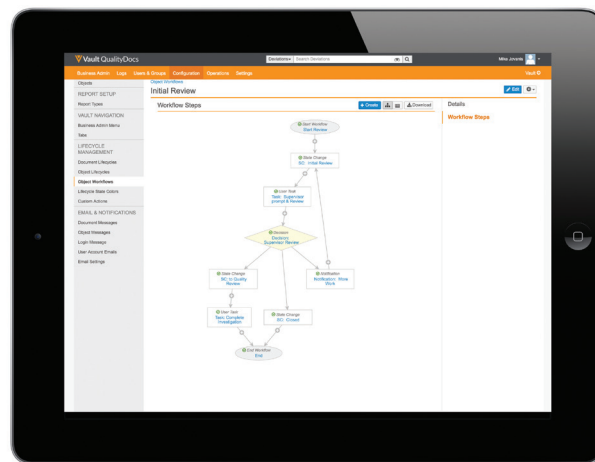


Veeva Vault QMS

for Medical Devices & Diagnostics

Modernizing Quality Management



Greater regulatory scrutiny and the growth of global outsourcing have led to unprecedented levels of complexity for managing quality. Most life sciences companies have implemented at least one quality system. However, they are usually point solutions confined internally — limiting the ability to extend processes to contract manufacturers, research organizations (CRO), and other partners.

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. Gaps between applications create risk and manual overhead is necessary to support continuous processes.

Vault QMS is a cloud-based quality management solution that is easily accessible, and provides best practice processes for non-conformances deviations, internal and external audits, complaints, lab investigations, change controls, CAPAs, and proactive management initiatives. With a modern consumer web interface, Vault QMS is intuitive and drives higher user adoption with minimal ongoing support.

Key Business Benefits

- **Global alignment with partners:** Easily incorporate all parties (sites, suppliers, and contract manufacturers, labs, and research organizations) for continuous quality management processes, driving and end-to-end control.
- **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.

Features

Delivered Quality Processes

Rapidly deploy delivered quality processes for proactive management initiatives, non-conformances deviations, internal and external audits, complaints, lab investigations, change controls, 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.

Always Current, Never Stuck

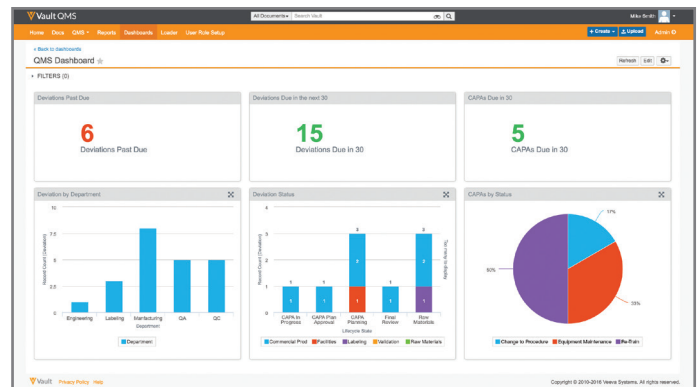
With modern cloud Software-as-a-Service (SaaS), you won't get stuck with an inflexible application that is heavily customized and quickly out-of-date. Veeva is constantly innovating and validating new releases (IQ/OQ qualified), so no one is on an old version. Veeva customers are always on the most current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

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

Leverage pre-defined reports and dashboards or create your own showing information on processes including: non-conformances deviations, investigations, complaints, audits, and CAPA actions by different combination of attributes. 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 continuous processes across business systems.

Veeva Vault Quality Suite

Veeva Vault Quality is a suite of applications that enables the management of quality events from event origination to changing controlled content on a single cloud-base platform. Connecting quality processes with critical documentation, Vault QMS with Vault QualityDocs 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.