

Vault CP&C 21R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault Consumer Products & Chemical (CP&C) applications in 21R1 that may affect a customer's vault. We release a version of the RIA in advance of the general release. The CP&C Validation Impact Assessment, which contains validation information for new features in 21R1, will be available in your VeevaDocs vault on March 22nd for QualityOne and April 5th for RegulatoryOne and Veeva Claims. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. On March 15th, the 21R1_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_21R1_Release_Impact_Assessment for validation information for the Vault Platform.

Revision Date: 15 Mar 2021

This feature list is subject to change prior to the 21R1 release. We will begin tracking changes on March 1st, 2021.

Feature:	Name of the feature introduced in 21R1					
GxP Risk:	GxP 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 GxP risk items.					
High	May affect security, patient confidentiality, application areas that support GxP functions (audit trails, eSignature, etc.) or other ERES controls data					
Medium	May affect core application functions (workflows, revision history, etc.)					
Low	May affect metadata/notifications					
N/A	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					
Visible to All Users	Automatically on and visible to both Admins and end users					
Visible to Admins Only	Only visible to Admins, or it requires configuration by an Admin before it is available to end users					
None	Not visible in Vault unless enabled by Support					

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
QualityOne	Inspection Sampling & Evaluation	High	Configuration	Visible to Admins Only	This feature allows the user to generate samples and define the success criteria for incoming, in-process, and outgoing inspections using a fixed count or percentage-based criteria.
QualityOne	QualityOne Mobile for iOS – Incident Management	High	Configuration	,	This feature allows users to submit incidents using the QualityOne Mobile for iOS.
QualityOne	COA Characteristic Matching Variant Enhancements (Synonyms Management)	Medium	Configuration	Visible to Admins Only	This feature allows Admins to configure more specific matching rules for characteristic matching variants.
QualityOne	Comments on Objects with User Mentions	Medium	Support		By mentioning users in comments, this feature allows and notifies multiple internal and supplier stakeholders to collaborate on various quality processes and records.
QualityOne	Incident Management Standard Object Enhancements	Low	Auto-on	Visible to Admins Only	This feature adds new fields to the HSE Event Object Model in QualityOne.
QualityOne	COA Header Ingestion Enhancements	Low	Configuration	Visible to Admins Only	This feature improves the accuracy of COA header ingestion.
QualityOne	Audit Checklist Enhancements for QualityOne Mobile for iPadOS	Medium	Auto-on	Visible to All Users	This feature allows users to be able to create one or more Audit Findings per question when responding to an Audit Checklist while using the QualityOne Mobile for iPadOS.
QualityOne	QualityOne: Root Cause Analysis support on NCR and HSE Event	Medium	Auto-on	Visible to All Users	This feature allows the ability to perform 5Whys Analysis from the NCR and HSE Event object.
QualityOne	Support for Multiple Findings on Audit Checklist Responses	Medium	Auto-on	Visible to All Users	This feature allows users to create one or more audit finding records from a checklist respondent UI when the checklist target object is Audit.
RegulatoryOne Registration & Dossier Management	Registration & Dossier Management Data Model	Low	Configuration		This feature provisions new objects for the Registrations & Dossier Management application.
RegulatoryOne Compliance Management,	Product Hierarchy Data Model	Low	Configuration	Visible to Admins Only	This feature adds standard objects to support the storing of complex hierarchical products.

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RegulatoryOne Registration & Dossier Management, RegulatoryOne Regulatory Documents, Veeva Claims				
Veeva Claims	Auto-Populate Local Pack Copy	Medium	Configuration	This feature allows users to generate a local pack copy from an existing global pack copy.
Veeva Claims	Self-Referencing Statement Records	Medium	Configuration	This feature allows users to store a statement's translation or dialect variation in the Statement Library.
Veeva Claims	Claim Creation Uniqueness Check	Medium	Auto-on	This feature prevents duplicate claim record creation when users manually create a claim record.
Veeva Claims	Pack Copy Hierarchy Viewer Enhancement	N/A	Auto-on	To ensure consistent performance, the Hierarchy Viewer displays a message to users instead of records if the total number of records in a hierarchy exceeds 5000.

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N/A

22 Feb 2021

Initial RIA Published