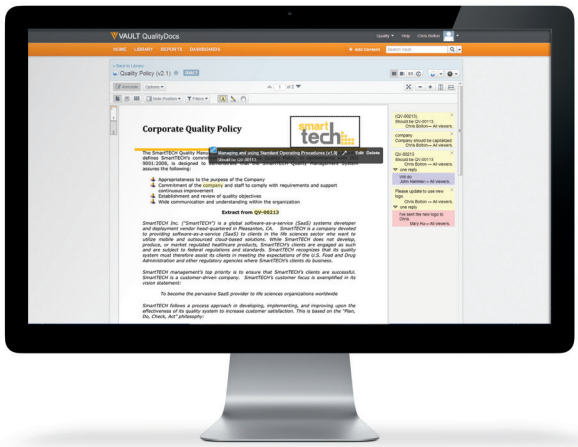
Vault QualityDocs

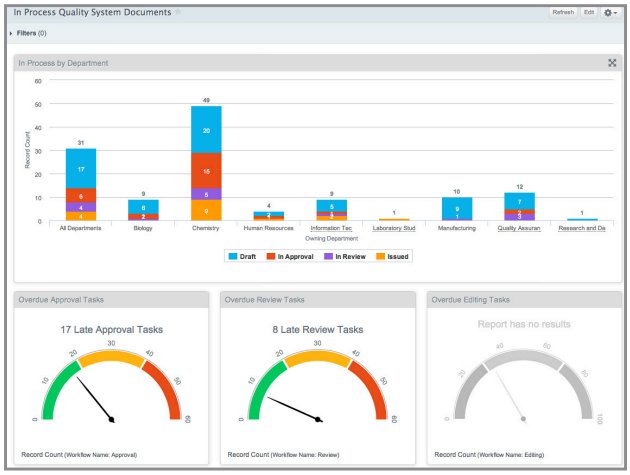
Serious Regulatory Compliance. Seriously Easy to Use.



Quality involves many people, which makes the interface design an important part of your quality documentation system. The ease-of-use and cloud access assure high adoption of the solution—even for occasional users—across departments, contractors, and partners, reducing overall risk of noncompliance.

Veeva Vault QualityDocs provides a single, secure application for employees and partners to author, collaboratively review, and approve documents. The cloud model makes it easy and cost-effective to provide all parties with direct access to a single source of truth, eliminating compliance risks associated with other means of distributing copies, such as email or FTP.

Veeva Vault QualityDocs also provides greater visibility and control. Predefined lifecycles and workflows enable efficient document control processes, and helps everyone stay on task with approval, training, release, review and withdrawal processes. Compliance managers can monitor status and collect metrics using reports and dashboards to identify risks, bottlenecks, and promote continuous improvement.



Key Business Benefits

- Easy access anywhere, anytime, and from any device enables a single system of record
- Cloud application provide partners secure and easy access
- Quickly establish good quality practices and facilitate 21 CFR Part 11, Annex 11, GMP, and other regulatory compliance
- Reporting and metrics identifies state of control, risk, and drives continuous improvement
- Ease-of-use increases user adoption, minimizing uncontrolled copies

Veeva Vault QualityDocs

> Get rid of paper, assure compliance and quality, and embrace a future that is more reliable, more productive, and unites your global organization.

Always Current, Never Stuck

With modern cloud Software-as-a-Service (SaaS), you are always current; you won't get stuck with an inflexible application that is heavily customized and quickly out-of-date. Veeva is constantly innovating and validating new releases, so no one gets stuck on an old version. Veeva customers are always on the most current release.

Read and Understood

Training documents and videos can be delivered easily and cost-effectively for every employee in an organization. With traceability and reporting on all "read and understood" actions, easily track when users view content, sign off on training tasks, or are overdue on activities.

Watermarking and Overlays

Define and apply dynamic overlays and watermarks on a document's header, footer, or across each page to see the current status or effective date on an SOP. Overlay relevant document, user, or access information onto printed versions of controlled documents so everyone inside or outside of Veeva Vault sees the important information.

Document Change Control

Users can easily request, review and approve, or reject changes to controlled documents. This flexible feature with pre-defined workflows and reports tracks and traces all changes through version-aware relationships.

Periodic Review

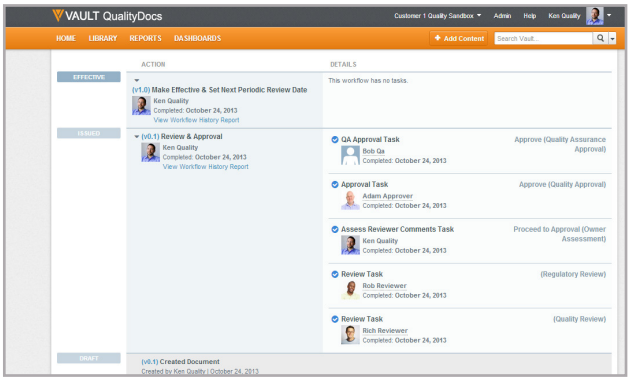
Quality managers can easily ensure that reviews are started and completed in a timely fashion. The periodic review feature automatically triggers review reminders for documents based on predefined rules, and reports can be generated on the status of review tasks across the organization.

Real-time Collaborative Authoring

Seamless integration between Vault QualityDocs and Microsoft Office Online provides simultaneous authoring for real-time collaboration.

Flexible Workflows

Best practice workflows and lifecycles improve the authoring, reviewing, approving, issuing, superseding, and obsoleting of quality-focused content. Manage workflow changes with ease: add recipients, delegate tasks, and cancel activities even for in-progress workflows.



Reports and Dashboards

Time-based reporting let customers leverage best practice reports, including documents set to expire, documents with upcoming periodic reviews, and more. Users and administrators can quickly create their own reports, then copy and share them with other team members, providing a comprehensive view of all content-related activities.

Controlled Copies

Get complete control over document copies. Control who can create document copies and take them outside of Vault QualityDocs; track individual document copies' statuses in the field or during/after recall.

Signature Manifestation

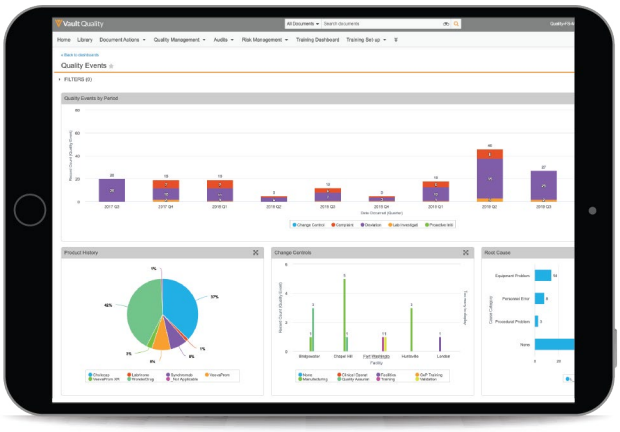
With Vault QualityDoc's configurable signature page, organizations choose when and how to display the signatory's name, date, and reason for sign-off, eliminating the need for wet signatures on hard copy documents.

Application Integration

The open, published Vault API easily integrates with complementary systems, such as QMS, LIMS, and LMS.

Datasheet

Veeva Vault QMS



Modernizing Quality Management

Greater regulatory scrutiny and the growth of global outsourcing have made quality management complex. Most life sciences companies are using legacy systems that are not designed for collaborating with external partners, such as contract manufacturers and suppliers.

Further complicating quality management, there are often separate solutions for managing controlled processes and regulated content. Even for a simple corrective and preventive action (CAPA) that generates a change control requiring document modifications, content workflows are managed independently from quality processes. This gap between systems creates risk and manual overhead.

Veeva Vault QMS is a cloud-based quality management solution that provides best practice processes for deviations, internal and external audits, complaints, lab investigations, change controls, CAPAs, quality risk management (QRM), and proactive management initiatives. With a modern, easy-to-use web interface, Vault QMS drives higher user adoption with minimal ongoing support.

Key Business Benefits

- **Better align with partners:** Easily bring departments, sites, suppliers, contract manufacturers, contract test labs, and other partners into continuous quality improvement processes.
- **Gain complete visibility into quality processes:** Track quality processes proactively with the right level of visibility to support timely decisions and accelerate cycle times.
- **Greater compliance:** Ensure global compliance with seamlessly connected and controlled processes that are part of the Vault suite of applications.
- **Rapid time-to-value:** Leverage a ready-to-use, scalable application with built-in best practices and automated workflows to improve operational efficiency in record time.

Veeva Vault QMS

Features

Delivered Quality Processes

Rapidly deploy delivered quality processes for proactive management initiatives, deviations, internal and external audits, complaints, lab investigations, change control, quality risk management, and CAPA processes.

Intuitive Interface

Drive high user adoption with an easy-to-use application. Providing a consumer web experience streamlines tasks, and reduces training time and support—boosting productivity.

Configurable Forms and Workflows

Using 'point and click' configuration, modify best practice workflows or create new processes. End users can quickly add tasks and link documents to a process.

Robust Audit Trails

Annex 11 and 21 CFR Part 11 compliant audit trails that capture every event in a process, including execution of a signature, task creation and assignment, and more.

Unified Risk Management

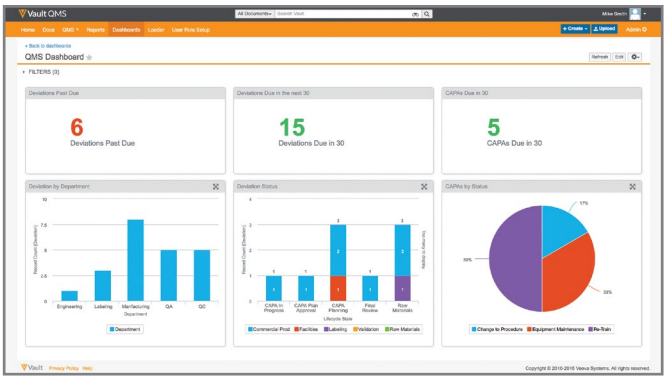
Easily incorporate risk management into existing quality processes across R&D and manufacturing. Effectively allocate resources with an enterprise-wide inventory of prioritized risks.

Document Control

Automatically trigger a document change control for impacted SOPs, work instructions, or other content in Vault QualityDocs—seamlessly connecting quality processes to critical documentation. Users can easily check status and ensure tasks are completed.

Reports and Dashboards

Gain actionable insights into quality events through selfserve reports showing information on different processes, including deviation, investigation, complaint, audits, CAPA actions, and more. Easily share information with the team and external partners.



Supplier Access and Visibility

Easily provide access to suppliers and contract manufacturers, integrating partners into key processes for greater visibility and control.

Mobile Solution

Effortlessly use the QMS application on any device, from anywhere. Easily check status, complete tasks, or fill out forms while away from your desk.

Application Integration

The open, published Vault API easily allows integration with complementary applications, such as enterprise resource planning (ERP), or laboratory information management (LIMS) for streamlining processes across business systems.

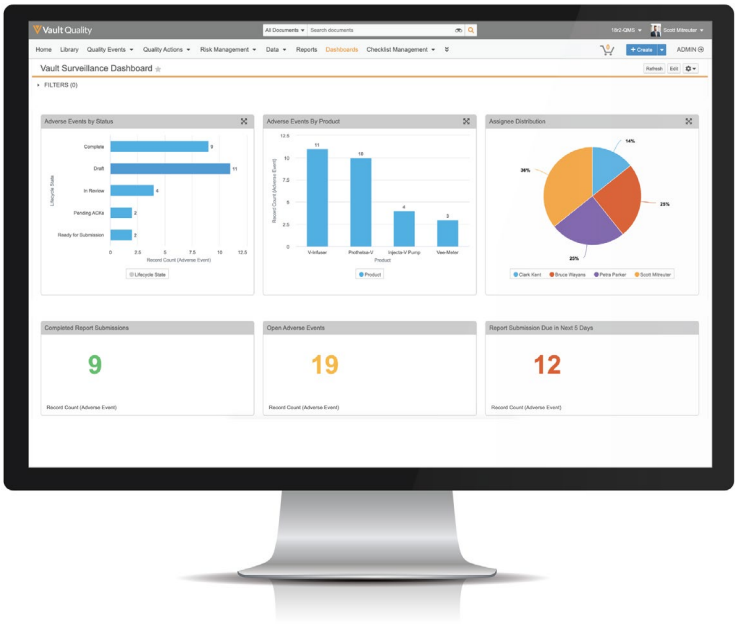
Vault Quality Suite

Veeva Vault Quality Suite of applications 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—with Vault QMS, Vault QualityDocs, and Vault 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.

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.

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

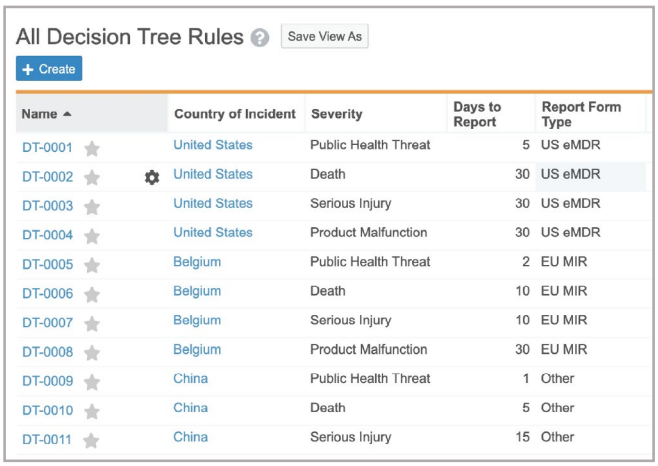
Real-time, interactive dashboards provide clear visibility into inefficiencies and bottlenecks that cause processing and reporting delays. Take action directly from reports to resolve issues and complete tasks to speed the submission process.

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.



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.

Vault Training

Easily manage training and role-based qualification

With unified training, content, and quality management solutions, organizations gain more efficient and effective training. Regulatory authorities continue to identify 'not following procedures' and/or training as a top challenge.[1,2] Globalization and increasing product and supply chain complexity is making it difficult for employees and partners to stay current on procedures that require continuous qualification.

Veeva Vault Training streamlines training from creation to distribution and completion by seamlessly working with Vault QMS and Vault QualityDocs. Quality events in Vault QMS can automatically trigger training tasks in Vault Training that are assigned to job functions or roles. Individuals are notified of new training requirements and can easily access training content and complete assignments in Vault QualityDocs—making it effortless for everyone to stay compliant. Demonstrating compliance is easy with centralized training records and a single audit trail, reducing audit preparation time and always staying inspection ready.

Benefits

- **Qualification management:** Manage sophisticated training matrices using flexible, role-based alignment of users and content.
- **Greater training compliance:** View upcoming or complete training tasks with an intuitive user experience that makes it easy even for the occasional user.
- **Unified quality:** Seamlessly manage training programs, quality processes, and content together with a unified suite of quality applications providing a single user experience.
- **Always audit and inspection ready:** Easily demonstrate compliance with training reports and centralized, comprehensive training records and activities.

[1] FDA's Top Ten Drug GMP Inspection Citations for 2016. December 2017.

[2] The Top 15 Pharmaceutical Deficiencies Cited by FDA in 2014.

Features

Industry-specific Application

Rapidly deploy an industry-specific training solution that includes best practice workflows, dashboards, and reports.

Role-based User Experience

Easily track and complete tasks, or monitor statuses with a role-based home page for trainees, managers, and compliance officers.

Training Matrices

Manage assignment maps by defining and viewing curricula and/or training tasks based on job functions or roles for knowledge, skill development, and qualification.

Automated Assignments

Reduce administration overhead by automatically assigning training tasks and or curricula based on job function or role.

QMS or Content Event-driven Tasks

Trigger training tasks based on quality events such as approval of relevant content changes, CAPA plans, periodic review, or retraining.

End-to-end Training Content Management

Collaboratively manage the complete lifecycle of training content—from authoring to approval, assignment, and completion—in one application.

Task Notification

Regularly notify trainees and managers on upcoming or past due training tasks.

Reports and Dashboards

Track, monitor, and demonstrate employee qualifications, see who trained on specific content, or create your own dashboards and reports

Audit Trail

Demonstrate compliance with a single, comprehensive audit trail capturing all training events—including adding/removing an assignment to curricula or job roles, or completion of training tasks.

Mobile Access

Trainees can securely access training content and managers can view status reports on any device, anywhere, anytime.

Vault Quality Suite

Veeva Vault Quality Suite of applications 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—with Vault QMS, Vault QualityDocs, and Vault 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.