

Empowering Global QA/RA Teams with an AI-Enabled QMS and RIM Solution

Vigilance Detect

Enable identification of cases from social media, audio files, and other structured or unstructured data sources

Post Market Surveillance (PMS)

Enhance post-market surveillance by leveraging MAUDE and other data sources to effectively track and trend potential issues

Summarization Capability

Generate summaries and track changes across QMS and RIM processes

Search Capability

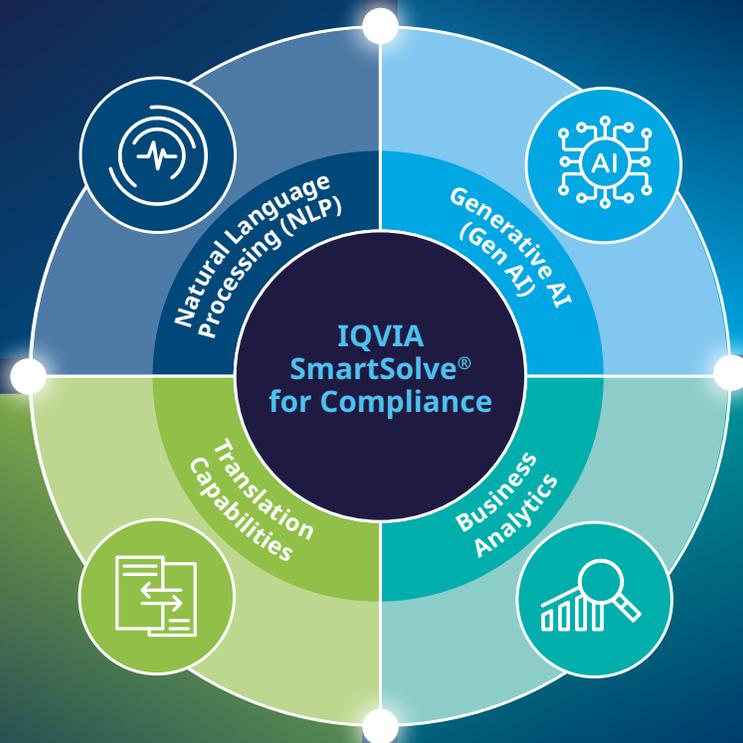
Extract content, identify duplicates and similars in a range of quality records

Recommendation Capability

Draft Identify missing data and leverage precedent information to drive next steps

IMDRF Code Capability

Use a trained model, built on five years of MAUDE data, to suggest Complaint AER codes



Business Analytics

Embedded dashboards deliver predictive and prescriptive analytics across key metrics, enabling **faster decisions**, **stronger compliance**, and **reduced risk** through real-time data visualization and enterprise system integration

Translation Capability

Translate any narrative text from **over 100 languages** into the user's local language, enabling seamless review and processing of quality records across multilingual teams

Improve processing times and ensure "right first time" outcomes by enabling source entry and system users to work in their native language.

Integrate analytics with existing company data to drive holistic dashboards with a focus on patient safety, product quality and process improvement metrics—all of which pull through to enhanced commercial performance.

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.