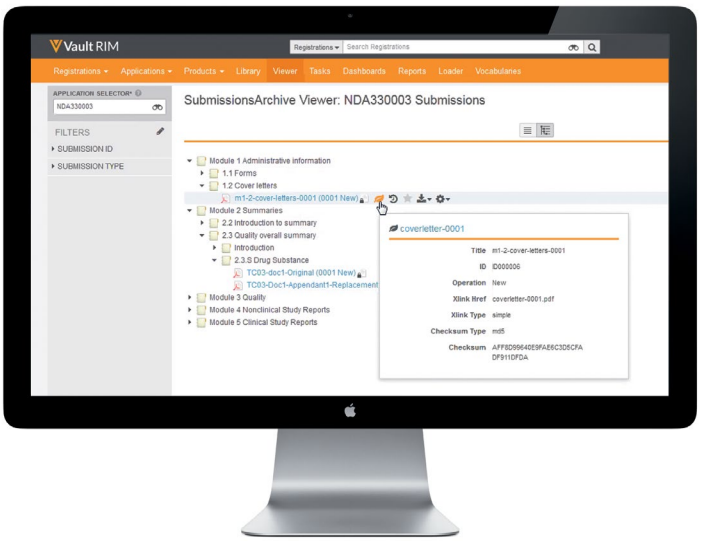
Datasheet

Veeva Vault Submissions Archive

An authoritative source for regulatory submissions around the world.



Veeva Vault Submissions Archive makes it easy to find the right information. Store eCTD and non-eCTD electronic submissions (NeeS) in a validated cloud environment, and link health authority correspondence to related submissions for a complete view of regulatory communications.

A high-performance cloud architecture makes access to published submissions fast and easy for authorized users. Affiliates can download submissions or submission components for reuse in local markets and upload submissions made to local health authorities.

Vault Submissions Archive will allow you to import submissions directly from file shares while preserving the eCTD XML backbone, folder structure, and inter-document hyperlinks. Users can navigate documents exactly as they were submitted to regulatory agencies and directly from the repository without needing to download files. An integrated eCTD viewer provides current, sequential, cumulative, and regulatory action views so users can quickly navigate the full lifecycle of an application.

Key Business Benefits

- **A global, authoritative source:** Access submissions and health authority communications from anywhere in the world.
- **Right content to the right people:** Easily manage access control to ensure people see only what they need.
- **Faster responses to health authorities:** Quickly locate historic submissions including those filed by regional offices or local affiliates.
- **Increased agility:** Use the full Vault RIM Suite for complete traceability—from planning to source content, published outputs, and health authority interactions.

Veeva Vault Submissions Archive

Features

eCTD and Non-eCTD Import

Import final submission packages for your records and future reference. Extract and normalize data from the XML to ensure greater accuracy.

Integrated Viewer

An integrated, cloud-based viewer for eCTD, NeeS, and legacy submission formats reduces the number of tools on the regulatory desktop.

PDF Link Navigation

Navigate PDF hyperlinks across documents within a submission, across submissions, and even across applications. There's no need for separate tools, file shares, or downloading files.

Full Lifecycle Viewing

View the complete dossier lifecycle with current, sequential, and regulatory action views. View cumulative changes for each document.

Dynamic Access Control

Use rules-based access control to dynamically calculate permissions that ensure people can see only what they need—and nothing else.

Dashboards and Reports

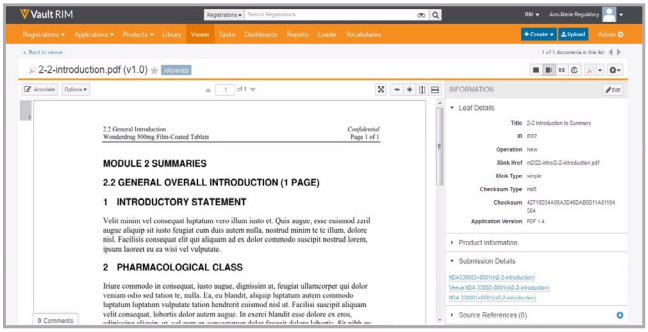
Easy, self-serve reporting shows historic submissions by any combination of attributes including: product, submission type, country, manufacturer, and more.

De-duplicate Documents

Documents used in multiple submissions are stored once and only once, yet are displayed with correct leaf details and other metadata for each submission.

Smarter Navigation Display

Eliminate the navigation challenges associated with minor metadata variations, such as duplicate 5.2.3 headings when field entries are not identical.



Get a complete view of where a document is used, including direct links to each submission.

View a document's complete history of lifecycle operations.

Veeva Vault RIM Suite

Veeva Vault RIM Suite unifies regulatory information management (RIM) capabilities on a single cloud-based platform for managing product registrations, submission documents, dossier publishing, health authority correspondence and commitments, and archived dossiers.

In today's fragmented RIM environment, with separate tools for each function and different systems in each region, it is impossible for organizations to respond quickly to regulatory events or information requests. Veeva's unified RIM suite delivers the data quality, visibility, and global alignment needed to transform regulatory processes. Only with a unified RIM solution can companies become more agile and maximize the value of their product portfolio.