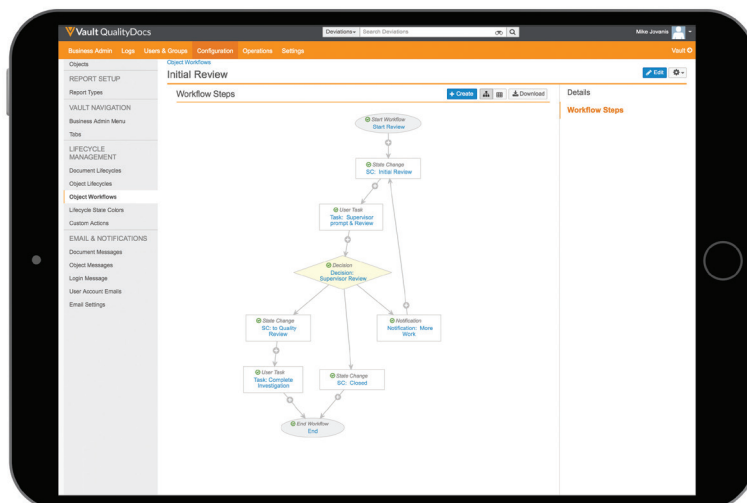




Modernizing Quality Management



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. These gaps between systems creates risk and manual overhead.

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

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.



More Efficient Registration Process

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 platform of applications.



Rapid Time-to-Value

Connect end-to-end regulatory processes and improve efficiency as part of Veeva RIM.

Features

✓ Delivered Quality Processes

Rapidly deploy quality processes for proactive management initiatives, non-conformances, risk management, internal and external audits, complaints, field actions, 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.

✓ Unified Risk Management

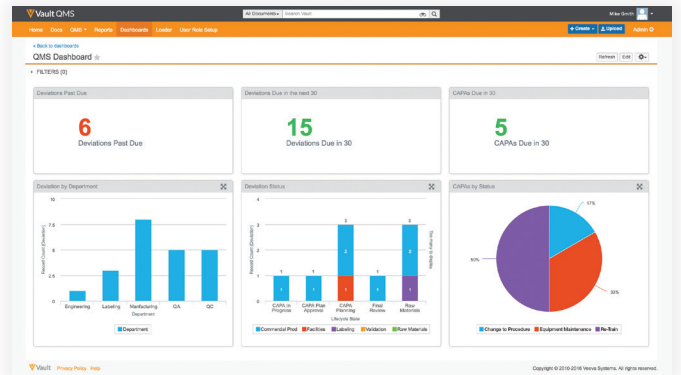
Easily incorporate risk management into existing quality processes across R&D and manufacturing. Effectively allocate resources with an enterprise-wide inventory of prioritized risks.

✓ Document Control

Automatically trigger a document change control for impacted SOPs, work instructions, or other content in Veeva 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 nonconformances, investigations, complaints, audits, and CAPA actions by different combinations 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 Quality Cloud

Veeva Quality Cloud 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 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.