

SOPVault™ Overview

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What is SOPVault™

SOPVault™ is a regulatory Compliance Engine integrated with Document Control and Training Management for regulated manufacturers, brand owners, and contract manufacturers.

SOPVault™ analyzes a facility's approved procedures and documents to understand and map how its documented processes operate. The Compliance Engine can then assess those processes and supporting documents against applicable regulatory and quality requirements, such as ISO 22716 or 21 CFR Part 111.

For each requirement, SOPVault™ identifies whether the available documentation is Compliant, Partially Compliant, Missing, or Insufficient Evidence. When gaps are identified, the system explains what is missing and provides recommended actions to help update procedures or processes. The Compliance Engine can be tailored to assess the regulatory and quality standards applicable to an organization's operation.

Because the Compliance Engine is integrated with Document Control and Training Management, compliance findings can be addressed within the same system used to manage controlled documents, revisions, approvals, employee training, quizzes, OJT task lists, electronic signatures, and audit-ready records.

Key Features

- Regulatory and quality compliance assessment
- Process mapping based on approved procedures and documents
- Requirement-by-requirement assessment: Compliant, Partially Compliant, Missing, or Insufficient Evidence
- Identification of compliance gaps and supporting document evidence
- Recommended actions for procedure or process updates
- Compliance assessment of new and revised documents
- Document Control with revision control, electronic approvals, and audit trails
- Employee Training Management
- AI-generated quizzes and OJT task lists from existing SOPs

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- CAPA Management and Change Control
- Equipment Preventive Maintenance, Work Orders, Spare Parts, and Cleaning Logs
- Flexible Approval Workflows, User & Role Management, and Audit-Ready Electronic Records

How It Works

- Upload existing approved SOPs, procedures, and controlled documents.
- SOPVault™ analyzes the documents to understand and map the facility's documented processes.
- Configure the regulatory or quality standard to be assessed.
- The Compliance Engine maps documented evidence to individual requirements and identifies compliance gaps.
- Review recommended actions for requirements that are Partially Compliant, Missing, or have Insufficient Evidence.
- Create or revise controlled documents to address identified gaps and route them through approval workflows.
- Assign and document employee training when approved changes require training.
- Continue assessing new and revised documents so compliance, document control, and training remain connected.

Why SOPVault™

- Compliance Engine integrated directly with Document Control and Training Management.
- Uses the organization's existing approved SOPs and procedures as the basis for process mapping and assessment.
- Can be tailored to assess applicable regulatory and quality standards.
- Connects compliance gaps to the procedures and documents that support the assessment.
- Provides recommended actions to help address identified gaps.
- Keeps compliance assessment connected to document revisions, approvals, and employee training.
- Supports manufacturers, brand owners, and contract manufacturers.