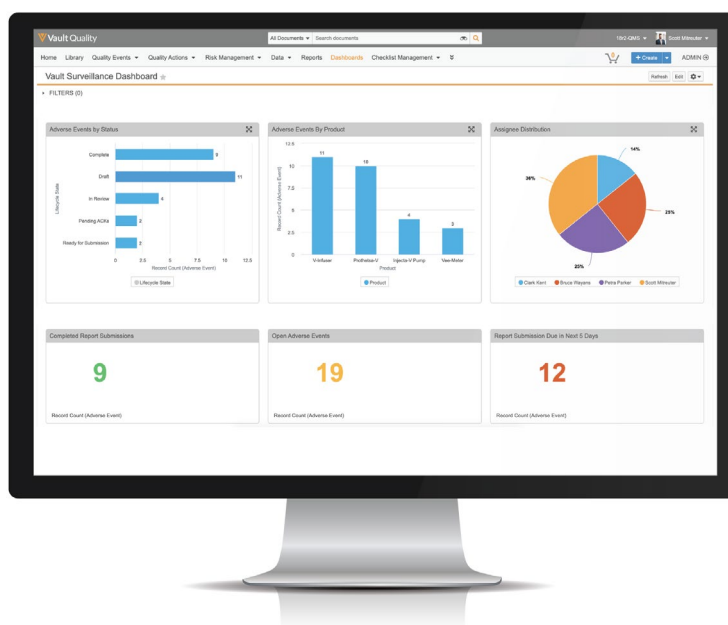# ⱽ Vault Product Surveillance

Simplify and standardize global postmarket surveillance

Vault 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.

Veeva Vault Product Surveillance

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 non-electronic submission for the EU manufacturer incident report (MIR).
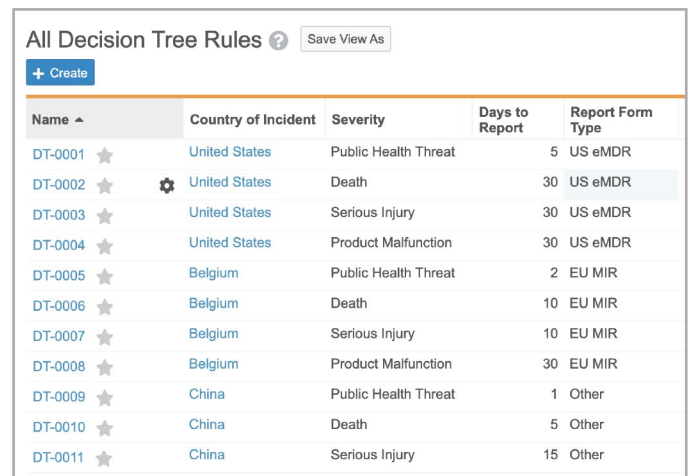
Interactive Dashboards and Reports

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 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 Vault Quality Suite

Seamless connection to Vault Quality Suite 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.

All Decision Tree Rules · Save View As

+ Create

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

Vault Quality Suite

Veeva Vault Quality Suite of applications enables seamless management of quality events from event origination to changing controlled content and completing training requirements. Connecting quality processes, postmarket surveillance, critical documentation, and training management on a single cloud-based platform accelerates event identification, correction, and change management. The unified application suite accelerates continuous quality improvements while meeting global compliance requirements. Veeva Vault Quality Suite includes Vault QMS, Vault Product Surveillance, Vault QualityDocs, Vault Station Manager, and Vault Training applications.