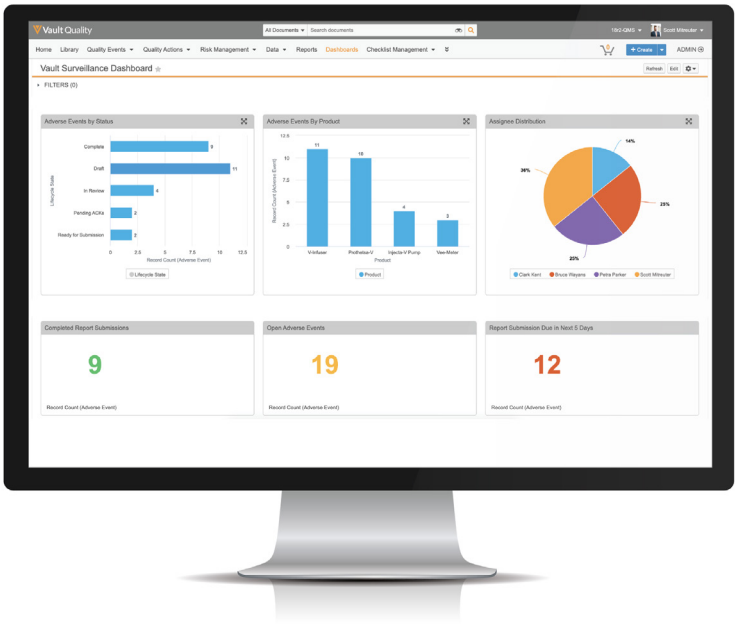
Product Surveillance

Simplify and standardize global postmarket surveillance

Veeva Product Surveillance simplifies and standardizes postmarket surveillance for medical devices, improving product safety, reliability, and quality. Fully automated electronic health authority submissions and non-electronic submission outputs ensure timely adverse event reporting. Seamless connection with quality and regulatory processes enables proactive complaints handling, accelerating continuous innovation throughout the product lifecycle.



Benefits

Improve product quality and patient safety: Proactively identify and resolve product quality issues for greater reliability, safety, and compliance.

Ensure submission timeliness: Meet submission timelines with an intelligent, global reportability decision tree with country-specific criteria.

Real-time visibility and end-to-end control: Make informed business decisions with real-time visibility into submissions and complaint-handling metrics.

Features

Global Reportability Decision Tree

Standardize and consolidate the complaint reportability process for various health authorities through a global decision tree.

Reporting Timeline Management

Efficiently manage event-specific reporting timelines to ensure compliance and timeliness across various health authorities. Enable quality and regulatory teams to allocate resources and prioritize submissions effectively.

Automated Adverse Event Reporting

Built-in XML payload generation and electronic data interchange (EDI) gateway provide a fully automated electronic submission for the FDA electronic medical device reporting (eMDR). Additionally, supports nonelectronic submission for the EU manufacturer incident report (MIR).

Interactive Dashboards and Reports

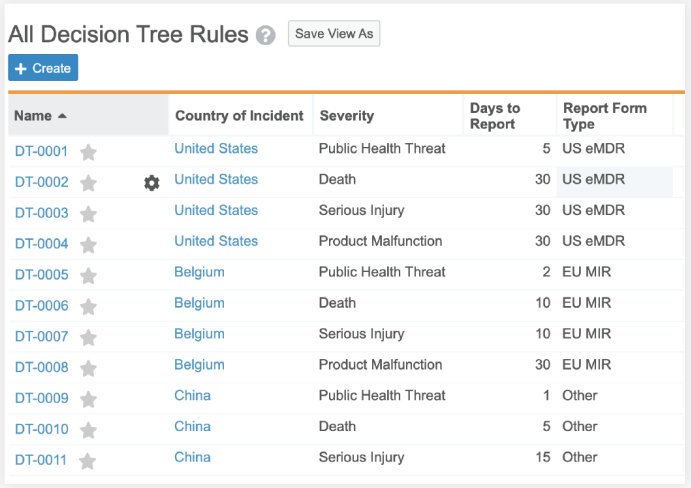
Real-time, interactive dashboards provide clear visibility into inefficiencies and bottlenecks that cause processing and reporting delays. Take action directly from reports to resolve issues and complete tasks to speed up the submission process.

Configurable Event Management Workflows

Automate and track events with standard and configurable workflows that provide assignment, routing, email notifications, escalation, and tracking of tasks for groups or individuals.

Part of Veeva Quality Cloud

Seamless connection to Veeva Quality Cloud applications enables end-to-end quality management improving product quality and patient safety. Unification with core quality processes, such as CAPA management and content management, eliminates the need to build and maintain complex cross-system integrations.



Name	Country of Incident	Severity	Days to Report	Report Form Type
DT-0001	United States	Public Health Threat	5	US eMDR
DT-0002	United States	Death	30	US eMDR
DT-0003	United States	Serious Injury	30	US eMDR
DT-0004	United States	Product Malfunction	30	US eMDR
DT-0005	Belgium	Public Health Threat	2	EU MIR
DT-0006	Belgium	Death	10	EU MIR
DT-0007	Belgium	Serious Injury	10	EU MIR
DT-0008	Belgium	Product Malfunction	30	EU MIR
DT-0009	China	Public Health Threat	1	Other
DT-0010	China	Death	5	Other
DT-0011	China	Serious Injury	15	Other

Veeva Quality Cloud

Veeva Quality Cloud enables the management of quality events from event origination to changing controlled content and completing training on a single cloud-based platform. Connecting quality processes, critical documentation, and training accelerates and streamlines event identification, correction, and change management. This end-to-end visibility equips organizations to respond to quality events faster and provides a complete picture of quality management activities to regulators.