Audit response workflow	Address audit findings in a timely manner using a simple response form and workflow.
CAPA Management integration	Integrate audit findings into your quality system to quickly identify high-risk trends.
Follow-up audits	Ensure action plan effectiveness and reduce the risk of recurring findings.

IQVIA
TECHNOLOGIES