

Vault CP&C 22R1 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in Vault Consumer Products & Chemical (CP&C) applications in 22R1 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 22R1, will be available in your VeevaDocs Vault by March 21st. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. On March 14th, the 22R1 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 22R1 Release Impact Assessment for validation information for the Vault Platform.

Revision Date: 14 Mar 2022

This feature list is subject to change prior to the 22R1 release. All changes after initial publication are listed in the Change Log. Updates will stop after April 23, 2022.

Feature:	Name of the feature introduced in 22R1				
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				

CP&C	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	QualityOne Station Manager	QualityOne Station Manager Enhancements	Medium	Auto-on		This feature adds a number of new features to QualityOne Station Manager such as: Custom URL & QR Code Support (including support for Document Categories), Sync Interval updates (including warnings for out-of-date devices), Record Based Categorization, Recent Documents enhancements, and application update enforcement.
	QualityOne Mobile	QualityOne Mobile for iOS Compatibility with Extended Product Hierarchy Model	Low	Configuration	•	This feature updates QualityOne Mobile for iOS to use the extended standard Product Hierarchy Data Model.
	QualityOne	External Collaboration Management on CAR	High	Configuration	,	This feature allows customers to automanage the creation, activation, and inactivation of user accounts for third-party organizations, allowing such organizations to collaborate directly in Vault while responding to CARs (SCARs).
	QualityOne	Related Record Setup Enhancements	Medium	Auto-on	,	This feature extends the Related Record Setup capability to allow Admins the flexibility of configuring the "Create Related Record" action on the "Create Record" Event Action.
	QualityOne	FSMA Supplier Verification (FSVP/SCAC)	Medium	Configuration		This feature supports FSMA requirements for both SCAC (Supply Chain Applied Controls) and FSVP (Foreign Supplier Verification Programs) by offering the ability to verify the supplier's capability of controlling both known or foreseeable hazards associated with the supplied material.
	QualityOne	Inspections Compatibility with Extended Product Hierarchy Data Model	Medium	Configuration	_	This feature updates QualityOne's Inspection Management to use the extended standard Product Hierarchy Data Model.
	QualityOne	QualityOne Team Enhancements	Medium	Configuration	•	This feature extends the QualityOne Team capability to allow Admins the flexibility of configuring Team roles and members.
	QualityOne	Risk Management: Detectability Support for	Medium	Configuration	Visible to Admins Only	This feature adds support for modeling Detectability as another axis of the Risk

	Qualitative & Quantitative Risk Matrices				Matrix. QualityOne users can create 3D risk matrices (Severity x Occurrence x Detectability) within their Vaults with this feature.
QualityOne	Admin Menu for Comment Setup	Low	Auto-on	Visible to Admins Only	This feature allows Admins to access the Comment Setup page from Admin.
QualityOne	Linking Quality & HSE Events to Risk Register	Low	Configuration	1	This feature allows users to link Quality and HSE Events to Risk Register.
QualityOne	Product Hierarchy Data Model Extension for Packaging & Materials	Low	Configuration	Visible to Admins Only	This feature provisions new objects in QualityOne to extend the standard product hierarchy data model.
QualityOne	Update View 5 Whys Analysis Action	Low	Configuration	Visible to Admins Only	This feature adds a new record action for viewing 5 Whys Analysis diagrams. The previous user action is still available as a legacy user action.
QualityOne	COA Ingestion Enhancements	Medium	Auto-on	Visible to All Users	This feature enhances the overall COA ingestion capability to accurately ingest a wider format of COA files and improve the user experience to define Matching Rules and Component Matching Variants.

CP&C	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	RegulatoryOne Registration & Dossier Management	Create Dossier Binder	Medium	Configuration		This feature enables users to create a binder for a Registration Item Requirement that includes a list of locked expected documents for a requirement while maintaining the requirement hierarchy as a hierarchy of folders.
		Generate Requirements for Registration Objective	Medium	Configuration		This feature allows Admins to configure the Generate Requirements action on the Registration Objective.
	RegulatoryOne Registration & Dossier Management	Local Impact Assessment	Medium	Configuration	•	This feature allows users to automatically find existing registrations for a Registration Item and set the regulatory process.
		Split Registration Items Enhancement: Recursion	Medium	Configuration		This feature allows Admins to configure the Split Registration Items action to create multiple related records recursively, such as kits that include a product in a product.
		Registration Item Hierarchy Viewer	Low	Configuration		This feature allows users to view related records in a hierarchy viewer, such as kits that include a product in a product.
	RegulatoryOne Registration & Dossier Management	Track Authority Questions	Low	Configuration		This feature gives users the ability to create Authority Questions using the standard Regulatory Request object.
	RegulatoryOne Compliance Management	Formulation Questionnaires	Medium	Configuration		This feature gives Public Safety and Regulatory Affairs (PSRA) users the ability to send targeted formulation questionnaires, such as Raw Material Questionnaires (RMQs), to their suppliers and the ability for those suppliers to respond without logging into Vault.
	RegulatoryOne Compliance Management	Formulation Composition Viewer Enhancements	Low	Configuration	,	This feature allows regulatory users to distinguish between hierarchical levels of a composition and to easily identify constituent chemicals that don't meet regulatory requirements.
	1 9 1	Enable Checklists in RegulatoryOne	Low	Auto-on	1	This feature enables Checklists in all RegulatoryOne Vaults.

Dossier Management, RegulatoryOne Regulatory Documents, Veeva Claims					
RegulatoryOne Compliance Management, RegulatoryOne Registration & Dossier Management, RegulatoryOne Regulatory Documents, Veeva	Product Hierarchy Data Model Extension for Packaging	Low	Configuration	Visible to Admins Only	This feature adds the Packaging, Product Packaging, and Packaging Composition objects to all RegulatoryOne Vaults.

CP&C	Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
	RegulatoryOne Compliance Management, RegulatoryOne Registration & Dossier Management, RegulatoryOne Regulatory Documents, Veeva Claims	Enable Checklists in RegulatoryOne	Low	Auto-on	,	This feature enables Checklists in all RegulatoryOne Vaults.
	RegulatoryOne Compliance Management, RegulatoryOne Registration & Dossier Management, RegulatoryOne Regulatory Documents, Veeva Claims	Product Hierarchy Data Model Extension for Packaging	Low	Configuration		This feature adds the Packaging, Product Packaging, and Packaging Composition objects to all RegulatoryOne Vaults.
	Veeva Claims	Auto-Populate Statement Translations for Local Adaptations	Medium	Configuration		This feature provides an action that automatically adds Statement translations to Local Adaptations.
	Veeva Claims	Dynamic Deep Copy Project	Medium	Configuration		This feature allows users to copy existing projects to create new Project records and gives users control over which Project relationships they want to copy over to the new record.
	Veeva Claims	Copied from Project Link	Low	Auto-on		This feature adds a new system-managed field to the Project object to indicate which project record the current record is copied from.
	Veeva Claims	Project Hierarchy Viewer	Low	Configuration		This feature enables users to navigate easily between different levels of a Project.
	Veeva Claims	Claims UX Enhancement	Low	Auto-on		This feature is comprised of minor improvements to the UX of existing Claims features.

Change Log

This feature list is subject to change prior to the 22R1 release. Change tracking is effective as of February 22nd, 2022.

Date	Change	Impact	
14 Mar 2022	Added link to the 22R1 release notes.	The RIA now includes a link to the 22R1 release notes.	
22 Feb 2022	Initial RIA published	N/A	