

# SmartSolve<sup>®</sup> CAPA Management

## Risk-based corrective and preventive action management

Managing CAPA (Corrective and Preventive Action) is essential for reducing regulatory risk, avoiding costly recalls, and protecting your organization's reputation. Robust CAPA processes safeguard patient safety, ensure regulatory compliance, and drive operational efficiency and continuous improvement.

### Situation

Medical Device, In-Vitro Diagnostic and Pharmaceutical companies often struggle with fragmented or manual CAPA processes, leading to delayed investigations, incomplete root cause analysis, and recurring quality

issues. These challenges can result in regulatory non-compliance, financial penalties, and loss of trust with patients and regulators.

### Our solution

SmartSolve's CAPA Management allows organizations to record problems, establish and monitor corrective and preventive actions, and review the effectiveness of each CAPA. By facilitating an effective CAPA process, CAPA Management helps shorten cycle times, resolve issues quickly and prevent recurrence — ensuring your organization's future well-being and compliance with industry, quality, and regulatory requirements. CAPAs are integrated into the Deviation Management module or may be created as standalone CAPAs.

### Key benefits:



#### Automation and optimization:

Streamline quality processes and business activities for faster, more reliable CAPA resolution.



#### Integrated quality processes:

Seamlessly connect CAPA with Complaint Management, Document Management, Change Management, Event, Audit, Nonconformance, and Deviation Management.



#### AI-Enabled automation:

Use AI to draft summaries, leverage precedent information, and improve consistency.



#### Business system integration:

Integrate CAPA data with CRM, ERP, LIMS, MES, and PLM systems via SmartSolve APIs.



#### Analytics and oversight:

Access reporting, trend analysis, and Pareto charts to identify risks and drive improvement. Quality Intelligence powered by Microsoft Power BI delivers actionable insights.



#### Easy data capture and risk assessment:

Record CAPA issues via simple forms or automated integration; assess risk using RPN (Risk Priority Number).



#### Efficient CAPA cycle:

Automated notifications, escalation, and milestone tracking ensure timely closure.



#### Effective problem solving:

Map actions to root causes, validate effectiveness, and monitor for recurring issues.



#### Data security and compliance:

Role-based security, audit trails, and electronic signatures support regulatory requirements. SmartSolve is ISO 27001 and ISO 9001 certified.

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.

## 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.