

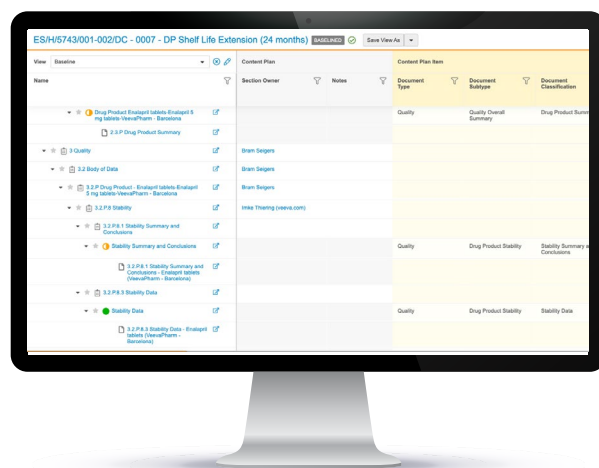
Veeva Vault RIM

Submission Content Plans

Streamline submission content planning and management to save significant time and effort

Submission content plans are a unique feature of the Veeva Vault RIM Platform that enables organizations to actively create and associate submission documents, track submission metadata, manage status and approvals, and assign responsible users to specific content without having to switch between multiple systems, use manual spreadsheets, or develop a homegrown tracking system.

With submission content plans, organizations can dramatically streamline the first three steps of any submission management process: content planning, document creation and collection, and tracking plan completion.



Benefits

- **Usability:** Submission content plans provide a visual and dynamic layout from which content managers can easily view and update the current status
- **Increased productivity:** Managers can create new documents when needed, assign ownership of content, link existing documents to the plan, and take immediate action to facilitate plan completion
- **Save time:** Regulatory project managers can save significant time by reducing effort around importing documents, keeping data up to date, and assigning ownership to documents to specific people
- **Reportability:** Regulatory stakeholders can pull dynamic, real-time reports and dashboards to see document data and status to make informed decisions

Submission Content Plans

Dynamic Content
Planning

Unified Document
Management

Streamlined Submissions
Publishing and Archiving

Dynamic Content Planning

Reusable submission content plans are easy to adapt to any submission type. Content plan templates take into account submission information like country, region, submission type, involved product, and other regional requirements. They are also fully configurable to meet specific needs. The plan also includes placeholders for direct links to required documents as they are assembled.

Users can also track important information about content plan sections and expected documents including planned document approval date, actual approval date, assignees and owners, or additional eCTD metadata such as XML operators. Many of these data points are updated in real-time, eliminating the possibility of human error and ensuring faster time to submission.

Regulatory project managers can also use the submission content plan to filter on specific data fields, such as document type, owner, due date, status, etc. Dashboards, reports, and submission content views can give managers rapid insight into the overall status and what needs to be done next.

Unified Document Management

By combining submission content plans with relevant documents on the same unified platform, regulatory teams can instantly create new documents using authoring templates, track the status of missing documents, and ensure that the latest versions of documents are being used at all times.

With automatic document matching, Vault will match and link existing documents or newly created documents to your content plan using applicable matching rules based on section information and document properties, saving time and effort.

Submission documents can also be added by simple drag and drop from the Vault Library directly to the submission content plan.

Streamlined Submissions Publishing and Archiving

For organizations working with a publishing vendor or a 3rd party publishing tool, the submission content plan can be converted into a binder and the plan itself can be exported as a spreadsheet to then sent to partners. Once the submission is complete, organizations can archive their submissions manually with Veeva Vault Submissions Archive.

For organizations with Veeva Vault Submissions Publishing enabled, the submission content plan effectively works as your eCTD submission assembly. Vault Submissions Publishing uses all the information in the content plan to automatically generate and update the submission XML backbone. Therefore, they can take advantage of a continuous submission process where XML generation and validation occurs behind the scenes, dramatically speeding up submission delivery. The published output is automatically sent to Vault Submissions Archive and populated in the submission viewer.

From building the plan, to attaching the first document, through finalizing the submission, submission content plans have made the submission collection process more structured and streamlined. Organizations can now create, refine, and compile all submission aspects they need to satisfy regulatory requirements in a dynamic, configurable, and efficient manner.

Veeva Vault RIM Platform

Submission content plans are a key feature of Vault Submissions, which is part of the Veeva Vault RIM Platform.

Learn more: To see Veeva's submission content plans in action, [watch this demo](#).