Fact Sheet

SmartSolve® Nonconformance Management

Streamlined handling of product and process nonconformances

As global regulations become more complex, Medical Device, In-Vitro Diagnostic, and Pharmaceutical companies face growing pressure to maintain compliance while efficiently managing product and process issues. Organizations need purpose-built digital solutions for Nonconformance Management that provide automated workflows, improve transparency, accelerate investigations, and reduce the risk and cost of scrap, rework, and customer returns, ultimately enabling faster product approvals and market access.

Situation

Many life sciences companies struggle with manual, fragmented nonconformance processes. This leads to slow cycle times, reporting errors, compliance risks, and increased costs due to delayed containment and investigation of defects.

Solution

SmartSolve Nonconformance Management enables organizations to capture and assess nonconformance data in standardized formats, automate workflows for containment and disposition, and integrate with document management and core business systems. This results in faster resolution, improved compliance, reduced costs, and greater visibility into quality trends.

NONCONFORMANCE MANAGEMENT PROVIDES USER-FRIENDLY TOOLS

- Capture nonconformance data and conduct risk assessments
- Reduce nonconformance cycle time
- Integrate with Document, Nonconformance, and CAPA Management
- Integrate with core business systems
- Make compliance-driven decisions

Capture nonconformance data and conduct risk assessments

A best-practice NC management process requires participation throughout your organization, as well as from suppliers and customers. Nonconformance Management enables personnel across your organization to initiate NCs using an intuitive, web-based form. The ability to capture NC information in standardized fields and categories facilitates accurate NC reporting and trend analysis.

Nonconformance Management enables risk assessment by capturing severity, occurrence, and detection, and uses them to calculate each NC's Risk Priority Number (RPN). This enables a risk-based approach to NC and CAPA management — NCs with high RPNs can trigger a CAPA process, while low-severity NCs are monitored for future action. Nonconformance Management captures both initial and final risk assessments to ensure that each NC's risk is appropriately understood after investigation.

Reduce nonconformance cycle time

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

Integrate with Document, Nonconformance, and CAPA Management

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

Nonconformance Management's automated disposition process ensures swift action on defective materials, while integrated CAPA investigation 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 and 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 bi-directionally integrate key data such as disposition, products, work centers, suppliers, customers, sites, and departments. The ability to share data with CRM, ERP, LIMS, MES, and PLM applications reduces administration time and improves data integrity between systems.

Manage compliance-driven solutions

Nonconformance Management provides Pareto and trend analysis capabilities. Ad hoc reports allow you to create business-specific reports and graphs based on failure modes, defect categories, suppliers, risk, and more. Problems can be detected and trends identified to enable you to make risk-based, compliance-driven decisions.

Secure Nonconformance records and data

SmartSolve allows you to automate your defect 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 Nonconformance entry form	Increase participation in the defect management process.
Standardized form fields and categories	Reduce reporting and recording errors to facilitate trend analysis.
Risk assessment	Increase efficiencies and improve new products and processes.
Containment workflow	Reduce risk of patient harm.
Automated disposition	Shorten Nonconformance cycle time, and scrap and rework costs.
Investigation workflow	Reduce risk of future errors and noncompliance.
Online document access	Increase efficiencies and reduce errors caused by improper version control.
Document reference to NC record	Improve accuracy during audits.
Corrective and preventive actions	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 defects.
Trend analysis	Reduce risk and increase patient safety through early problem detection.
Consumer-grade UI/UX	Increase user adoption, simplify tasks, and reduce errors and training needs through an intuitive user interface and user experience.

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

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