

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault Consumer Products & Chemical (CP&C) applications in 21R2 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 21R2, will be available in your VeevaDocs vault on July 16th for QualityOne and July 26th for RegulatoryOne and Veeva Claims. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. On July 6th, the <u>21R2 Release Notes</u> will be available. Refer to the release notes for additional details about each feature and data model changes in your vault. Refer to the <u>Vault 21R2 Release Impact Assessment</u> for validation information for the Vault Platform.

Revision Date:

06 Jul 2021

This feature list is subject to change prior to the 21R2 release. We will begin tracking changes on June 21st, 2021.

Feature:	Name of the feature introduced in 21R2	
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	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	
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CP&C	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	RegulatoryOne Registration & Dossier Management	Create Registrations in Bulk	Medium	Configuration		This feature provides users with the ability to create registrations for a registration item or a group of registration items from an event.
		Dynamic Template to Create Requirements	Medium	Configuration		This feature provides users with the ability to create a list of requirements from an Admin-configured template that can include tokens.
		Regulatory Request Management	Medium	Configuration		This feature allows the ability to create and respond to internal and external regulatory requests in a structured way.
		Training Management Phase 3	High	Configuration		This feature enhances QualityOne Training Management by including features such as eLearn, Facilitate & Substitute Training, Manager View, and more.
	QualityOne Mobile	QualityOne Mobile for iOS – Local Storage Support	High	Auto-on		This feature allows items to be stored locally on a device when attempting to submit an Incident or NCR when there is no active network connection. Users may attempt to resubmit manually when they move into an area with network coverage.
		QualityOne Mobile for iOS – Run User Actions on Submit	Medium	Auto-on		This feature allows users to run configured User Actions on NCR & HSE Incidents when submitting a record to Vault via QualityOne for iOS.
		QualityOne Mobile for iPadOS - Audit Checklist UI Enhancements	Low	Auto-on		This feature updates the QualityOne for iPadOS user interface (UI) of the Audit Checklist application.
		QualityOne Entry Action: Create Related Record	High	Configuration		This feature allows an entry action to automatically create related records when the source record reaches a certain Lifecycle State.
		Inspection & NCR Product Model Compatibility	Medium	Configuration		This feature updates the existing Inspection and NCR features to support both old and new product hierarchy data models.
	QualityOne	QualityOne Teams	Medium	Configuration		This feature allows users to assign individual work assignments to individual Quality processes within a defined list of

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					authorized users to perform a specified role on a record.
QualityOne	Incident Management - Track Labor Information	Low	Auto-on	Visible to Admins Only	This feature extends the existing Incident Management object model with a new Labor Information object that enables tracking of labor hours and headcount for employees and contractors.
QualityOne	Product Hierarchy Data Model for QualityOne	Low	Auto-on	Visible to Admins Only	This feature adds standard objects to support the storing of complex hierarchical products.
QualityOne	COA Textract Response File Download	Low	Configuration	Visible to Admins Only	This feature helps Admins retrieve detailed OCR data within their vault for complex matching rules configuration of header key value extraction.
QualityOne	HACCP Data Model	Low	Configuration	Visible to Admins Only	This feature will allow users to create and manage their Food Safety plans and Food Quality plans based on the HACCP method.
QualityOne	Support Localized Number Separator for COA	Low	Auto-on	Visible to All Users	This feature extends the support of various decimal and grouping separator formats when ingesting from COA documents.
Veeva Claims	Auto-Localize Pack Copy Enhancements	Medium	Configuration	Visible to Admins Only	This feature allows users to check for missing localizations before generating a local pack copy from an existing global pack copy. Admins can define the number of records to create localizations for based on the type of element.
Veeva Claims	Selective Creation of Local Adaptations from a Project	Medium	Configuration	Visible to Admins Only	This feature allows users to selectively control which countries to automatically create local adaptations for.
Veeva Claims	Auto-Create Element	Low	Configuration	Visible to Admins Only	This feature allows Admins to set up the auto-creation of a corresponding element after a claim reaches a specified lifecycle state.
Veeva Claims	Multi-Country Pack Copy Localization	Low	Configuration	Visible to Admins Only	This feature allows users to localize a global pack copy for multiple countries.

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Change Log				
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Date	Change	Impact		
06 Jul 2021	Added links to the 21R2 release notes.	The RIA now includes links to the 21R2 release notes.		
14 Jun 2021	Initial RIA Published	N/A		

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