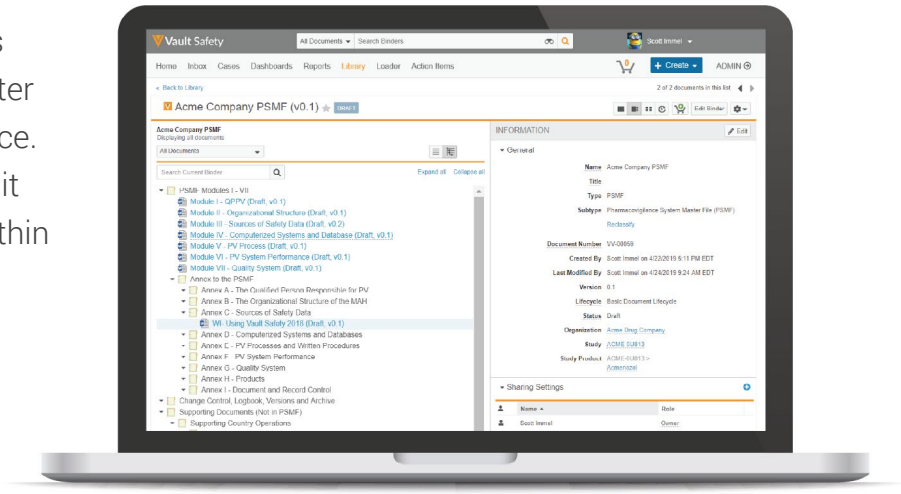
Veeva Vault SafetyDocs

Centrally manage pharmacovigilance content and collaborate globally

Vault SafetyDocs centrally manages pharmacovigilance content for greater operational efficiency and compliance. With easy access to safety content, it also enables global collaboration within teams and across clinical, quality, regulatory, and other organizations.



Key Business Benefits

- **Improve compliance:** Detailed audit trail, version control, intuitive search capabilities, and real-time status visibility improves compliance for audits and inspections
- **Enable collaboration:** Easily share content internally or externally and collaborate across quality, regulatory, clinical, safety, and other organizations
- **Increase efficiency:** Intuitive solution that is easy to use and maintain for more effective document management

Features

Controlled Access

Securely enable internal and external users to access safety documents on any device from a major web browser. Users can only see and perform tasks based on their security role.

Version Control

Automate versioning and easily compare documents to previous versions to see how the content has changed.

Content Binders

Quickly organize and manage documents with binders for the pharmacovigilance system master file (PSMF) or an inspection. Link to source documents in the safety, quality, regulatory, clinical, or other Vaults to ensure a single source of truth for regulated content.

Electronic Signature and Manifestation

Approve documents using electronic signatures and manifestations that are compliant with Title 21 CFR Part 11 and Annex 11.

Comprehensive Audit Trail

Demonstrate compliance with detailed audit trails capturing every event in a document's history – including document approvers and reviewers, status changes, execution of a signature, and more.

Real-time Collaborative Authoring

Seamless integration between Vault and Microsoft Office Online provides real-time collaborative authoring and does so in a compliant way. See a demo.

Interactive Dashboards and Reports

Self-service reporting and dashboards enable users to see the status of content and processes, making it easy to identify bottlenecks or compliance risks. Click through the report for more detail or easily share information with your team or partners.

Document Taxonomy

Easily establish a document taxonomy and standard picklists for safety documentation to facilitate harmonization and collaboration of safety information across quality, regulatory, clinical, and other departments or organizations.

Configurable Workflows

Automatically route content for review and approval to align with business processes, and trigger workflows based on document expiration and periodic review notification.

Validation Ready

Veeva performs and documents all elements of Infrastructure Qualification (IQ) and Operational Qualification (OQ) for each major release. A sandbox / test environment and user acceptance testing (UAT) scripts are also provided that can be leveraged and adapted for Performance Qualification (PQ).