

General Service Description

This Service Description Document gives a high level description of the Veeva Vault products available from Veeva Systems. To see which products you have subscribed, please refer to your Order Form. To see the legal terms of your agreement, please refer to your Veeva Systems Master Subscription Agreement (the "Agreement"). For a more detailed description of how your Veeva Service works, please see the documentation of the Veeva products you have purchased.

Veeva Vault Service

The Veeva Vault Service ("Vault Service") is a set of software programs ("Vault Software") that are built upon the Veeva Vault platform. Customer data is stored in the Veeva Vault data center and accessed directly by Vault Software and supporting third party applications using the Veeva Vault services architecture and API.

Product List

The Veeva Vault Service currently includes the following products:

Vault Platform Application

- Vault Platform Base
- Vault Platform Full User

Vault PromoMats Application

- Vault PromoMats Base
- Vault PromoMats Full User

Vault Submissions Application

- Vault Submissions Base
- Vault Submissions Full User

Vault MedComms Application

- Vault MedComms Base
- Vault MedComms Full User

Vault QualityDocs Application

- Vault QualityDocs Base
- Vault QualityDocs Full User

Vault eTMF Application

- Vault eTMF Active Site
- Vault eTMF Archived Site

Multichannel Vault

- Multichannel Vault Full User
- Approved Email Integration
- Engage Integration
- CLM Integration

Vault Add-On Products

- Read-only User
- External User

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- Vault 10K Document Bundle
- Vault Config Sandbox
- Vault Investigator Portal Site
- Web Distribution

Purchase of one Vault application entitles the customer to one Production vault and three Config Sandbox vaults:

Production vault – A Production vault contains content, configurations (document type model, properties, lifecycles, workflows, catalogs, security, etc.), users, and functionality used in the customer's ongoing business. The Production vault is also referred to as a "customer vault."

Config Sandbox vault – A Config Sandbox vault is used for testing, training, or development. It can contain all the configurations and functionality required to support the customer's business. It may not be used as a production environment and is limited to 1,000 documents.

Vault Platform Application

Product Description: Vault Platform Base

The Vault Platform Base provides the software and hardware environment to run the Vault Platform application. One Vault Platform Base license is required for each new Platform customer vault. A user license must then be added to the Vault Platform Base for each user that will be using that specific customer vault. Add-On products can optionally be added to the Vault Platform Base.

The Vault Platform Application has been designed with regulated system compliance in mind and includes robust document, system and user audit trails in accordance with industry guidance, such as 21 CFR Part 11.

Product Description: Vault Platform Full User

The Vault Platform Full User ("Platform Full User") is designed for any user that requires the ability to store, search, review, approve and otherwise manage regulated content. The Platform Full User license includes the following:

1,000 Documents/Full User

Each Platform Full User license provides storage for 1,000 documents. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple versions and renditions. This storage is pooled across all licensed Full Users in the assigned customer vault.

Content Management

Platform Full Users can create new documents in the Vault Service by importing files, by creating placeholder documents, or by copying existing documents. Upon creation, the Vault Software will create a rendition of the file for viewing and annotations. Platform Full Users can then specify relevant document properties, role-based document access, additional renditions, and relationships between documents. Platform Full Users may subsequently update document properties and version content or delete documents in accordance with a document's security policy.

Searching & Viewing

Platform Full Users can search across content and properties within their specific customer vault for all documents they have permission to view. This is presented to the users through a type-ahead search bar and includes the ability to refine search results based on search facets. Platform Full Users can also use the same facets to narrow the results when browsing a list of documents without having to execute a search. Platform Full Users can view document properties and content for any document found via a search.

Reports

Platform Full Users can view reports they have created or have been shared with them. Document-based reports will only include documents for which the user has access. Platform Full Users can refine report results through additional filtering and can export reports to CSV or Excel for further processing. Platform Full Users can also

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create reports using a visual report builder, save the report for future use, and share the report with other Platform Full Users.

Binders

Platform Full Users can create binders; update binder properties; add, move, or remove documents from Binders; and navigate a Binder structure.

Lifecycles & Workflows

All documents within the Vault Service are assigned a lifecycle based on document properties. Every lifecycle contains different lifecycle states that have specific security settings, available set of workflows, executable user actions, validation logic, and automatic tasks. Platform Full Users can send documents through workflows to users for review and approval. Workflow task recipients are alerted to new tasks on both their home page and through email notifications and are guided through to completion of each task.

API Access

The Vault Service provides a Web Services API that allows search, view, create, update, and delete functions on documents. The API must be authenticated as a Platform Full User and API results will be delivered based on the user's security.

Compliance

All actions affecting documents are tracked within the document's audit trail. The audit trail can be viewed and filtered on-line or can be exported to CSV for further analysis. The Vault Software provides E-Signature capabilities through a specific workflow task type. The results of the E-Signature are tracked in the document's audit trail. Non-document actions like failed login attempts as well as configuration changes are tracked in the System Audit Trail. The System Audit Trail is available to users with administrator roles (business administrators and system administrators).

Administration

Platform Full Users with a System Administrator role will be able to configure their specific customer vault, including creation of users and groups; modification of the document types and properties; configuration of workflows and document lifecycles; and maintenance of picklists, catalogs, and other system settings. Platform Full Users with a Business Administrator role will be able to manage picklists and catalogs and will be able to view other configuration settings.

Vault PromoMats Application

Product Description: Vault PromoMats Base

The Vault PromoMats Base provides the software and hardware environment to run the Vault PromoMats application. One PromoMats Base license is required for each new customer vault running the Vault PromoMats application. A PromoMats user license must then be added to the Vault PromoMats Base for each user for that specific customer vault. Add-On products can optionally be added to the Vault PromoMats Base.

Product Description: Vault PromoMats Full User

The Vault PromoMats Full User ("PromoMats Full User") is designed for any user that manages regulated promotional materials. The PromoMats Full User license includes the following:

1,000 Documents/Full User

Each PromoMats Full User license provides storage for 1,000 documents. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple versions and renditions. This storage is pooled across all licensed PromoMats Full Users in the customer's vault.

Vault Platform Full User Functionality

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The PromoMats Full User license contains all the functionality provided to a Platform Full User (Content Management, Searching & Viewing, Reports, Binders, Lifecycles & Workflows, Compliance, Web Services API, and Administration) in addition to the following PromoMats-specific functionality:

Vault PromoMats Standard Document Types and Properties

The Promotional Materials, Reference, and Claim document types and associated properties and processing logic are only available with the PromoMats application.

Vault PromoMats Administration Area

The PromoMats application includes specific administration capabilities such as the ability to default workflow roles by country and product.

Vault Submissions Application

Product Description: Vault Submissions Base

The Vault Submissions Base provides the software and hardware environment to run the Vault Submissions application. One Submissions Base license is required for each new customer vault running the Vault Submissions application. A Submissions user license must then be added to the Vault Submissions Base for each user for that specific customer vault. Add-On products can optionally be added to the Vault Submissions Base.

Product Description: Vault Submissions Full User

The Vault Submissions Full User ("Submissions Full User") is designed for any user that managing clinical documentation. The Submissions Full User license includes the following:

1.000 Documents/Full User

Each Submissions Full User license provides storage for 1,000 documents. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple versions and renditions. This storage is pooled across all licensed Submissions Full Users in the customer's vault.

Vault Platform Full User Functionality

The Submissions Full User license contains all the functionality provided to a Platform Full User (Content Management, Searching & Viewing, Reports, Binders, Lifecycles & Workflows, Compliance, Web Services API, and Administration) in addition to the following Submissions-specific functionality:

Vault Submissions Standard Document Types and Properties

The Clinical, Nonclinical, Quality, Regulatory, Literature, and Pharmacovigilance document types and associated properties and processing logic are only available with the Submissions application.

Vault Submissions Administration Area

The Submissions application includes specific administration capabilities for the Submissions application.

Vault MedComms Application

Product Description: Vault MedComms Base

The Vault MedComms Base provides the software and hardware environment to run the Vault MedComms application. One MedComms Base license is required for each new customer vault running the Vault MedComms application. A MedComms user license must then be added to the Vault MedComms Base for each user for that specific customer vault. Add-On products can optionally be added to the Vault MedComms Base.

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Product Description: Vault MedComms Full User

The Vault MedComms Full User ("MedComms Full User") is designed for any user that manages regulated medical information. The MedComms Full User license includes the following:

1,000 Documents/Full User

Each MedComms Full User license provides storage for 1,000 documents. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple versions and renditions. This storage is pooled across all licensed MedComms Full Users in the customer's vault.

Vault Platform Full User Functionality

The MedComms Full User license contains all the functionality provided to a Platform Full User (Content Management, Searching & Viewing, Reports, Binders, Lifecycles & Workflows, Compliance, Web Services API, and Administration) in addition to the following MedComms-specific functionality:

Vault MedComms Standard Document Types and Properties

The Publications, Response, Reference Document, and Medical Communications document types and associated properties and processing logic are only available with the MedComms application.

Vault MedComms Administration Area

The MedComms application includes specific administration capabilities for the MedComms application.

Vault QualityDocs Application

Product Description: Vault QualityDocs Base

The Vault QualityDocs Base provides the software and hardware environment to run the Vault QualityDocs application. One QualityDocs Base license is required for each new customer vault running the Vault QualityDocs application. A QualityDocs user license must then be added to the Vault QualityDocs Base for each user for that specific customer vault. Add-On products can optionally be added to the Vault QualityDocs Base.

Product Description: Vault QualityDocs Full User

The Vault QualityDocs Full User ("QualityDocs Full User") is designed for any user that manages regulated quality documents. The QualityDocs Full User license includes the following:

1,000 Documents/Full User

Each QualityDocs Full User license provides storage for 1,000 documents. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple versions and renditions. This storage is pooled across all licensed QualityDocs Full Users in the customer's vault.

Vault Platform Full User Functionality

The QualityDocs Full User license contains all the functionality provided to a Platform Full User (Content Management, Searching & Viewing, Reports, Binders, Lifecycles & Workflows, Compliance, Web Services API, and Administration) in addition to the following QualityDocs-specific functionality:

Vault QualityDocs Standard Document Types and Properties

The Site Master File, Policies & Process, Equipment, Raw Materials, Packaging, Master Control Records, Batch Records, Laboratory Records, and Change Management document types and associated properties and processing logic are only available with the QualityDocs application.

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Vault QualityDocs Administration Area

The QualityDocs application includes specific administration capabilities for the application.

Vault eTMF Application

Product Description: Vault eTMF Active Site

The Vault eTMF Active Site license provides the software and hardware environment to run the Vault electronic Trial Master File (eTMF) application. A minimum of one Active Site ("site") license is required for each active study defined within the Vault eTMF application. A site is considered active if:

- 1) It is part of a study that is marked as 'Active'
- 2) Is not marked as 'Inactive' (i.e. a site within an active study that has not enrolled a patient and has been dropped from the study by marking it as 'Inactive')

A site is defined within the context of a study, thus a site that is used across several studies would need a license for each study it is associated with. There is no limit to the number of users that can use the Vault eTMF application. Add-On products can optionally be added to a Vault eTMF Active Site .

The eTMF Active Site license includes the following:

10,000 Documents/Site

Each eTMF Active Site license provides storage for 10,000 documents. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple versions and renditions. This storage is pooled across all licensed, active sites in the customer's vault.

Vault eTMF Functionality

The eTMF Active Site license contains, for all users, all the functionality available to a Platform Full User (Content Management, Searching & Viewing, Reports, Binders, Lifecycles & Workflows, Compliance, Web Services API, and Administration) in addition to the following eTMF-specific functionality:

Vault eTMF Standard Document Types and Properties

eTMF Standard Document Types reflect the DIA TMF Reference Model. These include the Trial Master File, Trial Management, Central Trial Documents, Regulatory, IRB/IEC and other Approvals, Site Management, IP and Trial Supplies, Safety Reporting, Centralized Testing, Third Parties, Data Management, and Statistics. These document types and associated properties and processing logic, including TMF Study binders, are only available with the eTMF application.

Vault eTMF Administration Area

The eTMF application includes specific administration capabilities, such as the ability to define Studies, Study binders, Sites, and Locations.

Product Description: Vault eTMF Archived Site

The Vault eTMF Archived Site license provides the software and hardware environment to run the Vault electronic Trial Master File (eTMF) application. An Archived Site license is required for each archived site within an archived study. A minimum of one Archived Site license is required for each archived study. An archived site is defined within the context of an archived study, thus a site that is used across several archived studies would need a license for each study it is associated with. A site is considered archived if the status of its study is "Archived" or "In Migration". Add-On products can optionally be added to the Vault eTMF Archived Site Base.

The eTMF Archived Site license is identical to the eTMF Active Site license with the following exceptions:

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Vault eTMF Functionality

- For documents related to 'In Migration' studies; the license includes all functionality available to a Platform Full User
- For documents related to 'Archived' studies; the license permits users to edit role-based document access, document properties, and delete documents in accordance with a document's security policy. Users cannot create new documents for the archived study and sites in the Vault Service by importing files, by creating placeholder documents, or by copying existing documents.

Vault eTMF Administration Area

For archived studies, study and site catalog data cannot be edited.

Enterprise License Agreements

Some Vault applications are available with Enterprise Licenses Agreements (ELA) to avoid the administration of Users and to provide a fixed cost over multiple years. An ELA will have specific restrictions listed in the Specific Restrictions area of the Order Form. These restrictions may be based on revenue and/or employee count and/or maximum number of Users and may include geographic restrictions on Users. The ELA includes the appropriate Vault Base.

An Enterprise license is restricted to the specific business process of the application and cannot be used to build new applications.

Enterprise License Product List

The follow Enterprise License products are available.

- Vault PromoMats ELA
- Vault MedComms ELA
- Vault QualityDocs ELA
- Vault Submissions ELA

Product Description: Multichannel Vault

The Vault Multichannel License provides the software and hardware environment to support Approved Email, Engage, or CLM integrations. One Multichannel Full User license is automatically included that can leverage any of the integrations. Additional licenses can be purchased as needed.

Product Description: Multichannel Vault Full user

The Multichannel Vault Full User is designed for any user that manages Approved Email, Engage, or CLM content from within Vault and uses the Approved Email, Engage, or CLM integrations to manage and publish content.

5.000 Documents/Full User

Each Multichannel Vault Full User license provides storage for 5,000 documents. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple attachments, versions, and renditions. This storage is pooled across all licensed Multichannel Full Users in the customer's vault.

Multichannel Vault Full User Functionality

The Multichannel Vault Full User license contains all the functionality provided to a PromoMats Full User (Content Management, Searching & Viewing, Reports, Binders, Lifecycles & Workflows, Compliance, Web Services API, and Administration) in addition to the integration-specific functionality:

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Product Description: Approved Email Integration

The Vault Approved Email Integration is designed for any Multichannel Full User to manage Approved Email content within Vault and publish Approved Email content to Veeva CRM. The Approved Email integration includes the following:

Vault Approved Mail Standard Document Types and Lifecycles

In a vault with Approved Email enabled, the following standard document types will be available: Email Template, Email Fragment, Master Email Fragment, and Template Fragment. All Approved Email document types will follow the Approved Email standard lifecycle.

Manage Approved Email Assets

Vault will allow the Multichannel Full User to upload HTML source documents for the Template, Fragment and template fragment document types. The user will be able to add a zip file of images as "Assets" to Email template, Email Fragment and Template Fragment. These images will be referenced within the content of the email template. In Vaults with Approved email turned on, users will be able to identify if the viewable rendition will be downloadable from the Approved Email external landing page.

Product Description: Vault Engage Integration

The Vault Engage Integration is designed for any Multichannel Full User that manages Engage content within Vault and pushes content to Veeva Engage. The Engage Integration includes the following:

Vault Engage Standard Document Types, Objects and Lifecycles User Actions

In a vault with Engage enabled, the standard document types Multichannel Presentation and Multichannel Slide will be available. The following Key Message and Website standard objects will also be available. The Send to Engage and Create Presentation user actions will be available to be added to any lifecycle state.

Managing Engage Assets

The Multichannel Full User will be able to publish documents with a Distribution Package rendition to Engage and withdrawal previously published content from Engage.

Product Description: Vault CLM Integration

The Vault CLM Integration is designed for any Multichannel Full User that manages CLM content within Vault and pushes content to CLM. The CLM Integration license includes the following:

Vault CLM Standard Document Types, Objects and Lifecycles User Actions

In a vault with CLM integration enabled, the following standard document types will be available: Multichannel Presentation and Multichannel Slide. The following standard objects will also be available: Survey, Directory, and Distribution. The Send to CLM user action will be available to be added to any lifecycle state.

Managing Engage Assets

The Multichannel Full User will be able to publish documents to CLM and withdrawal previously published content from CLM.

Vault Add-On Products

Product Description: Vault External User

The Vault External User is designed for users that do business with companies that are using a Vault application. PromoMats External User licenses do not increase the number of documents that may be stored in a specific customer's vault. It is applicable for all Vault applications except eTMF, which is licensed by site, not users.

The External User has the same functionality as a Full User except:

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- They cannot be a business administrator or a system administrator (no access to configuration functionality)
- Cannot access or create reports
- Cannot be a user of the Web Services API
- Cannot execute an Electronic Signature
- Cannot be an employee of or share an email domain with the Vault customer.

Product Description: Vault Read-only User

The Vault Read-only User is designed for users that only need to search and view regulated documents and participate in read & understood tasks (within applications that support read & understood workflows). It can be added to Platform or any application-specific customer vault except eTMF. Read-only User licenses do not increase the number of documents that may be stored in a specific customer's vault.

Read-only Users have search & view access to binders, document properties, content, renditions, and the document's audit trail. They do have read-only access to Vault through the API. Read-only Users have no access to administrative functions or reports. Read-only Users may not update document properties, content, relationships, renditions, or annotate documents. Read-only Users may not initiate workflows nor may they participate in any workflow task other than acknowledging a "read & understood" task. Currently "read & understood" tasks are only supported in eTMF and QualityDocs.

Product Description: Vault 10K Document Bundle

The Vault 10K Document Bundle provides storage for an additional 10,000 documents within any specified customer vault, regardless of application. It cannot be split across vaults. The 10,000 documents are in addition to the document storage allotment provided to each Full User license. A document consists of metadata and a corresponding file (unless it is a placeholder) and may contain multiple versions and renditions.

Product Description: Vault Config Sandbox

The Vault Config Sandbox license provides an additional Config Sandbox vault to any Vault Base license. This Config Sandbox Vault is a vault that is used for testing, training, or development. It can contain all the configurations and functionality required to support the user's business. It may not be used in a production environment and is limited to 1,000 documents. This Config Sandbox Vault will be in addition to the three Config Sandbox Vaults automatically provided for a Vault Base license.

Product Description: Vault Investigator Portal Site

The Vault Investigator Portal Site license is an add-on product for Vault eTMF Active Site licenses. One Vault Investigator Portal Site license is required for each active site ("site") that is using or is expected to use the Vault Investigator Portal application. As with Vault eTMF Active Site base licenses, a site that is used in several studies would need a Vault Investigator Portal license for each study in which the site is participating.

Users for the Vault Investigator Portal must be created in the Vault eTMF application with the specific user type of 'Portal-only Users'. Portal-only Users have access to the same Content Management functionality: search, view, upload, and download. Portal-only Users may participate in workflow tasks. Portal-only Users have no access to administrative functions or reports. Portal-only Users may not update document properties, relationships, renditions, or annotate documents.

Product Description: Web Distribution

The Vault Web Distribution License provides the software and hardware environment to support anonymous access from a Veeva Vault using the API or the Approved Viewer. Vault Web Distribution can only be enabled on PromoMats or MedComms vaults.

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100,000 Anonymous Document Views

The Web Distribution license allows 100,000 anonymous document views per year through the API or the Approved Viewer. Only steady state documents may be viewed through the Approved Viewer. All anonymous document views through the Web Distribution license will be tracked in the audit trail.

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