



Vault OLS 19R3 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault OLS applications in 19R3 that may affect a customer's vault. We release a version of the RIA in advance of the general release. On November 5th, the OLS Validation Impact Assessment, which contains validation information for new features in 19R3, will be available in your VeevaDocs vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. On October 28th, the [19R3 Release Notes](#) will be available. Refer to the release notes for additional details about each feature and data model changes in your vault. Refer to the [Vault 19R3 Release Impact Assessment](#) for validation information for the Vault Platform.

Revision Date: 28 Oct 2019

This feature list is subject to change prior to the 19R3 release. We will begin tracking changes on October 14th, 2019.

Feature:	Name of the feature introduced in 19R3
Feature Risk:	Feature risk analysis takes into account data integrity, security, and confidentiality assuming the feature is turned on (either automatically or via configuration). Veeva performs validation testing on all High and Medium feature risk items.
<i>High</i>	May affect security, patient confidentiality, application areas that support GXP functions (audit trails, eSignature, etc.) or other ERES controls data
<i>Medium</i>	May affect core application functions (workflows, revision history, etc.)
<i>Low</i>	May affect metadata/notifications
<i>N/A</i>	The feature is a minor UI enhancement and not a functional change. The feature has no validation impact.
Enablement Setting:	Indicates whether the feature is available automatically, requires configuration by an Admin (an Admin area checkbox or a more complex setup), or must be enabled by contacting Veeva Support. Note that in some cases, an Auto-on feature is dependent on another feature that must be enabled or configured. In other cases, individual users (not Admins) need to perform some setup, for example, with new Reporting capabilities that require creation of a new report.
Default Impact:	Impact to business users and processes at Day 1 if no configuration occurs
<i>Visible to All Users</i>	Automatically on and visible to both Admins and end users
<i>Visible to Admins Only</i>	Only visible to Admins, or it requires configuration by an Admin before it is available to end users
<i>None</i>	Not visible in Vault unless enabled by Support

OLS	Application	Feature Name	Feature Risk	Enablement	Default Impact	Description
	RegulatoryOne	Formula Compliance by Internal & Regulatory Agency Standards	High	Configuration	Visible to Admins Only	This feature allows Admins to define a list of ingredient concentration restrictions based on internal standards and regulatory agency standards. Users can then perform a check, based on the Admin-defined list, that a submission's product ingredients and their specified concentrations are compliant with the list of concentration restrictions for the product type, the ingredient's function within the product, and market location.
	QualityOne	5 Whys Analysis	High	Configuration	Visible to Admins Only	This feature allows users to create a visual representation of a root cause analysis using the standard 5 Whys methodology. Enables users to determine the root cause of a problem and track all questions and answers in a tree diagram.
	QualityOne	Extensible Controlled Copy for QualityOne	High	Support	None	Extensible Controlled Copy allows Admins to configure Vault to perform the same functions as the legacy Controlled Copy feature, while also providing for more advanced configurations and record tracking. This feature requires configuration after Support enables it.
	Vevea Claims	Comments on Claims	Medium	Configuration	Visible to Admins Only	This feature allows multiple stakeholders to collaborate on claim records. Users can notify other users via @mentions, fostering engagement and helping to create a consolidated space within the Veeva Claims application to capture feedback.
	Vevea Claims	Comments on Projects	Medium	Configuration	Visible to Admins Only	This feature allows multiple stakeholders to collaborate on project records. Users can notify other users via @mentions, fostering engagement and helping to create a consolidated space within the Veeva Claims application to capture feedback.
	Vevea Claims	Lightweight Project Management	Low	Configuration	Visible to Admins Only	This feature allows brand managers to initiate a project and group claims pertaining to a particular initiative in this project so that key R&D, regulatory, and

						legal stakeholders can track and work on the related claims as a group.
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Change Log

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Date	Change	Impact
28 Oct 2019	Added link to 19R3 Release Notes	The 19R3 OLS RIA now includes a link to the 19R3 Release Notes.
07 Oct 2019	Initial RIA Published	N/A

