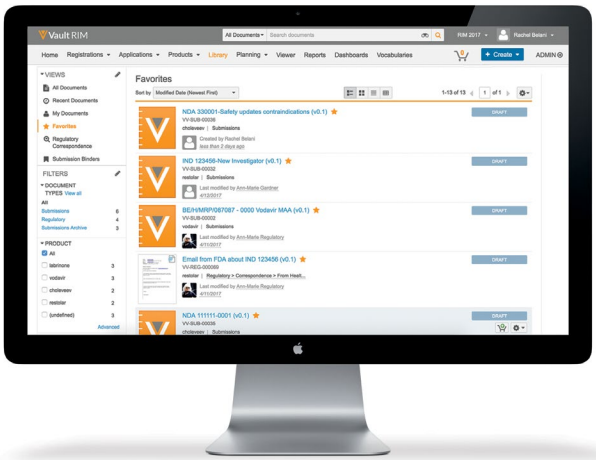
Datasheet

Veeva Vault Submissions

Regulated document management in the cloud



Veeva Vault Submissions is a modern cloud application for authoring and managing regulatory submissions content. Vault Submissions gives life sciences companies greater access, visibility, and control over their submissions information. Content creators securely access and contribute to documents from any location, at any time, and on any device.

While managers track the progress of submission documents through actionable reports and dashboards, mitigating risks to submission timelines. And with a global system, companies establish greater control over documents that affiliates submit to local authorities.

Vault Submissions is part of the Veeva Vault RIM suite of applications. The suite provides fully unified regulatory information management (RIM) capabilities spanning submission document management, submission archiving, health authority correspondence and commitments, and product registration management.

Extensible Content Model

Vault Submissions supports and extends the content models needed by organizations around the world. This allows your content taxonomy (document types, subtypes, properties, etc.) to align with industry best practices, like the DIA EDM Reference Model, and be extended to meet your specific business needs.

Submission Binder Templates

Create binder templates with pre-configured planned documents and your Microsoft Word® templates to streamline content into defined submission structures. Then auto-populate document names and metadata fields based on binder values to further reduce manual overhead.

Master and Regional Dossiers

Vault Submissions can meet the needs of global publishing teams and regional affiliates with the flexibility to support all major filing types and rest-of-world needs. Repurpose submissions globally by creating copies that maintain document relationships and allow country-specific modifications.

Robust Lifecycle Management

Flexible workflows and lifecycles guide the authoring, reviewing, and approving of submission content. Authorized individuals can easily change in-process flows by adding, removing, or emailing participants. Country specific actions accommodate regional variations in global processes.

Global Access and Collaboration

Vault Submissions combines the ease-of-use of the consumer web with the stringent control required for validated systems. Authorized users log in via the web to a single, secure, cloud location, eliminating the need to bring users behind corporate firewalls or issue laptops, network IDs, or tokens.

Real-time Collaborative Authoring

Work fast and in parallel during crunch times. Seamless integration between Vault and Microsoft Office Online provides simultaneous authoring for real-time compliant collaboration.

Auto-generation of 2253 Forms

Auto-populate 2253 forms based on the promotional materials within a binder and related document metadata. If your organization also uses Vault PromoMats, Vault ensures proper attribute mapping and where appropriate, retains previously entered fields and picklist values.

Submission-ready Rendering

Vault automatically renders all documents with the correct PDF standards for submission publishing. Links in a document's source file are rendered as blue clickable text, and users can navigate web links, cross references, and tables of contents directly from the viewer—eliminating the need to download files when viewing submission content.

Veeva Vault Submissions

Breakthrough Usability

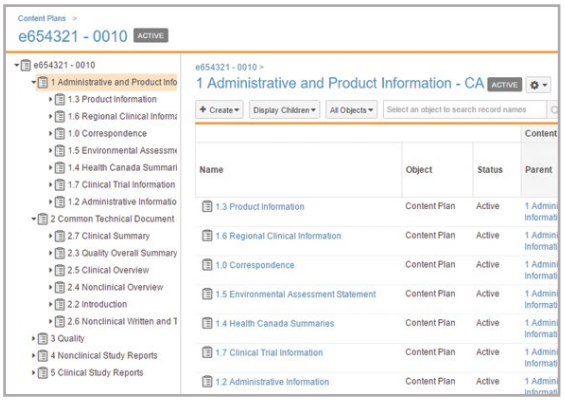
Vault provides a clean, intuitive interface that is easy to navigate and requires minimal training. The user experience is modeled after consumer websites like Amazon.com and LinkedIn and is updated as needed to stay current and fast.

Real-time Visibility

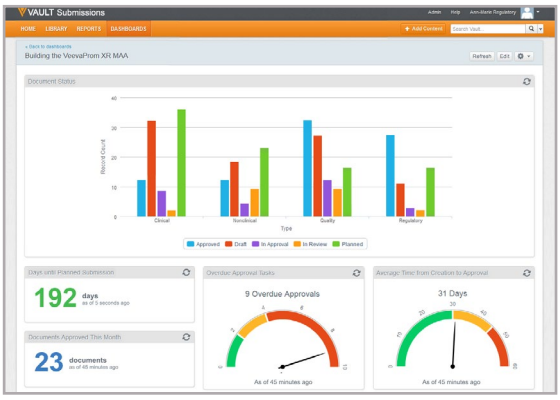
In any regulatory environment, it is critical to know what content exists, what state it is in, and where it has been used. Users drill down through real-time, interactive reports to answer questions about progress and readiness.

Affordable for All

With Vault Submissions, there are no servers to buy or maintain, no software upgrade projects, and system validation costs are dramatically reduced. And with scalable pricing, Vault Submissions is affordable for even the smallest organizations.



Configurable submissions content plans define what's needed so you know what's missing.



Interactive dashboards help managers identify and remedy process bottlenecks.

Solving the Affiliate Challenge

Globalization is increasing the complexity of regulatory information management. Many companies have difficulty recording and reporting what affiliates and distributors send to local health authorities. Status updates are often collected via email and manually recorded in spreadsheets. Affiliates spend hours duplicating data entry, updating status reports, and responding to questions from headquarters.

Vault Submissions addresses these challenges with a global system for content distribution and tracking, enabling you to:

- Increase visibility into documentation sent to local authorities.
- Ensure the use of current approved materials.
- Reduce affiliate time spent on non-value add activities.
- Improve adherence to country-level regulations and commitments.

How Vault Helps

- An intuitive interface and reliably high performance enable casual users to input documents and updates directly into Vault.
- Predefined distribution workflows ensure activities are compliant with SOPs.
- Affiliate-specific views, searches, and reports improve usability and minimize the need for training.
- Integrated reporting eliminates manual recordkeeping and auto-generates compliance documentation.
- Flexible data models and security accommodate local variations to enable system consolidation.

Submission Content Across the Enterprise

When used in conjunction with other Vault applications, such as Vault eTMF and Vault QualityDocs, Vault Submissions provides additional efficiencies and control over submission documents. A number of cross-Vault capabilities make life easier for the regulatory team. Cross-Vault search empowers users to find authorized content from other departments. CrossLink documents can be statically or dynamically linked to source materials such as clinical documents, manufacturing details, SOPs, and promotional materials. The "My Vaults" page displays open tasks across Vaults, so other Vault users see a visual reminder of outstanding tasks from regulatory. Taken together, the cross-Vault capabilities streamline interactions between departments, enabling each group to manage content within their own context, while maintaining a single source of truth across the enterprise.