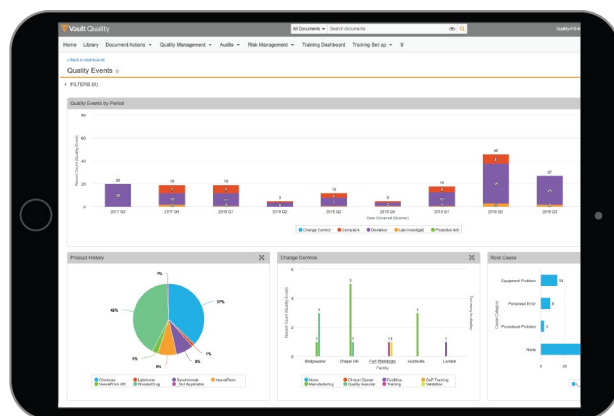


Veeva Vault QMS

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.

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

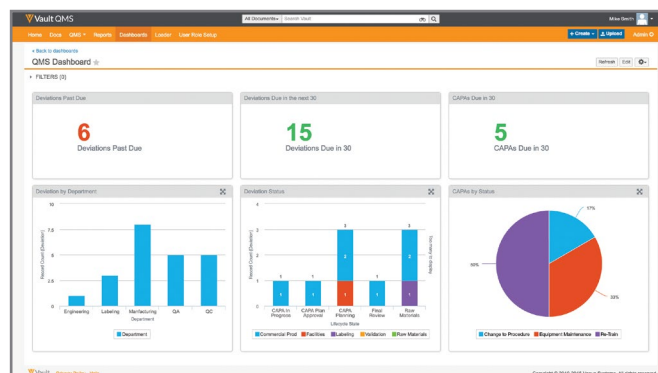
Easily incorporate risk management into existing quality processes across R&D and manufacturing. Effectively allocate resources with an enterprise-wide inventory of prioritized risks.

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.

V 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.