FACT SHEET

IQVIA SmartSolve® CAPA Management

Risk-based corrective and preventive action management

IQVIA SmartSolve® eQMS CAPA Management assists life sciences organizations in developing a risk-based, compliance-driven process for problem resolution. CAPA Management allows users to record a problem, verify and assess any associated risk, investigate to the appropriate level, implement corrective and preventive actions, and review each CAPA's effectiveness.

CAPA MANAGEMENT PROVIDES USER-FRIENDLY TOOLS

- Capture CAPA data and assess risk
- Reduce CAPA cycle time
- Ensure CAPA effectiveness
- Integrate with Document Management, Quality Event Management, Nonconformance and Deviation Management
- Integrate with core business systems
- Drive continuous improvement
- Secure CAPA records and data

CAPTURE CAPA DATA AND ASSESS RISK

CAPA information is captured in a simple, user-friendly form or automatically generated through integration with SmartSolve® Event Management, Nonconformance, or Deviation Management. The ability to capture CAPA information in standardized fields and categories facilitates accurate reporting and trend analysis. CAPA Management policies provide the flexibility to automatically adjust the CAPA workflow based on risk, failure mode, or any information captured for the CAPA.

CAPA Management enables risk assessment by capturing severity, occurrence, and detection, and using them to calculate each CAPA's Risk Priority Number (RPN). This enables a risk-based approach to CAPA management — problems with high RPNs can trigger a more rigorous CAPA process and notifications than those with lower RPNs.

REDUCE CAPA CYCLE TIME

With email notification, escalation capabilities, and configurable best-practice workflows, CAPA Management enables you to collaborate with responsible parties on tasks and investigations to resolve problems quickly. Milestone dates, with escalation triggers, ensure that CAPAs are closed out on time. You can also communicate rapidly and clearly with suppliers about CAPAs affecting them. A wide range of search options helps you swiftly locate CAPA records, event records, and related information.

ENSURE CAPA EFFECTIVENESS

CAPA Management's investigation process lets you map actions to their root causes to correct and eliminate problems at their source. You can validate your corrective or preventive actions and schedule effectiveness reviews to ensure that a corrective or preventive action has functioned as intended. Failure mode tracking enables you to establish thresholds that will identify when an adverse trend is developing, allowing you to determine if a CAPA has failed to eliminate a recurring problem, and enabling you to monitor and control emerging risks.

INTEGRATE DOCUMENT MANAGEMENT AND OTHER QUALITY PROCESSES

CAPA Management is fully integrated with SmartSolve® Document Management to ensure that the most current Standard Operating Procedures (SOPs) and other documents are available online. It also has been designed to integrate with other document management systems to achieve the same level of integration. Online access to current documentation increases efficiencies and reduces errors caused by inadequate version control. Electronic document references within the CAPA record also improve traceability and accuracy during customer and regulatory audits.

Nonconformance and Deviation Management's electronic disposition process ensures swift action on defective materials, while integrated CAPA investigation, planning, and effectiveness review capabilities ensure that problems have less risk of recurring due to ineffective corrective and preventive action. The result is a significant reduction in raw materials defects disposition costs.

INTEGRATE WITH CORE BUSINESS SYSTEMS

Compliance and quality data may be utilized in other business systems within your organization. SmartSolve provides Web Services to integrate key data such as products, work centers, suppliers, customers, sites, and departments. The ability to share data with CRM, ERP, LIMS, MES, and PLM applications reduces administrative time and improves data integrity between systems.

DRIVE CONTINUOUS IMPROVEMENT

With both standard and ad hoc reporting capabilities, including aging reports and Pareto analysis, CAPA Management provides real-time visibility so you can identify regulatory threats and areas for improvement, and make timely, informed decisions. The system's reporting and trend analysis tools provide the information needed to drive continuous improvement throughout your business.

SECURE CAPA RECORDS AND DATA

SmartSolve allows you to automate your CAPA 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
Standardized, user-friendly CAPA entry form	Reduce reporting and recording errors.
Risk assessment	Easily assess and calculate risk to improve products and processes.
Automatic email notifications and escalation	Reduce risk of future errors and noncompliance recurrence.
Investigation workflow	Reduce risk of future errors and noncompliance recurrence.
Failure mode monitoring	Reduce cost of poor quality by discovering problems earlier in product lifecycle and/or value chain.
Online document access	Increase efficiencies and reduce errors caused by improper version control.
Document reference to CAPA record	Improved accuracy during audits.
Quality Event Management	Perform rules-based triage and escalation of any quality event.
Nonconformance and Deviation Management	Streamline processes and increase efficiency.
CRM, ERP, LIMS, MES, and PLM integration	Increase efficiencies and reduce errors caused by inaccurate or unavailable data.
Drill-down Pareto analysis	Reduce cost of poor quality through increased visibility into high-frequency problems.
Trend analysis	Reduce risk and increase patient safety through early problem detection and insight into CAPA effectiveness.
Consumer-grade UI/UX	Increase user adoption, simplify tasks, and reduce errors and training needs through intuitive user interface and user experience.

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