

SmartSolve® Quality Event Management

Consistent and systematic quality event handling

Centralized quality event management streamlines the reporting and processing of any quality event or issue, including the assessment and investigation of quality records. SmartSolve Quality Event Management's unified approach empowers organizations to recognize and act on patterns and trends across all quality channels, driving more informed decisions and continuous improvement.

Track all quality events

Organizations often need to track a variety of quality events. Discrete processes, such as CAPA and Deviation, limit which events can be captured and who can report them. Distinct quality channels can also limit an organization's ability to recognize and act on patterns and trends across multiple channels. Quality Event Management enables any user to report an event without categorizing or selecting a particular quality process. Event Setup allows organizations to define the types of events that are applicable to their environment.

Simplified event reporting

Quality Event Management's simple and customizable intake form allows anyone in the organization to report an event, even if they don't know whether or how the event should be triaged or routed. This simplified initiation process avoids costly and unnecessary training.

With many users involved in various roles, it is important that the ability to report an event or quality issue be quick and efficient. Built on best practices, Quality Event Management can be customized to fit your organization's specific event reporting process.

Risk-based assessment and escalation

Quality Event Management provides risk-based assessment and escalation of all events. First, a user completes a questionnaire based on event type and reporting site. Next, a customizable decision tree provides consistent



and systematic triage and routing of all events. The triage result can automate the creation of other quality records, such as Deviation and CAPA records, route the event for investigation, or even close the event if no further action is required. Past events combined with analytic tools allow additional assessment, enabling appropriate action based on event frequency and other patterns and trends.

Integrate with key quality systems

Quality Event Management seamlessly integrates with other SmartSolve modules — including Nonconformance and Change Management — providing a single entry point to collect and route information through the appropriate channels. Each event is automatically cross-referenced with records generated from triage and escalation, as well as related documents, change plans, and external resources. The integrated SmartSolve ecosystem links all relevant records, giving organizations comprehensive insight into quality-related events. This enables better-informed actions, reduces cycle times, and improves end-to-end processes, while ensuring quality professionals maintain full chain of custody for associated records within a unified QMS platform.

Additionally, SmartSolve's flexible configuration allows any user to report an event without categorizing or selecting

a specific quality process. Event Management Setup empowers organizations to define event types tailored to their unique environment.

AI and analytics

Leverage advanced AI capabilities to optimize process efficiency, elevate quality, and strengthen overall company performance across your entire QMS. With Quality Intelligence powered by Microsoft Power BI, gain actionable insights that empower proactive management of events and modules within the SmartSolve solution.

Facilitate IT and regulatory compliance

SmartSolve automates your event management process while ensuring your data remains secure. The system offers role-based security, robust password authentication, and comprehensive audit trails to help facilitate IT and industry compliance with requirements for electronic signatures and records, such as FDA 21 CFR Part 11 and EU Annex 11. Backed by ISO 27001 and ISO 9001 certifications, SmartSolve provides the assurance of trusted security and quality management for your organization. You can further strengthen oversight and efficiency by integrating SmartSolve with your existing infrastructure — including CRM, ERP, LIMS, MES, and PLM systems — via SmartSolve APIs, ensuring seamless connectivity across your business systems.

FEATURES	BENEFITS
Event setup	Tailor processes to the organization’s unique needs, including event types, policy, and roles.
Custom fields	Capture all relevant metadata for each event type.
Decision tree setup	Easily create and maintain questionnaires and triage rules for event determination.
Request for information	Automate requests for additional information, streamlining event verification and triage for faster, more accurate resolution.
Investigation and approval	Capture investigation results and approval prior to escalating an event.
Action plan creation and routings	Create and route Action Plans for events that do not require CAPA escalation.
Comprehensive and integrated eQMS	Directly access all event details and related records.

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.



CONTACT US
eQMS@iqvia.com
iqvia.com/smartsolve