Fact Sheet

SmartSolve® Complaint Management

A comprehensive solution for managing evolving global adverse event regulations

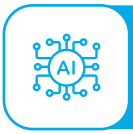
Complaint handling and global regulatory reporting are critical in the life sciences industry to maintain compliance and safeguard patient safety. Manual, fragmented processes often cause delays, inefficiencies, and increased risk. Organizations need integrated, automated solutions to streamline workflows and ensure timely resolution of issues. These systems also provide greater visibility and insights for continuous quality improvement.

Leverage artificial intelligence for smarter complaint management

SmartSolve® eQMS now harnesses the power of Artificial Intelligence (AI) to further streamline and optimize complaint handling and regulatory reporting in the life sciences industry. AI-driven features include:

Natural Language Processing (NLP): NLP AI enables the system to extract key information from free-text complaint submissions, social media, and third-party sources, improving intake accuracy and accelerating case creation.

Generative AI: Generative AI supports the human in the loop to identify similar case records, draft information chase letters and create investigation summaries to assist in optimizing case processing time and investigation quality.



Automated complaint triage: AI algorithms analyze incoming complaints to prioritize cases based on risk, urgency, and regulatory requirements, ensuring timely and effective adverse event reports and product quality investigations.

Intelligent decision support: Assists users in navigating complaint evaluation decision trees, recommending optimal investigation paths and regulatory actions based on historical data and real-time insights.

Translation capabilities: Accelerate case processing through assisting users to read quality records and associated complaint information in their local language in cases where the original record is in another language.

Predictive analytics: Advanced machine learning models identify patterns and trends in complaint data, helping organizations proactively address recurring issues and improve product quality.

By integrating AI, SmartSolve empowers life sciences organizations to achieve greater efficiency, compliance, and quality leadership in global complaint management.

Streamline complaint intake

There are many potential sources of incidents, complaints, and adverse events within your demand chain. SmartSolve provides flexible complaint intake options and gives all stakeholders the most direct path possible from the incident to correction within your quality management system.

Complaint intake options include:

- **Web-based forms:** Standard intake forms allow internal personnel to consistently capture and submit incident information.
- **Quality intake portal:** Enables field personnel and extended demand chain partners (including healthcare professionals, clinical investigators, and customers) to quickly submit incident information in a secure, consistent format.
- **Third-party integrations:** Incident data can also be received through integration with ERP or CRM systems or from your organization's web portals.
- **Integration with IQVIA's Vigilance Detect:** Monitors social media for hidden complaints or adverse events and automatically creates a case in Complaint Management.

Consistently evaluate complaints

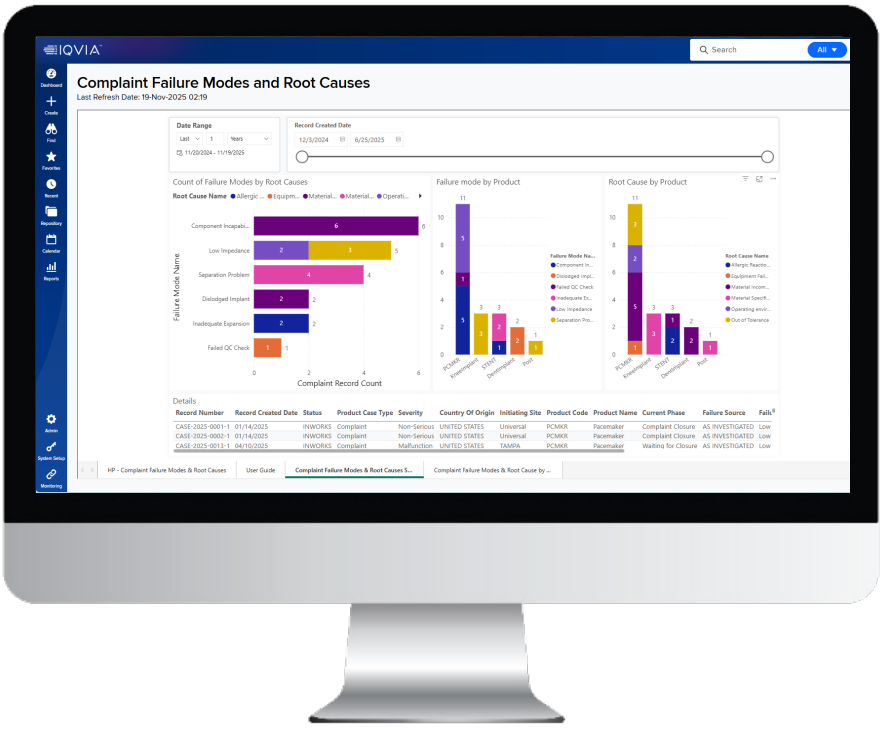
Complaint Management provides configurable decision trees that allow system users to accurately identify and differentiate complaints and adverse events from other inquiries. This ensures consistent investigation and reporting, shortens audit time, reduces risk of noncompliance, and simplifies processes.

Harmonize complaint investigation and reporting

Dynamic direction of intake forms and investigations based on product type, alleged failure, risk, or other complaint data ensures compliance-driven resolution processes aligned with SOPs.

Simplify global adverse event reporting

Finished product profiles capture key information including market approval dates, production classifications, UDI, and license numbers, helping you stay in control of global regulatory requirements.



Streamline post-market regulatory submissions

Pre-configured decision trees assist in determining reportability for:

- FDA (MedWatch — eMDR)
- EU (MIR — MDR, IVDR)
- Health Canada (MDPR)
- Japan (ARR)
- Australia (MDIR)
- UK (MIR — MDR, IVDR)
- Switzerland (MIR — MDR, IVDR)

Maintains compliance with electronic reporting requirements and supports integration to CDRH, MedDRA, and IMDRF codes.

Increase management oversight

Built-in reporting and trending capabilities provide insights into recurring complaints, resolution times, and historical data for better decision-making. Quality Intelligence powered by Microsoft Power BI delivers actionable insights.

Integrated quality processes

Seamlessly connect Complaint Management with other SmartSolve modules including Nonconformance, CAPA, Change Management and Document Management to reduce risk from manually connecting legacy systems and to drive oversight of the full chain of custody of associated quality activities.

Secure complaint records and data

Role-based security, password authentication, and audit trails ensure compliance with FDA 21 CFR Part 11 and EU Annex 11. SmartSolve is ISO 27001 and ISO 9001 certified.

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

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