Veeva Vault Safety — 22R3 Release Impact Assessment

The Release Impact Assessment (RIA) documents the new capabilities introduced in the Vault Safety Suite 22R3 release that may affect a customer's vault. Refer to the Enablement and Default Impact for each feature to determine the visibility and configuration requirements. The RIA serves as an early preview of the Validation Impact Assessment (VIA). Once the VIA is available on Veeva Docs, refer to it for more detailed validation information.

This feature list is subject to change prior to the 22R3 release. We will begin tracking changes on October 3, 2022.

Revison Date:	November 8, 2022
VIA Availability Date:	November 4, 2022
Vault Safety Help	For detailed feature descriptions, refer to the product release notes, which are available on Vault Safety Help. On November 24, 2022 we will also release the 22R3 Template Revisions page on Safety Help about optional or recommended upgrades to your vault configuration for general usability improvements, unrelated to configuration changes for new features introduced in this release.
Vault Platform RIA	This document does not include changes introduced as part of the Vault Platform release. See the Vault Release Impact Assessment and consult Veeva Docs for Vault Platform validation details.
Feature:	Name of the feature introduced in 22R3
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 some configuration, or must be enabled by Veeva Support
Auto-On	This feature is available automatically. Note that in some cases, an Auto-on feature is dependent on another feature that must be enabled or configured.
Config	This feature requires configuration by an administrator.
Admin Checkbox	An administrator must use a checkbox or field in the Admin area to make this feature available.
Support	This feature must be enabled by Veeva Support.
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
Safety	Automated Case Promotion and Bulk Manual Upload (for EMA and Other HA)	High	Auto-On	Visible to All Users	Vault Safety now supports automatic Inbox Item promotion for sources that rely on manually uploaded E2B files. In addition, .zip files can now be manually uploaded in bulk and processed like multi-E2B import for sources such as the EMA.
Safety	Cross Reporting Most Conservative Submission	High	Auto-On	Visible to All Users	With this feature, Vault Safety will support the evaluation of additional cross-reporting scenarios for situations where there are multiple cross-reporting obligations within the same jurisdiction. This feature is automatically available if cross reporting rules are enabled. Otherwise, configuration is required.
Safety	Distribution Reporting Obligation Evaluation for Study Cases with Non-Study Co-Suspect Products	High	Auto-On	Visible to All Users	This release ensures the "Most Conservative Case Product and Case Assessment" reporting rules evaluation method correctly generates Distributions for Study Cases containing suspect or interacting marketed Case Products in addition to suspect Study Product(s).
Safety	Domestic Case Processing and Submission: Report Type-Based Localization	High	Configuration	Visible to Admins Only	Vault Safety now supports the ability to configure localizations by Case Type. For example, this enhancement allows for the localization of Postmarket Cases for the following countries: Spain, Czech Republic, Switzerland, and Canada.
Safety	Exclude Literature and Attachment Files in E2Bs by Destination	High	Configuration	Visible to Admins Only	Administrators can now configure literature references and attachments to exclude them from E2B(R2) and (R3) files based on the destination of the Transmission.
Safety	IMDRF: Dictionary Maintenance, Case Processing, and Submissions	High	Configuration	Visible to Admins Only	Vault Safety now supports all code types for the International Medical Device Regulators Forum (IMDRF) and the management of dictionary updates. When entering a Case Product Device Problem, you can select the Device Code Type and then search for the Device Code from the IMDRF Dictionary. In addition, when generating FDA E2B(R2), FDA VAERS E2B(R3), and FDA MedWatch 3500A forms, the system can export multiple IMDRF device codes, prioritizing the lowest-level Medical Device Problem codes.
Safety	Localized Case Child and Grandchild Record Deletion from Case	High	Configuration	Visible to Admins Only	Vault Safety now supports automatically deleting Localized children when global Case children are deleted. Previously, users had to delete Localized children manually before deleting the global versions. For example, Local Dosage had to be deleted prior to deleting a Dosage record.
Safety	Remedial Actions and Malfunction for Combination Products	High	Configuration	Visible to Admins Only	Vault Safety now supports data entry for Remedial Actions and Malfunction at the device level, as well as device codes for Cases that involve multiple Combination Products or a Combination Product that has multiple device constituents. Case Product Remedial Action and Malfunction can be exported in FDA Medwatch 3500A, FDA E2B(R2), and FDA VAERS E2B(R3) formats.
Safety	PADER Date Filtering Criteria	High	Support	None	Vault Safety will now provide a choice for the Date used to filter the reports. Aside from Transmission Date, users can choose to use Receipt Date/New Info Date instead.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Match Study Product / Study Product Placeholder Names	Medium	Auto-On	Visible to All Users	During E2B-import, the system can now match products and studies using the blinded product name (Study Product Placeholder) configured on Study Products in the Business Admin library.
Safety	Rule Set Administration Safeguards	Medium	Auto-On	Visible to Admins Only	This feature introduces safeguards when configuring rule parameters in custom rule sets.
Safety	Automatic Email of Case Questionnaire for Inbox Items	Medium	Configuration	Visible to Admins Only	With this release, sending a follow-up questionnaire to a primary Reporter is supported for Inbox Items. Previously, this capability was available only for AERs and Cases. In addition, Vault Safety can now email questionnaires to a non-primary Reporter, with their consent, for Cases and Inbox Items. Finally, Vault Safety can now send non-Product-specific questionnaires for Cases and Inbox Items. Previously, a Product must have been specified to send questionnaires.
Safety	Cosmetics, OTC Drugs, Nutritionals, and Non-Physical Devices for Case Processing	Medium	Configuration	Visible to Admins Only	With this release, to support agency-specific reporting requirements, Products can include multiple Product Registrations for different Product Types. In addition, Product Registrations can be created for the following new Product Types: OTC Drugs, Cosmetics, and Nutritionals.
Safety	MedDRA Bulk Recode Cases	Medium	Configuration	Visible to Admins Only	Vault Safety now supports bulk recoding of MedDRA-coded terms on Cases. When the MedDRA Dictionary is updated to the latest version, admins can now use the Dictionary Bulk Recode feature to upload replacement terms and preview impacted terms in Cases prior to the bulk recode. Bulk recode can be applied to open and closed Cases, where changes are tracked in the audit trail.
Safety	MedDRA Synonym Field Exclusion and Candidate Auto-Creation	Medium	Configuration	Visible to Admins Only	To streamline MedDRA coding, administrators can now enable the automatic creation of synonym candidates for reported terms with no match. Synonym candidates are reviewed and approved before becoming available for coding. In addition, administrators can configure field exclusions for synonyms, which supports coding reported terms based on context.
Safety	Disable Auto-Calculations on Case Promotion	Medium	Admin Checkbox	Visible to Admins Only	You can now bypass the calculations that occur automatically during Case promotion for Inbox Items received through AS2 gateway transmissions or Vault REST API. A new setting is introduced on the Transmission Profile, which administrators can use to control this functionality.
Safety	Generate Transmissions and Auto-Submit Enhancements	Medium	Admin Checkbox	Visible to Admins Only	Administrators can now configure the system to suppress document generation for transmissions eligible for auto-submit. This resolves a possible race condition if the Evaluate Submission Obligations and Submit to Gateway actions are triggered in rapid succession.
Safety	New Duplicate Search Algorithm	Medium	Support	None	With this release, Vault Safety offers even more search intelligence to enable surfacing similar Cases and eliminate the need for manual searching. When this feature is enabled, duplicate Cases are surfaced even when the Inbox Item includes sparse details.

Application	Feature Name	GxP Risk	Enablement	Default Impact	Description
Safety	Translation Connections and Localized Case Auto-Translation for Submissions	Low	Configuration	Visible to Admins Only	To facilitate the automated translation of Case text fields to local languages for submissions, Vault Safety introduces Translation Connections. This feature enables customers to use a third-party service, such as Amazon Translate, for translation. Administrators can configure Translation Connections by localization, controlling which fields are translated and setting volume limits.
Safety	Automated Updates to EDQM Dictionary	N/A	Auto-On	Visible to Admins Only	The Vault Safety EDQM dictionary will now be automatically updated with each change to the EDQM standard terms database. Previously, EDQM updates were included with Vault Safety releases.
Safety	EMA PII Masking Exceptions	N/A	Auto-On	Visible to All Users	The enablement for EMA-compliant PII Masking, specific to when Patient Content Protection is used for an EMA Submission, will be changed to Auto-On in all Safety Vaults in 22R3. This is an enablement change from when the fix was originally patched in the 22R2.0.20 maintenance release, which required support enablement (SAF-30486).
Safety	Automated Case Promotion for API Transmissions	N/A	Configuration	Visible to Admins Only	With this release, support for Automated Case Promotion is extended to Safety Intake API (E2B and JSON) sources by leveraging Transmission Profiles for settings.
Safety	Product Hierarchy Data Model	N/A	Configuration	Visible to Admins Only	This release introduces Product Family and Inactive Ingredients into the Product Data Model. Product Family can be optionally used to group related products. One or more Inactive Ingredients can be optionally added to Product Registrations when required for certain types of reporting.
Safety	Create Archived Documents Directly on Batch Narrative API Import	N/A	Support	None	Vault Safety can now import narratives from the bulk import narrative API endpoint directly to the document archive if Document Archive is turned on in the Vault. This is to support better search performance when migrating in a large set of cases. *To use this feature, Document Archive must first be enabled by Veeva Support.
Safety<>ClinOps	ClinOps-Safety Study and Study Country Vault Connection	Medium	Configuration	Visible to Admins Only	Organizations using both a Clinical Operations Vault (ClinOps) and Vault Safety can now create a Vault Connection to transfer Study and Study Registration records across Vaults. When a Study or Study Registration is created or updated in ClinOps, the data is synchronized to Vault Safety. The Safety to ClinOps connection is an important step towards ensuring compliance while reducing time and inconsistencies in managing a Study library in Vault Safety.
SafetyDocs	PSMF Automatic Logbook Generation	Medium	Configuration	Visible to Admins Only	Vault SafetyDocs can now automatically generate a PSMF logbook when merging to a PSMF PDF. Vault SafetyDocs will generate a placeholder logbook entry for each major version of a PSMF Document. This feature also includes dedicated PSMF doctypes and lifecycles that will be built upon in future releases.

Change Log

Date	Change	Impact
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03 Oct 2022	Initial RIA Published.	N/A
04 Oct 2022	Updated the GxP Risk analysis from N/A to High for the feature "Cross Reporting Most Conservative Submission". Updated the Application and name of the "ClinOps-Safety Study and Study Country Vault Connection" feature, previously named "Safety-ClinOps Study and Study Country Synchronization Vault Connection".	The RIA has up-to-date GxP Risk analysis, applications and feature names.
05 Oct 2022	Updated the name, description, and default impact of the feature "Create Archived Documents Directly on Batch Narrative API Import", previously named "Create Archive Document Directly on Batch narrative import".	The RIA has up-to-date feature names, descriptions, and default impact.
12 Oct 2022	Updated the enablement and description of the feature "Create Archived Documents Directly on Batch Narrative API Import".	The RIA has up-to-date feature descriptions and enablement.
24 Oct 2022	Removed the feature "Support for Blinded Studies and Product Placeholder Names in CIOMS II Line Listing". This support is not an enhancement to Vault Safety, but is a Fixed Issue that is being tracked with issue number SAF-34978.	The RIA has an up-to-date listing of new features.
25 Oct 2022	Updated the Enablement and Default Impact of the feature "New Duplicate Search Algorithm".	The RIA has up-to-date enablement and default impact.
27 Oct 2022	Updated the description of the feature "EMA PII Masking Exceptions".	The RIA has up-to-date feature descriptions.
07 Nov 2022	Added the feature "PADER Date Filtering Criteria".	The RIA has an up-to-date list of features.
08 Nov 2022	Removed the feature "Vault Signal".	The RIA has an up-to-date list of features.