FACT SHEET

SmartSolve® Deviation Management

Streamlined deviation management

IQVIA SmartSolve® eQMS Deviation Management streamlines deviation processes for pharmaceutical organizations. The solution provides a closed-loop workflow to capture, verify, disposition, and investigate product and process deviations to resolve them in a timely and compliant manner.

DEVIATION MANAGEMENT PROVIDES INTUITIVE TOOLS

- Reduce deviation cycle time
- Capture deviation data and conduct risk assessment
- Integrate with document, event, and CAPA management
- Management
- Integrate with core business systems
- Make informed quality decisions
- Secure deviation records and data

REDUCE DEVIATION CYCLE TIME

Deviation Management helps you identify the source of deviations throughout your value chain and product lifecycle, and facilitate quarantine, disposition, investigations, and action plans. With email notifications, dashboards, and configurable best-practice workflows, the system enables you to collaborate with task and investigation owners to quickly resolve issues and maintain compliance with regulatory standards. This includes communicating with suppliers about dispositions and investigations affecting them. A wide range of search options helps you quickly locate deviation records and related information.

CAPTURE DEVIATION DATA AND CONDUCT RISK ASSESSMENT

A best-practice deviation management process requires participation throughout your organization and even from suppliers and customers. Deviation Management enables personnel across your organization to initiate deviations using an intuitive, web-based form. The form allows users to indicate deviation classification, type, source, category, incident date, any initial actions or quarantine, description of the event, notation of impacted products and batches if appropriate, and the ability to add attachments.

Deviation Management enables risk assessment by capturing severity, occurrence, and detection numbers, using them to calculate each deviation's Risk Priority Number (RPN) or plotting their risk on a heat map Deviations with high risk can trigger a CAPA process, while less severe deviations are monitored for future action. Deviation Management captures both initial and final risk assessments to ensure that each defect's risk is appropriately understood after investigation.

INTEGRATE WITH DOCUMENT, EVENT, OOS AND CAPA MANAGEMENT

Deviation Management is fully integrated with SmartSolve Document Management to ensure that the most current Standard Operating Procedures (SOPs) and work instructions are available online. If your organization has another document management system installed, the solution is designed to allow for the attachment of non-SmartSolve documents to the deviation record as well. Electronic document references within the deviation record also improve efficiency and accuracy during audits and regulatory inspections.

Deviation Management's electronic disposition process ensures swift action on affected materials, while integrated CAPA investigation and effectiveness review capabilities reduce the risk of recurrence due to ineffective corrective and preventive action.

INTEGRATE WITH CORE BUSINESS SYSTEMS

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

MAKE INFORMED QUALITY DECISIONS

SmartSolve business intelligence ad hoc reports allow you to create business-specific reports and graphs based on failure modes, deviation categories, suppliers, risk, and more. Additionally, business intelligence allows for Pareto and trend analysis capabilities that will help you detect problems and identify trends, enabling you to make proactive risk-based, compliance-driven quality decisions.

SECURE DEVIATION RECORDS AND DATA

SmartSolve allows you to automate your deviation 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.

Features	Benefits
Intuitive Entry Form	Increase participation in the deviation management process.
Policy-based Set Up	Harmonize core processes while maintaining flexible workflows with unique requirements based on pre-set parameters.
Risk Analysis	Increase efficiencies and improve new products and processes.
Quarantine Workflow	Reduce risk of patient harm.
Electronic Disposition	Shorten deviation cycle times, reduce scrap and rework costs.
Investigation Workflow	Reduce risk of future errors and noncompliance with the ability to track deviations across multiple products and/or batches.
Criticality-based Workflow	Categorize actions to be performed based on the criticality of the deviation from minor to critical.
Integrated QMS	Streamline processes and increase efficiency through integration with event, document, OOS and CAPA management.
CRM, ERP, LIMS, and MES Integration	Increase efficiencies and reduce errors caused by inaccurate or unavailable data.
Quality Intelligence Trend Reporting	Perform Pareto and trend analysis to reduce risk and cost, while increasing visibility into high-frequency deviations.
Consumer-grade UI/UX	Increase user adoption, simplify tasks, and reduce errors and training needs through an intuitive user interface and user experience.

IQVIA TECHNOLOGIES

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