

# IQVIA SmartSolve® Nonconformance Management

*Streamlined handling of product and process nonconformances*

Product quality, reliability, and safety depend on conformance to internal and customer specifications. IQVIA SmartSolve® eQMS Nonconformance Management streamlines nonconformance (NC) management processes for life sciences organizations. The solution provides a closed-loop workflow to document, verify, disposition, and investigate product and process nonconformances. This can mitigate risk and reduce costs associated with scrap, rework, and customer returns.



## NONCONFORMANCE MANAGEMENT PROVIDES USER-FRIENDLY TOOLS

- Capture Nonconformance data and risk assessment
- Reduce Nonconformance cycle time
- Integrate with document, Nonconformance, and CAPA Management
- Integrate with core business systems
- Make compliance-driven decisions

## CAPTURE NONCONFORMANCE DATA AND RISK ASSESSMENT

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 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
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.