Veeva Vault Platform

Life Sciences Leader Builds Application on Veeva Vault Platform to Streamline SOX Compliance

Drowning in financial paperwork, a global life sciences provider needed to improve its document management and reporting processes while providing easy access to internal and external auditors.

Veeva Vault, a cloud-based content management platform for business applications, gave it a powerful foundation on which to build an application to help establish and enforce standard operating procedures (SOPs) that comply with legal requirements.

About the Customer

The customer is a global provider of medical devices for home and hospital use, with manufacturing facilities in multiple countries. Bound by Sarbanes-Oxley (SOX) to document and monitor internal controls and SOPs around financial reporting, the company's compliance requirements had generated a huge volume of regulated records and non-regulated supporting documentation.

The Challenge of SOX Compliance

In the absence of a single content management system, keeping track of thousands of documents required for SOX compliance was extremely challenging. Each office created its own SOX records, and paper documents were scattered across binders, office drawers, and storage rooms. Without a standardized system, it was difficult to enforce SOPs, process documents in a timely manner, and keep track of important content. In fact, vital evidence of reviews and approvals often went missing, significantly increasing risk. Because there was no visibility into the process, it was almost impossible for managers to monitor whether SOPs were observed or to flag incomplete and missing documentation.

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>
> *-SOX Compliance Manager*

When it came to audits, these problems were even more acute. The organization faced three annual inspections, one internal and two external, each taking about three weeks. Each audit required the presentation of extensive documentation—a struggle every time. First, teams had to hunt down the required records, and then make physical copies to pass to the auditors. When documents were deemed too large to copy, originals were handed over. Inevitably, some were lost.

It made for a stressful, time-consuming event three times a year and took a toll on the organization's audit performance and speed.

A content management application providing robust workflows was needed to address reporting and audit issues. "My goal was to never give a piece of paper to an auditor again," said the SOX compliance manager.

Searching for a Comprehensive Compliance Application

At first, the compliance team tried building the application using a workflow tool on an existing content management platform. While it initially worked well, limitations emerged over time. There was insufficient space to retain all the necessary records, which meant the company had to revert to paper copies and flash drives for backup. Granting access to external users was also impossible, so paper duplicates were still required for auditors. Finally, as the system couldn't be validated, it proved unsuitable for long-term SOX compliance records retention. These limitations compelled the team to seek a more comprehensive application.

They turned to their in-house IT group to develop and build an application from scratch. Further explorations with IT revealed that building an application to manage complex workflows, enforce role-based security, and generate iron-clad audit trails would prove highly complex. And critically, IT could not commit to ongoing development and feature enhancements after the initial project was completed.

Having exhausted existing tools and in-house options, the next step was to evaluate external providers. They established specific technical, functional, and security requirements and began to research their options.

Requirements for a new content management platform:

Technical requirements

- GxP-validated
- Automatic monitoring and documenting of system changes
- Cloud-based
- Secure access for external partners and auditors
- Integration with existing single sign-on framework

Functional requirements

- Manages SOX-related documents from creation through finalization
- Provides intuitive UI for auditors to locate and view SOX documents
- Monitors and can report on all document activities through an audit trail
- Provides self-service reporting against SOX information
- Stores supporting documents together with regulated documents

Security requirements

- Document-level security based on user role
- Audit trail and workflow history
- Secure exchange of information between system and users

The company needed a robust system that would manage multiple document types, making it easy to create, store, and retrieve content from a single location. Standardized workflows and powerful reporting capabilities were also key. Because compliance was important, the application needed to record all document activities and system changes. To ensure users, approvers, and auditors were able to perform only those actions specific to their function, the solution had to deliver role-based security permissions.

Finally, the application had to be intuitive for the compliance team to configure. With limited technical support, they needed an application that was easy to develop, extend, and administer for non-technical business process owners.

Selecting Veeva Vault

The company chose to build a custom application on the Veeva Vault Platform. Veeva Vault is the first cloud platform built specifically to meet the rigorous requirements for content management in the life sciences industry. Building an application on Veeva Vault ensures reliable data backup and recovery, continuous performance monitoring to maintain speed, and installation qualification (IQ) and operational qualification (OQ) validation to reduce their validation efforts.

The Veeva Vault Platform easily met all technical, functional, and security requirements, and as a proven platform in the highly regulated life sciences industry, it was the right fit for their needs.

As Veeva Vault is a multitenant cloud-based platform, users are not responsible for hosting, maintaining, or updating the system. The platform is scalable and secure, and updates and improvements are delivered seamlessly on an ongoing basis. As an additional benefit, the organization could rely on Veeva's external audit firm for the SSAE-16 review of Veeva's data security and disaster recovery processes.

Rapid Implementation and Configuration

It took just 13 weeks to develop and launch a global SOX compliance application on Vault.

"We went live across five divisions and with four document types in place," said the SOX compliance manager. "Today, with our Veeva Vault application in place and everything following standardized procedures, I can add an entirely new division to our process in under two hours."

Vault Platform allows for easy customization of every aspect of the system, from object models and page layouts, to workflows and security permissions. The team quickly configured the user interface, workflows, and reports to manage its SOX-related content in an easy-to-understand format. Training new employees, and auditors, to use the system was straightforward.

"I'm in finance, not IT, and Vault is intuitive enough that I can do the configuration and administration for 300 people myself," said the SOX compliance manager.

Improved Compliance and Streamlined Processes

Since introducing the application, there have been significant operational improvements:

Easier Compliance

• Standardized document types and tailored workflows make it easier to enforce SOPs for SOX processes.

• Vault presents a complete picture of the SOX record by leveraging attachments for pairing supporting documentation with regulated content through a simple drag and drop. Complete records are now maintained in one place without difficulty.

• Customizable reports improve activity tracking and enable flagging of missing or incomplete documentation in the moment, ensuring ongoing compliance.

• Personalized views let users specify and save their preferred view of the system. Even infrequent users can quickly locate relevant information, with instant visibility into their data.

• "Segregation of duties" errors were reduced thanks to role-based security limiting user and approver permissions to specific tasks.

Improved Audit Performance in Less Time

• Employees no longer spend hours searching for and copying physical documents. Storage costs for paperwork were drastically reduced.

• Everything is available to auditors, wherever they are, from a single source. SOX Compliance simply creates and shares a report or view containing links to the requested information.

More Effective Training and Enforcement of SOPs

• Using reports or custom views, managers bring new employees up to speed on SOPs and other necessary instructions as soon as they start working.

• "Read and Understood" capabilities ensure required documents, including training manuals and SOPs, are routed to the appropriate people or groups. An easily configured report shows when those documents have been opened and read, and allowing for quick follow up of incomplete tasks.

Easy to Configure, Maintain, and Add New Business Groups

• Because Vault Platform is multitenant cloud, new functionality is regularly introduced, enabling continuous process improvement.

• Simple and flexible configuration means new types of documents, objects, or even whole new businesses are quickly incorporated.

At the first audit after go-live, the auditors were able to access the system remotely and pull documentation straight from the source. No paper copies changed hands, no documents were lost, and no time was wasted tracking down and copying physical documents. Upon completion, the auditors were so pleased, they recommended to the CIO that all other departments adopt the custom Vault application as a best practice for Sarbanes-Oxley.

Looking to the future, it will be simple to add new divisions to the system and to take advantage of new functionality.

"Building our own app on the Vault Platform has been a great experience," said the SOX compliance manager. "The ease of use and simple configuration has substantially reduced the amount of time we spend on SOX compliance. We've been able to create a streamlined process, enforce SOPs, and handle audits much more quickly and efficiently."