

Improve oversight and end-to-end control of PSMF management

Vault SafetyDocs streamlines global PSMF management and provides complete QPPV oversight for improved compliance in a validated and purpose-built solution.

With harmonized content across global and local regions, Vault SafetyDocs makes it easier to manage multiple PSMFs and meet varying local regulatory requirements.

Business Benefits

Stay inspection ready.

Improve QPPV oversight, reduce risk, and demonstrate compliance with controlled access, an automated logbook, document history, version control, and a detailed audit trail. Ensure confidence in safety information for inspection readiness.

Efficient role-based collaboration.

Automatically share data and documents internally and externally with defined responsibilities for content ownership and review. Effective collaboration ensures the most recent document versions are readily available and that content is always current.

Streamline global and local PSMF management.

A single source of content harmonizes processes and permits more effective document management. Simplify support for regional PSMFs by reusing content across multiple regions.

Features

✔ One-click PDF Merge

Easily generate a complete PDF file of a PSMF to share with sponsors or auditors for inspection.

✔ Automated Logbook and Audit Trail

Track document changes automatically in an electronic record, including who, what, and when information was modified.

✔ Easy Content Reuse

Manage global and local content with a universal PSMF binder template. Create a document once and reference it across multiple regional PSMFs.

✔ Schedule Automatic Periodic Reviews

Automatically detect PSMF documents that are due for review and assign review tasks to content owners. Easily ensure your PSMF is always compliant and up-to-date.

✔ Version Control

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

✔ Dynamic Table of Contents

Seamlessly link PSMF documents from the table of contents, with changes to the PSMF syncing in real-time.

✔ Reports and Dashboards

Track operational metrics to determine the status of PSMF contributor tasks and documents, as well as oversight of PSMF workflows.

✔ Configurable Workflows

Automatically route content to content owners or reviewers for authoring, review, or approval.

✔ User Access Management

Create secure user access roles to define what content users are allowed to view or edit and what activities they can complete.

✔ Electronic Signature and Manifestation

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