



Release Configuration Sheet

LORENZ eValidator 25.2

October 2025

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Table of Contents

| | |
|---|----|
| Disclaimer..... | 5 |
| 1. Getting Started | 6 |
| 1.1 Introduction | 6 |
| 1.2 How this guide is organized | 6 |
| 1.3 Where this software can be installed | 6 |
| 1.4 Installing into a validated environment..... | 6 |
| 1.5 Notes..... | 6 |
| 2. Release Notes | 8 |
| 2.1 Distribution Methods / Media | 8 |
| 2.2 Product Documentation | 8 |
| 2.3 Release Compatibility | 9 |
| 3. Installation Procedure Overview | 11 |
| 3.1 Software Installation Package | 11 |
| 3.1.1 eValidator Client Setup | 11 |
| 3.1.2 eValidator Server Setup | 12 |
| 3.2 License Types..... | 12 |
| 3.2.1 eValidator Basic License..... | 12 |
| 3.2.2 eValidator ONE License | 13 |
| 3.2.3 eValidator FIVE License..... | 13 |
| 3.3 New/Update Installation | 13 |
| 3.3.1 eValidator Client Setup | 13 |
| 3.3.2 eValidator Server Setup | 15 |
| 3.3.3 Silent Installations | 16 |
| 3.3.4 Customizing the Setup before Roll-Out | 18 |
| 4. Changes in the eValidator 25.2 Release..... | 19 |
| 4.1 eValidator Profiles | 19 |
| 4.1.1 AU eCTD | 19 |
| 4.1.2 AU NeeS..... | 23 |
| 4.1.3 BA eCTD | 25 |
| 4.1.4 BA NeeS..... | 27 |
| 4.1.5 CA eCTD | 28 |
| 4.1.6 CA Non-eCTD | 32 |
| 4.1.7 CA XML PM (Product Monograph) | 35 |



| | | |
|--------|--|-----|
| 4.1.8 | CH eCTD | 37 |
| 4.1.9 | CH eDok | 38 |
| 4.1.10 | CN eCTD | 40 |
| 4.1.11 | CN eSubmission..... | 42 |
| 4.1.12 | ECOWAS eCTD | 44 |
| 4.1.13 | ECOWAS eSubmission..... | 46 |
| 4.1.14 | EU eCTD | 47 |
| 4.1.15 | EU NeeS..... | 50 |
| 4.1.16 | EU eCTD 4.0 | 51 |
| 4.1.17 | GCC eCTD | 54 |
| 4.1.18 | JP eCTD | 56 |
| 4.1.19 | JP eCTD 4.0 | 57 |
| 4.1.20 | JO eCTD..... | 60 |
| 4.1.21 | KR eCTD | 62 |
| 4.1.22 | KSA NeeS..... | 63 |
| 4.1.23 | MD5/SHA256 Proofreader | 64 |
| 4.1.24 | PDF Document Validation (US FDA Requirements) | 66 |
| 4.1.25 | RS NeeS..... | 68 |
| 4.1.26 | SG eCTD | 69 |
| 4.1.27 | TH eCTD | 71 |
| 4.1.28 | TN eCTD | 72 |
| 4.1.29 | TN eSubmission | 74 |
| 4.1.30 | TW eCTD..... | 75 |
| 4.1.31 | UA eCTD | 77 |
| 4.1.32 | US eCTD (M1 v2.5, DTD v3.3) | 79 |
| 4.1.33 | US eCTD 4.0 | 83 |
| 4.1.34 | WHO PQT eCTD | 89 |
| 4.1.35 | ZA eCTD..... | 90 |
| 4.1.36 | ZA eSubmission | 92 |
| 4.1.37 | Expired Profiles | 94 |
| 4.2 | Reports and Style Sheets..... | 95 |
| 4.3 | eValidator Desktop Client & Batch Processing Application | 97 |
| 4.4 | Setup and System Configuration | 98 |
| 4.5 | eValidator webAccess (Submission Validation)..... | 100 |



| | | |
|-----|-----------------------------|-----|
| 4.6 | LORENZ Job Management | 105 |
| 4.7 | Other Items | 106 |
| 4.8 | Known Issues | 109 |



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1. Getting Started

1.1 Introduction

This document is the Release Configuration Sheet (RCS) for LORENZ eValidator 25.2.

The main objective of the Release Configuration Sheet is to provide an overview of the scope and impact of this release and to provide a description of the issues addressed and/or features that have been added or modified in the new version, as well as its potential impact on existing systems.

1.2 How this guide is organized

The RCS is organized in four chapters:

Chapter 1 contains general information about the release and the Release Configuration Sheet as well as an indication about expected target systems.

Chapter 2 contains the actual Release Notes including Distribution Media, Product Documentation, Release Compatibility Information and Release Impact Information.

Chapter 3 provides information about the installation process, as much as this information is of relevance to the Release Configuration Sheet.

Chapter 4 contains a description of Release Highlights and a brief narrative description of enhancements and addressed issues. Each item provides a reference to functional specification (FSP) item affected by this change.

1.3 Where this software can be installed

This software release can be installed on both client and server computers. It may be used side by side with the docuBridge client, and with the LORENZ Automator.

1.4 Installing into a validated environment

LORENZ suggests a careful analysis of the changes and/or issues of interest provided in Chapter 4 of this document, to assess necessary validation activities.

1.5 Notes

Throughout this document:

- The phrase eValidator refers to the LORENZ eValidator product.
- The phrase installation folder refers to the folder where the eValidator has been or shall be installed to (this is usually the folder named C:\Program Files (x86)\LORENZ Life Sciences\LORENZ eValidator).



- The phrase configuration folder refers to the folder where the eValidator configuration files have been or shall be installed to. This is the sub-folder named LORENZ Life Sciences\eValidator in the CommonAppData folder.
- The folder referred to by CommonAppData is `C:\ProgramData`.



2. Release Notes

2.1 Distribution Methods / Media

LORENZ distributes LORENZ eValidator 25.2 using the following distribution channels:

- HTTP download
- LORENZ eValidator Client update function (via LORENZ eValidator Update Service)

2.2 Product Documentation

This version of the LORENZ eValidator is created with the following documentation items:

| Documentation Item | Content |
|--|--|
| User Guide for LORENZ eValidator | This document describes how to use the LORENZ eValidator client application. |
| User Guide for LORENZ eValidator webAccess | This document describes how to use eValidator webAccess, which provides a web browser user interface for validation tasks. This document is included in the server setup package. |
| Administrator Guide for LORENZ eValidator | This document describes how to install and configure the eValidator server components. This document is included in the server setup package. |
| Functional Specification (FSP) | This document outlines the desired features and behavior of the system. |
| Release Configuration Sheet (RCS) | This document outlines the changes in LORENZ eValidator in this release. |
| System Requirements Specification (SRS) | The SRS lists the hard- and software prerequisites for the LORENZ eValidator. |

Table 1: Product Documentation



2.3 Release Compatibility

This version will automatically replace an existing previous version of LORENZ eValidator found on the computer when you install LORENZ eValidator 25.2.

Important Release Notification for the LORENZ 25.2 Releases

Cross-Capability Compatibility

LORENZ is moving from individual products to an integrated RIM solution with multiple capabilities. An increasing number of common functionalities are currently being developed centrally and utilized by multiple capabilities. The goal is to make deployments easier as well as provide more functionality to end-users across multiple capabilities. When such functionalities are centralized, cross-capability compatibility is given for the same major release version only.

This new installation process allows installation/update of licensed capabilities (e.g., docuBridge, drugTrack, and eValidator) to the newest major version. For the 25.2 release, multiple capabilities with diverging versions in one environment will not be compatible. Therefore, for customers with multiple LORENZ capabilities in one environment, the update to 25.2 applies to all LORENZ capabilities simultaneously.

.NET Support Policy and LORENZ Products

LORENZ software products are based on Microsoft technology with .NET as the underlying development framework. Therefore, Microsoft .NET is one vital system environment component.

Microsoft provides a three-year support cycle for each new .NET LTS version. Considering the increasingly dynamic software landscape and frequent technological advancements, keeping your system environment aligned with supported frameworks has become more critical than ever.

As development platforms evolve and support for Windows libraries and frameworks becomes shorter, LORENZ's customers need to upgrade to the latest versions of our solutions more frequently. To help ease this process, LORENZ is evaluating various release and validation strategies.

Currently supported LORENZ Releases:

| LORENZ releases | .NET version | .NET End of support date | Support phase |
|--------------------------------|--------------|--------------------------|---------------|
| 23.1, 23.2 | .NET 6 | Nov 12, 2024 | INACTIVE |
| 23.1.1, 23.2.2 24.x 25.x | .NET 8 | Nov 10, 2026 | Active |
| 26.1 (planned) | .NET 10 | November 2028 (est.) | Coming |

Table 2-2



Our current 25.2 release is based on .NET 8 and will be supported until November 2026, in accordance with Microsoft's support policy.

Looking ahead, we are planning to adopt .NET 10 with our 26.1 release. This move ensures that our software remains secure, performant, and compatible with modern environments.

In the future, we will also provide regular Maintenance Releases designed to address compliance requirements, security updates, and essential fixes. These releases are intended to have only minimal impact on the software and should be applied on an ongoing basis to ensure a secure and reliable system environment. We strongly recommend that you monitor your system environment policies and begin planning your upgrade path accordingly. Staying within the official support window helps you maintain system stability, benefit from security updates, and ensure continued compatibility with future software features.

For more information on Microsoft's .NET support policy, refer to <https://dotnet.microsoft.com/en-us/platform/support/policy/dotnet-core>.

Release Strategy

As part of our ongoing commitment to delivering the best possible software solutions to meet your needs, we would like to inform you about some important discussions and potential adjustments we are considering for our support cycles and release packages.

There is an increasing number of factors that lead to a higher frequency of software releases, e.g., security patches.

We recognize the importance of providing consistent and reliable support throughout the lifecycle of our products, and we are exploring ways to refine our approach to better serve your needs.

In tandem with these discussions, we are also focusing on implementing essential improvements to our release packages. These improvements are designed to streamline the upgrade process and make transitioning to a new version of our software much simpler and more efficient for you.

Our aim is to ensure that future upgrades are seamless, minimizing any disruption to your operations and maximizing the value you derive from our software. We understand the significance of a smooth upgrade process in maintaining productivity and reducing downtime, and we are committed to delivering on this front.



3. Installation Procedure Overview

3.1 Software Installation Package

The distribution contains the software setup for LORENZ eValidator 25.2. The setup is provided as a full setup. It does not require any previous installation. If a previous version of the LORENZ eValidator is found when executing the setup, it will be updated.

3.1.1 eValidator Client Setup

This setup package installs the eValidator desktop client applications. It can be downloaded from the LORENZ web site directly.

- eValidator Client Application

This application allows verifying and validating electronic submissions purposely conforming to the ICH eCTD standard (see www.ich.org) based on configured check options and dynamic verification rules. Validation results will be created as XML and as HTML reports (optionally, also PDF); adequate XSL style sheets for viewing the report content in a web browser are also provided. LORENZ will periodically provide updates for the configuration base to keep the eValidator synchronized with the official specifications. The eValidator also supports validating certain specified non-eCTD submissions (NeeS and VNeS). For details about the predefined validation rules for non-eCTD submissions, please refer to the User Guide or the Functional Specification (FSP).

- eValidator Batch Processing Application

Like the eValidator Client Application, this application allows verifying and validating electronic submissions purposely conforming to the ICH eCTD standard (see www.ich.org) based on configured check options and dynamic verification rules. With the Batch Processing Application, you can control the validation of multiple submissions (applications, sequences, folders) through validation lists. The program is available as a separate feature in the installation package (disabled by default). Please note that an eValidator FIVE license is required to use the program.



3.1.2 eValidator Server Setup

This setup package (which is available for users with an eValidator FIVE license only) contains the eValidator server components:

- eValidator Job Runner
- eValidator webAccess

For these components, LORENZ Foundation is required.

For your convenience, the server setup package also contains the desktop client components as an optional feature to install on server systems (e.g., for remote desktop or Citrix).

If you want to use the eValidator as part of the publishing task from within your docuBridge 25.2 system, you need to install the eValidator Server Setup on the Foundation server.

3.2 License Types

For the LORENZ eValidator different license types are available:

3.2.1 eValidator Basic License

This is a free of charge license which allows running validations for eCTD or non-eCTD submissions. Several features have been disabled for this license type:

- You cannot use customized profiles or change the report branding text and logo.
- The use of the LORENZ eValidator Batch Processing client is not supported.
- You cannot change the user interface language.
- You cannot create or use custom profiles.
- You cannot change any severity settings for the validation rules.
- You cannot change any rule parameters in a loaded profile.
- You cannot change the profile you have selected at the first start of the software. Only reinstalling the software will allow re-selecting the profile.
- Only one instance of the LORENZ eValidator program can be used at a time.
- If you are using a “branded” version of the eValidator (such as CDE Validator), changing the profile is limited to the region-related profiles.
- You cannot validate submissions on a server operating system such as Microsoft Windows Server 2019, 2022, or 2025.
- The eValidator PowerShell host is not supported.
- You will not get the summary report in addition to the full validation report.
- You cannot use parallel execution of validation rules to improve the overall performance for large submissions.
- Profile content reports are not available.
- You cannot use “Baseline Optimized Validation”.



- eValidator REST Service is not available.
- eValidator webAccess is not available.
- Advertisement screens will be displayed during when starting the application and when starting a validation.

3.2.2 eValidator ONE License

This license provides the same features as the Basic version plus the option to switch between profiles (regions) without reinstalling the software. The other limitations of the Basic license are still effective.

The license can be purchased online at <https://www.lorenz.cc/Solutions/eValidator/>.

3.2.3 eValidator FIVE License

This license (previously named “eValidator Enterprise”) does not have the functional limitations of the eValidator Basic or eValidator ONE license.

Please note:

The available extended profiles may depend on the modules you purchased. For detailed information please contact LORENZ Sales or speak with your LORENZ Account Manager

The eValidator webAccess can be used with any eValidator FIVE license.

3.3 New/Update Installation

Before installing LORENZ eValidator, please unzip the distribution file to a temporary directory.

Please check the System Requirements Specification document before installing the update. The setup will refuse to start on no longer supported operating systems (e.g., Windows 7 and Windows Server 2008).

3.3.1 eValidator Client Setup

Please follow these steps to perform the installation:

1. In case Windows Installer or Microsoft .NET Core 8.0.x Runtime, ASP.NET Core 8.0.x and Windows Desktop Runtime 8.0.x runtimes cannot be found, these components will not be installed automatically. You need to do this manually before you start the installation of the eValidator. Otherwise, you will be prompted to install those components upon first start of the eValidator client.
2. Start the file **Setup.msi** from the extracted distribution content.



3. Acknowledge the confirmation dialogs and follow the instructions on the screen. Completing the installation of these components might require restarting the computer.
4. Please acknowledge the **User Account Control** message only if the verified publisher is "LORENZ Bridge Software GmbH". You can click on **Show details** to see additional information about the publisher's identity.
5. Follow the instructions displayed to complete the installation. For a quick and easy procedure, it is recommended to accept the default settings provided by the wizard.
6. Desktop shortcuts and new start menu items will be created. These shortcuts can be used to start the application.
7. After starting the eValidator client application, you can select the profile you want to use for your validation(s). Profiles contain collections of validation rules and settings for a specific validation scope (e.g., submitting an application to the US FDA or to Health Canada). The LORENZ eValidator installs a set of different profiles you can choose from.

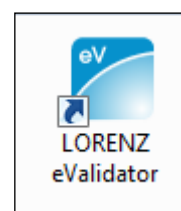


Figure 1: Shortcut

Please note: With a Basic license, the profile chosen by the user who ran the application cannot be changed and will also apply to all other users accessing the installation. To select another profile, please re-install your eValidator Basic.

The FIVE and ONE licenses allow switching profiles (File > Open Profile > Select & OK or Double-click on desired profile). The next time you start the LORENZ eValidator, the last used profile will be loaded again automatically.

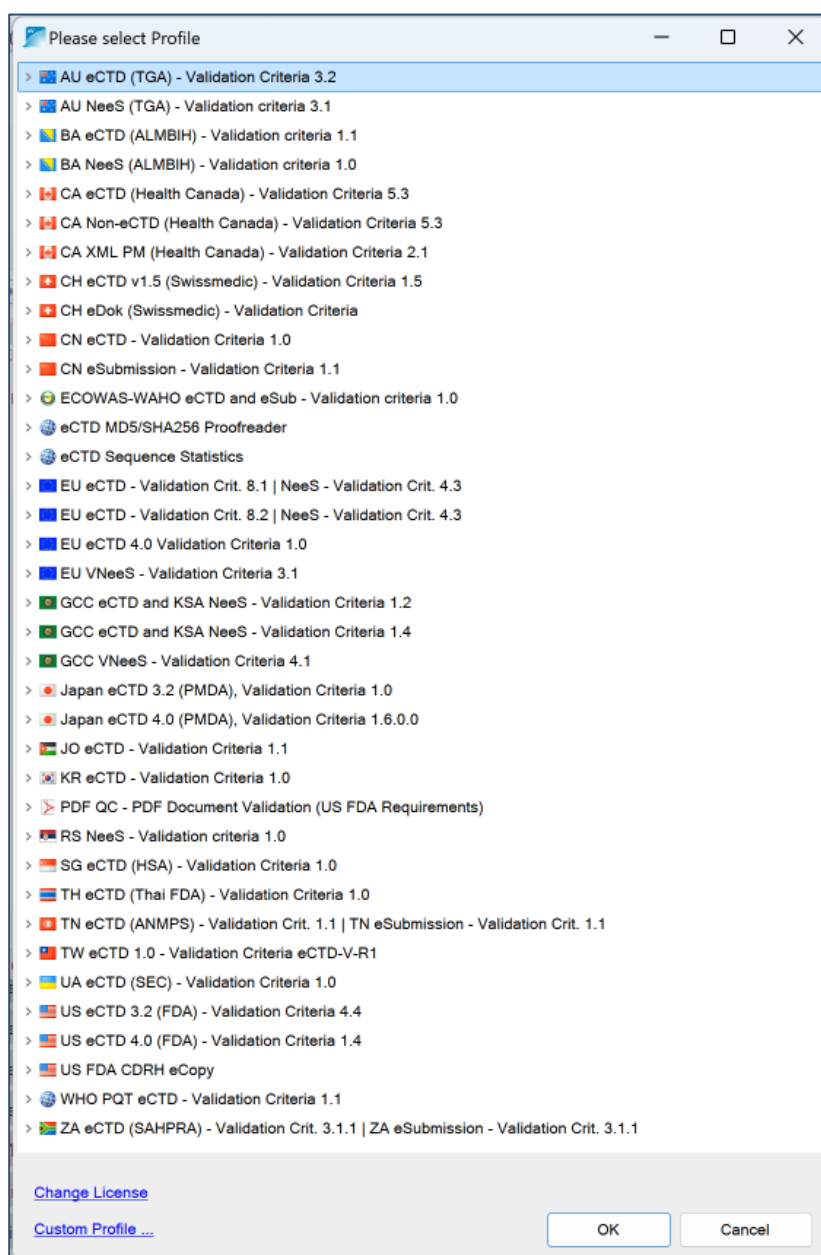


Figure 2: Profile Selection Dialog

3.3.2 eValidator Server Setup

Please follow these steps to perform the installation:

1. In case Windows Installer, .NET Core 8.0.x and ASP.NET Core 8.0.x runtimes cannot be found, these components will not be installed automatically. You need to do this manually before you start the installation of the eValidator.
2. Start the file **Setup.msi** from the extracted distribution content.



3. Acknowledge the confirmation dialogs and follow the instructions on the screen. Completing the installation of these components might require restarting the computer.
4. From the **Feature selection** dialog, choose the components you want to install, and click **Next**. The available features depend on whether you are installing the eValidator Client or eValidator Server package.

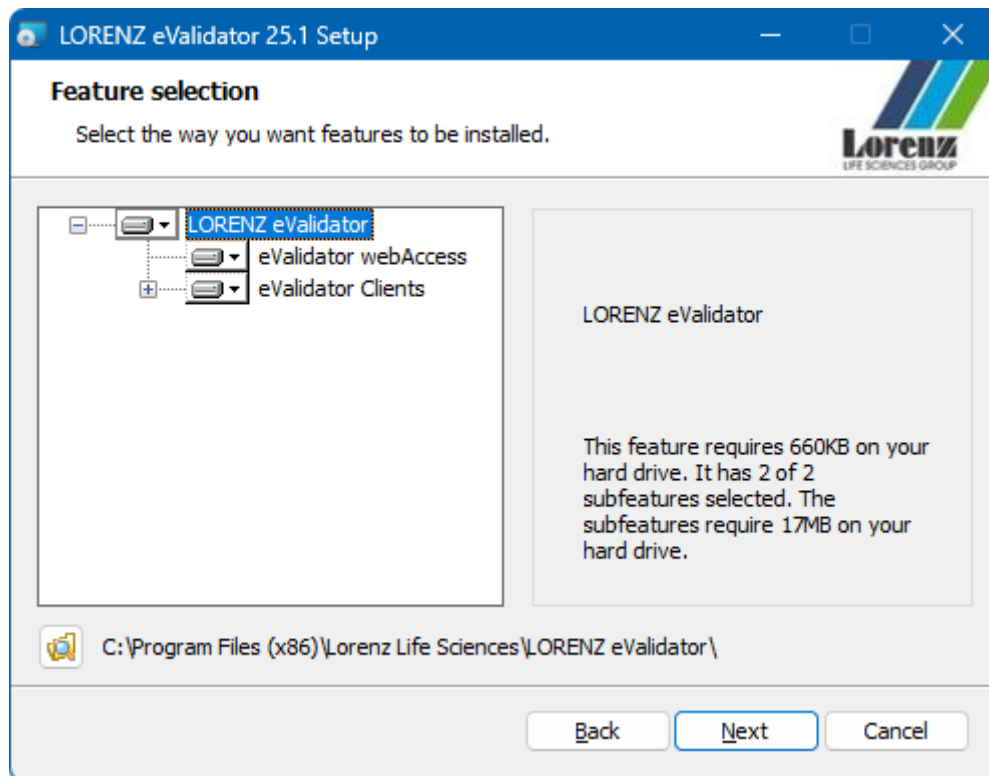


Figure 3: Server Setup

Currently, the eValidator webAccess feature cannot be unselected in the setup. If you do not want to use eValidator webAccess in your environment, please complete the installation first and then refer to the eValidator Administrator Guide, section 4.2.

5. The eValidator installation wizard will be started.
6. Please acknowledge the **User Account Control** message only if the verified publisher is "LORENZ Bridge Software GmbH". You can click on **Show details** to see additional information about the publisher's identity.
7. Follow the instructions displayed to complete the installation. For a quick and easy procedure, it is recommended to accept the default settings provided by the wizard.

3.3.3 Silent Installations

For a **silent Installation** through the Windows Installer, the following parameters can be used with the **msiexec** command.



3.3.3.1 Client Setup

```
msiexec /quiet /i {Path to setup.msi}
```

This will install the standard eValidator client application only.

```
msiexec /quiet /i {Path to setup.msi} ADDLOCAL=ALL
```

This will install the eValidator client application and the eValidator Batch Processing client application.

3.3.3.2 Server Setup

```
msiexec /quiet /i {Path to setup.msi}
```

This will install the eValidator webAccess and the eValidator job runner components.

```
msiexec /quiet /i {Path to setup.msi} ADDLOCAL=ALL
```

This will install all components and features (incl. the client applications).

For individual selection, the optional feature names are as follows (only the eValidator client components are optional):

```
F_eValidatorClient_DoInstall  
F_BatchProcessing_DoInstall
```

For the credentials to run the “LORENZ SubmissionValidationServices”:

```
SVC_ACCOUNT=AccountName SVC_PASSWORD=Password
```



3.3.4 Customizing the Setup before Roll-Out

If the eValidator Setup is executed, it checks for a folder named **eValidatorConfig** existing in the same folder as the setup is located. If the folder exists, all files in this folder will be copied to **C:\ProgramData\Lorenz Life Sciences\eValidator** as the final step of the installation. With this approach it is possible to apply a license and/or custom configuration settings or install a custom version of a profile. Example:

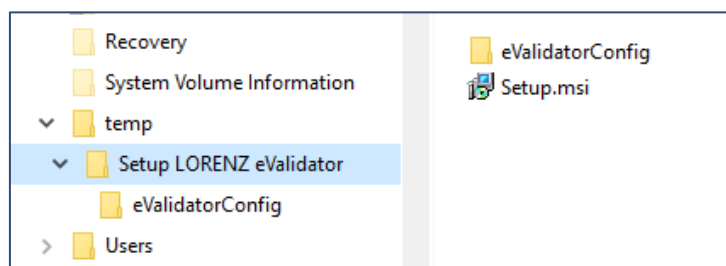


Figure 4: Customizing Setup

In the eValidatorConfig folder, you can place a customized copy of the system.config file, e.g., to preset the serial number for the license so users won't have to activate the license upon first start of the program. In addition, the license file itself can also be placed here. Both files will then be copied to the destination folder **C:\ProgramData\Lorenz Life Sciences\eValidator**, overwriting any already existing files with the same name.

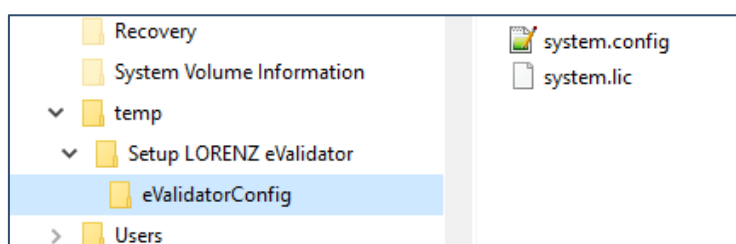


Figure 5: Customizing Setup - Example



4. Changes in the eValidator 25.2 Release

This section lists all issues that have been addressed for this release. Please note that the release also includes all updates from the regulatory update packages 1.16.0 to 1.16.7. For your convenience, the corresponding tickets have been highlighted accordingly.

4.1 eValidator Profiles

4.1.1 AU eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6583 | Critical | Bug | AU eCTD Validation Criteria 3.2 Validation Rule 2.7 Rule 2.7 has been adapted to no longer verify the checksum of the au-regional.xml if present. Verification of the au-regional.xml in rule 2.7 is not required by TGA. This update was already available with the regulatory update package 1.16.5. | eV-FSP-3002-23 |
| EVA-6597 | Major | Feature | AU eCTD Validation Criteria 3.2 Validation Rule 4.3.1 & 4.3.2 The newly released version 3.0.1 of the document-matrix.xml has been added to the configuration (only relevant when validation is performed in offline mode). For seq-type-54 (Safety related request) and seq-type-55 (Self Assessable Request/Variation) missing documents under 1.3.1.1 and 1.3.1.2 will no longer report an error, but a warning. This update was already available with the regulatory update package 1.16.5. | eV-FSP-3002-23 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------------------------|
| EVA-6483 | Major | Feature | AU eCTD Validation Criteria 3.1 and 3.2 Validation Rule 4.2.6a Multiple sequence-type elements are only allowed with submission-mode work-grouping. The rule will now trigger an error if multiple sequence-type elements were found and a different submission-mode has been used. This update was already available with the regulatory update package 1.16.3. | eV-FSP-3002-22, 3002-23 |
| EVA-6540 | Major | Bug | AU eCTD Validation Criteria 3.2 Validation Rules 3.LC1, 3.LC2, 3.LC3, 3.LC4, 3.LC5, 3.LC6, 4.1.LC1, 4.1.LC2, 4.1.LC3, 4.1.LC4, 4.1.LC5 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-23 |
| EVA-6475 | Major | Bug | AU eCTD Validation Criteria 3.1 and 3.2 Validation Rules 4.2.6a, 4.2.6b, 4.2.7a, 4.2.7b, 4.2.9 In case of multiple sequence-type elements, the rules listed above checked the first element only. This has now been resolved. This update was already available with the regulatory update package 1.16.3. | eV-FSP-3002-22, 3002-23 |
| EVA-6309 | Minor | Feature | AU eCTD Validation Criteria 3.1 and 3.2 An administrative information section has been added to the reports for Australian eCTD validation. The section shows the information from the au-envelope section in au-regional.xml. This update was already available with the regulatory update package 1.16.5. | eV-FSP-3002-22 eV-FSP-3002-23 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6460 | Minor | Feature | AU eCTD Validation Criteria 3.2 Validation Rule 2.11 In addition to an empty text, a justification text that copies the template text from the TGA web site will now trigger 2.11 ("Justification of warning text") Hint: This is to figure out if the user accidentally copied the text from the TGA website instead of providing useful information. This update was already available with the regulatory update package 1.16.3. | eV-FSP-3002-23 |
| EVA-6545 | Minor | Bug | AU eCTD Validation Criteria 3.2 Validation Rule 4.1.28 The generated warnings.xml template did not list warnings for all sections covered by the three instances of rule 4.1.28. Only a warning for the first one ("Lifecycle Operations in section 1.3.1") was added. This issue has been resolved now: Rule 4.1.28 has been combined into a single rule instead of having separate implementations for sections 1.3.1, 1.3.2, and 1.3.3, respectively. This update was already available with the regulatory update package 1.16.4. | eV-FSP-3002-23 |
| EVA-6510 | Minor | Bug | AU eCTD Validation Criteria 3.1 The expiration information in the profile incorrectly mentioned July 31, 2025. It has now been adjusted with the date given on the TGA's web site: Oct 31, 2025. This update was already available with the regulatory update package 1.16.3. | eV-FSP-3002-22 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> AU eCTD Validation Criteria 3.2 AU eCTD Validation Criteria 3.2, EXTENDED |
| Configuration Files | Changed |



| | |
|--------------|---------|
| Program Code | Changed |
|--------------|---------|

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6583: If you received an error in Rule 2.7 due to an incorrect checksum for au-regional.xml, verify that the error is no longer reported.</p> <p>EVA-6597: When validating seq-type-54 (Safety related request) or seq-type-55 (Self Assessable Request/Variation) submissions, verify that missing documents in section 1.3.1.1 and 1.3.1.2 are reported as warnings (Rule 4.3.2) rather than errors (Rule 4.3.1).</p> <p>EVA-6483: Verify that 4.2.6a will report an error if multiple sequence-type elements are provided in the envelope and the submission-mode is not work-grouping.</p> <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6475: Verify 4.2.6a, 4.2.6b, 4.2.7a, 4.2.7b, and 4.2.9 will also report issues found in sequence-type elements other than the first one.</p> <p>EVA-6309: Verify the correct data as entered in the au-envelope section is displayed in the administrative information section.</p> <p>EVA-6460: Verify that 2.11 will also trigger if the justification text is "Justification of warning text".</p> <p>EVA-6545: Verify that the generated warnings.xml template contains the warnings for sections 1.3.1, 1.3.2, and 1.3.3 if rule 4.1.28 reported any findings.</p> <p>EVA-6510: Verify that the expiration message for these profiles shows 31-Oct-2025.</p> |



4.1.2 AU NeeS

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6564 | Minor | Bug | AU NeeS Validation Criteria 3.1 Validation Rule 2.BP1 Rule 2.BP1 reported a false positive when the application sequence was validated from a network share directly, without an additional folder above the application folder. E.g. validating a sequence placed at a path like \\server\app\0000 returned a false positive, while \\server\apps\app\0000 returned the correct results. | eV-FSP-3002-24 |
| EVA-6483 | Major | Feature | AU NeeS Validation Criteria 3.1 Validation Rule 4.2.6a Multiple sequence-type elements are only allowed with submission-mode work-grouping. The rule will now trigger an error if multiple sequence-type elements were found and a different submission-mode has been used. <div>This update was already available with the regulatory update package 1.16.3.</div> | eV-FSP-3002-24 |
| EVA-6475 | Major | Bug | AU NeeS Validation Criteria 3.1 Validation Rules 4.2.6a, 4.2.6b, 4.2.7a, 4.2.7b, 4.2.9 In case of multiple sequence-type elements, the rules listed above checked the first element only. This has now been resolved. <div>This update was already available with the regulatory update package 1.16.3.</div> | eV-FSP-3002-24 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> AU NeeS Validation Criteria 3.1 AU NeeS Validation Criteria 3.1, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |



| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6564: Verify that rule 2.BP1 returns correct results when validating a sequence located on a network share.</p> <p>EVA-6483: Verify that 4.2.6a will report an error if multiple sequence-type elements are provided in the envelope and the submission-mode is not work-grouping.</p> <p>EVA-6475: Verify 4.2.6a, 4.2.6b, 4.2.7a, 4.2.7b, and 4.2.9 will also report issues found in sequence-type elements other than the first one.</p> |



4.1.3 BA eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6540 | Major | Bug | BA eCTD Validation Criteria 1.1 Validation Rules 11.12 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-49 |
| EVA-6591 | Major | Feature | BA eCTD Validation Criteria 1.1 A new profile has been added for the validation of Bosnian eCTD submissions, using validation criteria version 1.1. <div style="background-color: #e0f2f7; padding: 5px;">This update was already available with the regulatory update package 1.16.6.</div> | eV-FSP-3002-49 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> BA eCTD Validation Criteria 1.1 BA eCTD Validation Criteria 1.1, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool. |



| Validation Impact | Description |
|-------------------|--|
| | EVA-6591: Verify that the validation profile for BA eCTD validation criteria v1.1 is available in eValidator desktop client, eValidator webAccess, and LORENZ Job Management. |



4.1.4 BA NeeS

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6520 | Marginal | Feature | BA NeeS Validation Criteria 1.0 To align with other profiles, the Bosnian NeeS validation profiles will now be listed using the two-letter country code (BA) instead of the three-letter code (BIH). This has no effect on the validation results. <div>This update was already available with the regulatory update package 1.16.6.</div> | eV-FSP-3002-30 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> BA NeeS Validation Criteria 1.0 BA NeeS Validation Criteria 1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6520: Verify the validation profiles for Bosnia NeeS are now displayed with the two-letter country code (BA) in eValidator Desktop Clients, Job Management and eValidator webAccess. |



4.1.5 CA eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|--|
| EVA-6540 | Major | Bug | <p>CA eCTD Validation Criteria 5.3 Validation Rules E24, E25, E26, E27, E28, F17, F18, F19, G25, G26, G27, G28, G29, G30</p> <p>This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool.</p> | eV-FSP-3002-41 |
| EVA-7020 | Major | Bug | <p>CA eCTD Validation Criteria 5.3 Validation Rules I07, F22</p> <p>Rule I07 did not report an error when a replace was not targeting a leaf with an RT form in the previous sequence.</p> <p>Similar, rule F22 also did not check if the replace operation referred to a document in a different section in the previous sequence.</p> <p>These issues have now been resolved.</p> | eV-FSP-3002-41 |
| EVA-6838 | Minor | Bug | <p>CA eCTD Validation Criteria 5.3</p> <p>During validation of CA eCTD submissions, an internal test file was written to the c:\temp folder, and the file was not deleted when validation completed. This has been resolved now: The profile will no longer generate this file.</p> | eV-FSP-3002-41 |
| EVA-6457 | Critical | Bug | <p>CA eCTD Validation Criteria 5.2 & 5.3 Validation Rule B48</p> <p>The check for JavaScript caused the validation under rule B48 to fail for AES-256 encrypted PDFs. In these cases, a finding that the “document could not be opened” was reported. This issue has been resolved now.</p> <p>This update was already available with the specific releases 24.2.0.02 & 25.2.0.01.</p> | eV-FSP-3002-7, eV-FSP-3002-41, eV-FSP-6055 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6803 | Critical | Feature | <p>CA eCTD Validation Criteria 5.2 Validation Rule I11</p> <p>A new Regulatory Transaction Template v5.1.0 is available and required for eCTD Submissions to Health Canada. Applies to: Human Use Drugs (Pharmaceutical, Biologic and Radiopharmaceutical) and Disinfectants and Veterinary Drugs.</p> <p>This version has now been added to eValidator configuration for validations executed in offline mode.</p> <p>The eValidator will now report an error in rule I11 if a version other than v5.1.0 is used.</p> <p>When executing validation rule I11, the validation profiles will access the LORENZ server to check for updated version information. When access to the LORENZ server (https://support.lorenz.cc/files/ev5/configupdate/ca/rt-version.xml) fails or validation is executed in offline mode, the version information will be retrieved from the configuration files installed with the LORENZ eValidator.</p> <p>This update was already available with the regulatory update package 1.16.7.</p> | eV-FSP-3002-41 |
| EVA-6657 | Major | Feature | <p>CA eCTD Validation Criteria 5.3 Validation Rules H15, H20, G31, A09</p> <p>For the validation rules listed above, several temp files were written to the report folder. In rare cases this could interfere with security software, which would then lead to wrong results.</p> <p>This has been resolved; the profile will no longer use temp files that are written to multiple times.</p> <p>This update was already available with the regulatory update package 1.16.7.</p> | eV-FSP-3002-41 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6612 | Major | Feature | <p>CA Non-eCTD Validation Criteria 5.3 Validation Rule I11</p> <p>A new Biocides Application Form v1.1.0 is available and required for Non-eCTD Submissions to Health Canada. This version has now been added to eValidator configuration for validations executed in offline mode.</p> <p>The eValidator will now report an error in rule I11 if a version other than v1.1.0 is used.</p> <p>When executing validation rule I11, the validation profiles will access the LORENZ server to check for updated version information. When access to the LORENZ server (https://support.lorenz.cc/files/ev5/configupdate/ca/rt-version.xml) fails or validation is executed in offline mode, the version information will be retrieved from the configuration files installed with the LORENZ eValidator.</p> <p>This update was already available with the regulatory update package 1.16.5.</p> | eV-FSP-3002-42 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> CA eCTD - Validation Criteria 5.3 CA eCTD - Validation Criteria 5.3 EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ/PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-7020: Verify rule I07 reports an error when the replace is not applied to a leaf with the RT form (i.e., the modified-file references a leaf that is not an RT form).</p> <p>Verify rule F22 reports an error when the modified-file references a document in a different section.</p> |



| Validation Impact | Description |
|-------------------|--|
| | <p>EVA-6838: Verify that no jw.xml file is written to C:\temp during validation.</p> <p>EVA-6457: Verify that documents with AES-256 encryption are no longer reported as "Document could not be opened" under B48.</p> <p>EVA-6803: Verify that rule I11 will not report a finding when the submission date is set to after September 10, 2025, and the new RT Template v5.1.0 is used. Hint: When no submission date has been specified, "today" will be used as the submission date (i.e., the date the validation is executed).</p> <p>EVA-6657: If you experienced issues when validating because of your security software provider run the validation again and ensure that correct results are provided.</p> <p>EVA-6612: Verify that rule I11 will not report a finding when the new Biocides Application form v1.1.0 is being used.</p> |



4.1.6 CA Non-eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|--|
| EVA-6457 | Critical | Bug | <p>CA Non-eCTD Validation Criteria 5.2 & 5.3 Validation Rule B48</p> <p>The check for JavaScript caused the validation under rule B48 to fail for AES-256 encrypted PDFs. In these cases, a finding that the “document could not be opened” was reported. This issue has been resolved now.</p> <p>This update was already available with the specific releases 24.2.0.02 & 25.2.0.01.</p> | eV-FSP-3002-8, eV-FSP-3002-42, eV-FSP-6055 |
| EVA-6803 | Critical | Feature | <p>CA Non-eCTD Validation Criteria 5.3 Validation Rule I11</p> <p>A new Regulatory Transaction Template v5.1.0 is available and required for non-eCTD Submissions to Health Canada. Applies to: Human Use Drugs (Pharmaceutical, Biologic and Radiopharmaceutical) and Disinfectants and Veterinary Drugs.</p> <p>This version has now been added to eValidator configuration for validations executed in offline mode. The eValidator will now report an error in rule I11 if a version other than v5.1.0 is used.</p> <p>When executing validation rule I11, the validation profiles will access the LORENZ server to check for updated version information. When access to the LORENZ server (https://support.lorenz.cc/files/ev5/configupdate/ca/rt-version.xml) fails or validation is executed in offline mode, the version information will be retrieved from the configuration files installed with the LORENZ eValidator.</p> <p>This update was already available with the regulatory update package 1.16.7.</p> | eV-FSP-3002-42 |
| EVA-6657 | Major | Feature | <p>CA Non-eCTD Validation Criteria 5.3 Validation Rules A08, A09, I01, I06, I08, I09, I10, I11</p> <p>For the validation rules listed above, several temp files were written to the report folder. In rare cases this could interfere with security software, which would then lead to wrong results.</p> | eV-FSP-3002-42 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| | | | <p>This has been resolved; the profile will no longer use temp files that are written to multiple times.</p> <p>This update was already available with the regulatory update package 1.16.7.</p> | |
| EVA-6376 | Major | Feature | <p>CA Non-eCTD Validation Criteria 5.3 Validation Rule A08</p> <p>Rule A08 has been adjusted to accept HTML files for Biocides application forms only.</p> <p>This update was already available with the regulatory update package 1.16.1.</p> | eV-FSP-3002-42 |
| EVA-6453 | Major | Bug | <p>CA Non-eCTD Validation Criteria 5.3 Validation Rule I11</p> <p>For Biocides, a separate RT form will be used. Since the initial version number for the Biocides RT form is not available yet, the eV configuration cannot be updated accordingly. Therefore, please make sure to use online mode when validating a Biocides submission (once the Biocides RT form has been made available).</p> <p>This update was already available with the regulatory update package 1.16.1.</p> | eV-FSP-3002-42 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> CA Non-eCTD - Validation Criteria 5.3 CA Non-eCTD - Validation Criteria 5.3, Extended |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|-------------|
| IQ/PQ | EVA-6457: |



| Validation Impact | Description |
|-------------------|--|
| | <p>Verify that documents with AES-256 encryption are no longer reported as "Document could not be opened" under B48.</p> <p>EVA-6803: Verify that rule I11 will not report a finding when the submission date is set to after September 10, 2025, and the new RT Template v5.1.0 is used. Hint: When no submission date has been specified, "today" will be used as the submission date (i.e., the date the validation is executed).</p> <p>EVA-6657: If you experienced issues when validating because of your security software provider run the validation again and ensure that correct results are provided.</p> <p>EVA-6376: Verify rule A08 will report an error if an HTML file other than a Biocides HTML application form has been included in the submission.</p> <p>EVA-6453: This cannot be tested before RT forms for Biocides have been released by Health Canada. After May 31, verify that RT XML forms for Biocides will pass I11 when the correct form version has been used and will trigger an I11 error otherwise.</p> |



4.1.7 CA XML PM (Product Monograph)

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|---------------|
| EVA-6786 | Minor | Bug | CA XML PM Validation Criteria 2.1 The validation results for CA XML PM were not written to the database if database reporting was enabled. This has been resolved now. | eV-FSP-3002-9 |
| EVA-6644 | Major | Feature | CA XML PM Validation Criteria 2.1 The Controlled Vocabulary update for CA XML PM validation is now included in the validation profile. Previously the CV update had to be triggered manually through a separate profile, thus not being available to customers using docuBridge built-in validation. With this change CVs are updated automatically when running an XML PM validation. The validation report shows information about the updated CVs (and also about the not updated ones). Please note that due to the integration of the CV updates, the XML PM validation will now take longer than before (this could be several minutes if many updates were found). Please make sure the following URLs are not blocked by firewall or other security constraints: https://cv.hres.ca/en <div style="background-color: #e0f2f1; padding: 5px; border: 1px solid #c8e6c9;"> This update was already available with the regulatory update package 1.16.7. </div> | eV-FSP-3002-9 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> Health Canada XML PM Validation Criteria v2.1 |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|-------------|
| IQ | n/a |
| OQ | n/a |



| Validation Impact | Description |
|-------------------|--|
| PQ | <p>EVA-6786: If database reporting is enabled, verify that results of the CA XML PM validation are written to the database.</p> <p>EVA-6644: Verify CA XML PM validation always uses the latest version of the CVs provided by Health Canada and information about updated and not updated CVs is included in the validation report.</p> |



4.1.8 CH eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6540 | Major | Bug | CH eCTD Validation Criteria 1.5 Validation Rules 11.12, 11.13, 11.14, 11.15, 11.BP1 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-10 |
| EVA-6308 | Minor | Feature | CH eCTD Validation Criteria 1.5 An administrative information section has been added to the reports for Swiss eCTD validation. The section shows the information from the ch-envelope section in ch-regional.xml. | eV-FSP-3002-10 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> CH eCTD - Validation Criteria 1.5 CH eCTD - Validation Criteria 1.5, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool. EVA-6308: Verify the correct data as entered in the ch-envelope is displayed in the administrative information section. |



4.1.9 CH eDok

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6433 | Major | Feature | <p>CH Swissmedic eDok CTA (KlinV) Validation Rules E.5.0, E.5.4, E.4.5</p> <p>The folder structure expected by Swissmedic for eDoc CTA (KlinV) submissions has been updated. The updated folder structure can be found here: https://www.swissmedic.ch/swissmedic/en/home/medical-devices/klinische-versuche/klinische-pruefungen/emessage-ct-md.html.</p> <p>The eDok KlinV profile has been updated accordingly.</p> <p>This update was already available with the regulatory update package 1.16.1.</p> | eV-FSP-3002-11 |
| EVA-6458 | Marginal | Bug | <p>CH Swissmedic eDok Validation Rule PDF_5</p> <p>In the sub-report for rule PDF_5, the report title displayed the incorrect rule number (3.BP2) and the table header for the "Title" column incorrectly read "Page". This has been corrected now.</p> <p>This update was already available with the regulatory update package 1.16.1.</p> | eV-FSP-3002-11 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • Swissmedic eDok CTD • Swissmedic eDok KlinV • Swissmedic eDok NTA KPA • Swissmedic eDok NTA TAM • Swissmedic eDok NTA TAM Ext. |
| Configuration Files | Changed |
| Program Code | No changes |



| Validation Impact | Description |
|-------------------|---|
| IQ/PQ | <p>EVA-6433: Verify rules E.5.0, E.5.4 will report errors if the folder structure does not adhere to the updated template. The individual folder name length check in E.4.5 has been deactivated (path length check is still active).</p> <p>EVA-6458: Verify that PDF_5 is displayed as report title in the sub-report for rule PDF_5 and the table header is renamed to "Page/Title".</p> |



4.1.10 CN eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|--------------------------------|
| EVA-6540 | Major | Bug | <p>CN eCTD Validation Criteria 1.0 Validation Rules 3.30, 3.31, 3.32, 3.33, 3.34, 3.35, 4.1.25, 4.1.26, 4.1.27, 4.1.28, 4.1.29</p> <p>This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool.</p> | eV-FSP-3002-12 |
| EVA-6457 | Critical | Bug | <p>CN eCTD Validation Criteria 1.0 Validation Rule 6.24</p> <p>The check for JavaScript caused the validation under rule 6.24 to fail for AES-256 encrypted PDFs. In these cases, a finding that the “document could not be opened” was reported. This issue has been resolved now.</p> <p>This update was already available with the specific releases 24.2.0.02 & 25.2.0.01.</p> | eV-FSP-3002-12, eV-FSP-6055 |
| EVA-6634 | Critical | Bug | <p>CN eCTD Validation Criteria 1.0 Validation Rule 5.17</p> <p>Previously, all checks under 5 - STF were skipped when a sequence did not contain any STFs. However, rule 5.17 must always be executed to detect if content in certain sections has not been referenced from STFs.</p> <p>Furthermore, the rule did not work for STFs in section 5.</p> <p>This issue has been resolved now, rule 5.17 will always be executed to detect if content in sections m4-2-*, m5-3-1-*, m5-3-2-*, m5-3-3-*, m5-3-4-*, m5-3-5-* has not been referenced from STFs. This applies to sequences with or without any STFs.</p> <p>This update was already available with the regulatory update package 1.16.6.</p> | eV-FSP-3002-12 |



| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none">• CN eCTD Validation Criteria 1.0• CN eCTD Validation Criteria 1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6457: Verify that documents with AES-256 encryption are no longer reported as "Document could not be opened" under 6.24.</p> <p>EVA-6634: Verify that rule 5.17 will always be executed and will also detect missing STF references in sections 5.3.1 through 5.3.5.</p> |



4.1.11 CN eSubmission

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|---|
| EVA-6457 | Critical | Bug | CN eSubmission Validation Criteria 1.0 & 1.1 Validation Rule 4.8 The check for JavaScript caused the validation under rule 4.8 to fail for AES-256 encrypted PDFs. In these cases, a finding that the “document could not be opened” was reported. This issue has been resolved now. This update was already available with the specific releases 24.2.0.02 & 25.2.0.01. | eV-FSP-3002-50, eV-FSP-3002-13, eV-FSP-6055 |
| EVA-6604 | Critical | Feature | CN eSubmission Validation Criteria 1.1 A new profile has been added for the validation of submission in Chinese eSubmission format, using validation criteria version 1.1. Validation criteria version 1.1 is valid from July 2 nd , 2025 and version 1.0 has expired. This update was already available with the regulatory update package 1.16.6. | eV-FSP-3002-50 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> CN eSubmission Validation Criteria 1.1 CN eSubmission Validation Criteria 1.1, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6457: Verify that documents with AES-256 encryption are no longer reported as "Document could not be opened" under 4.8. |



| Validation Impact | Description |
|-------------------|--|
| | EVA-6604: Verify that the validation profile for CN eCTD validation criteria v1.1 is available in eValidator desktop client, eValidator webAccess, and LORENZ Job Management. |



4.1.12 ECOWAS eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6540 | Major | Bug | ECOWAS-WAHO eCTD Validation Criteria 1.0 Validation Results 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 4.5.5, 4.5.6, 4.5.7, 4.5.8 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-31 |
| EVA-6831 | Major | Feature | ECOWAS-WAHO eCTD Validation Criteria 1.0 Validation Rule 2.1.8 Rule 2.1.8 did not report an error about a wrong initial sequence under the following conditions: <ul style="list-style-type: none"> • The initial sequence is not 0001 • Submission type is not baseline • A folder xxxx-workingdocuments exists, where xxxx is a 4-digit number that is lower than the number of the sequence being validated | eV-FSP-3002-31 |
| EVA-6316 | Minor | Feature | ECOWAS-WAHO eCTD Validation Criteria 1.0 An administrative information section has been added to the reports for ECOWAS eCTD validation. The section shows the information from the wa-envelope section in wa-regional.xml for all recipients and countries. | eV-FSP-3002-31 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • ECOWAS-WAHO eCTD Validation Criteria v1.0 • ECOWAS-WAHO eCTD Validation Criteria v1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |



| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6831: Review your submissions for the conditions listed above and re-validate if required.</p> <p>EVA-6316: Verify the correct data as entered in the wa-envelope section is displayed in the administrative information section.</p> |



4.1.13 ECOWAS eSubmission

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6316 | Minor | Feature | ECOWAS-WAHO eSubmission Validation Criteria 1.0 An administrative information section has been added to the reports for ECOWAS eSubmission validation. The section shows the information from the wa-envelope section in wa-regional.xml for all recipients and countries. | eV-FSP-3002-32 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> ECOWAS-WAHO eSubmission Validation Criteria v1.0 ECOWAS-WAHO eSubmission Validation Criteria v1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6316: Verify the correct data as entered in the wa-envelope section is displayed in the administrative information section. |



4.1.14 EU eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6540 | Major | Bug | EU eCTD Validation Criteria 8.1 & 8.2 Validation Rules 11.12 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-46 |
| EVA-6984 | Major | Feature | EU eCTD Validation Criteria 8.2 Validation Rule 14.BP3 When the submission/@mode attribute is not provided (i.e., omitted), rule 14.BP3 will now report a finding if a value for submission/number is provided. This is because the number is allowed for submission modes grouping and worksharing only (and only if submission type is not psusa). Previously, the rule only reported a finding when the submission/@mode value was present but empty. | eV-FSP-3002-46 |
| EVA-6944 | Major | Feature | EU eCTD 3.2 Validation Criteria 8.2 Starting with this release, the EU eCTD 3.2 validation criteria 8.2 will be applied by default when using the docuBridge built-in validation. The validation criteria will be mandatory from December 1, 2025, but should already be evaluated during the two month transition period starting October 1st. | eV-FSP-3002-46 |
| EVA-7012 | Major | Bug | EU eCTD 3.2 Validation Criteria 8.2 Validation Rule 15.BP3 The following issue in rule 15.BP3 has been resolved: <ul style="list-style-type: none"> The check for the documents in 12-form was no longer working; an eAF that is not named xx-form-eaf.pdf was not reported, and a document that is not an eAF but is named xx-form-eaf.pdf, was not reported. | eV-FSP-3002-46 |
| EVA-6488 | Critical | Feature | EU eCTD Validation Criteria 8.1 Validation Rule 15.12 | eV-FSP-3002-40 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| | | | <p>Rule 15.12 reported false positives about the location of the tracking table when MRP/DCP was used. This has now been resolved.</p> <p>The issue was caused by the changes made for EVA-6394 in RUP 1.16.1.</p> <p>This update was already available with the regulatory update package 1.16.2.</p> | |
| EVA-6394 | Critical | Feature | <p>EU eCTD Validation Criteria 8.1 Validation Rules 15.11 & 15.12</p> <p>Rule 15.11 now also reports an error when extraneous tracking table files were found (in folders other than the expected one). Rule 15.12 now also reports an error when extraneous tracking table files were found (with file names other than the expected ones).</p> <p>This update was already available with the regulatory update package 1.16.1.</p> | eV-FSP-3002-40 |
| EVA-6521 | Major | Feature | <p>EU eCTD 3.2 Validation Criteria 8.2</p> <p>A new profile has been added for the validation of EU eCTD 3.2 (M1 DTD version 3.1) submissions, using validation criteria version 8.2.</p> <p>This update was already available with the regulatory update package 1.16.4.</p> | eV-FSP-3002-46 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • EU eCTD Validation Criteria 8.1 • EU eCTD Validation Criteria 8.1, EXTENDED • EU eCTD Validation Criteria 8.2 • EU eCTD Validation Criteria 8.2, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |



| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6984: Verify that rule 14.BP3 will report a finding if submission/number is provided but submission/@mode is not provided.</p> <p>EVA-6944: Verify EU eCTD 3.2 validation criteria 8.2 are applied automatically when using the docuBridge built-in validation.</p> <p>EVA-7012: Verify that rule 15.BP3 reports findings in the following cases: If documents in 12-form exist: <ul style="list-style-type: none"> An eAF is not named xx-form-eaf.pdf A document is not an eAF but is named xx-form-eaf.pdf </p> <p>EVA-6488: Verify rule 15.12 no longer reports false positives for common tracking tables used in MRP/DCP.</p> <p>EVA-6394: Verify that rule 15.11 reports an error if an additional tracking table is found in an unexpected location. Verify rule 15.12 reports an error when additional tracking tables with incorrect names were found. Both conditions apply when there is also a correctly named tracking table file in the correct location.</p> <p>EVA-6521: Verify that the validation profile for EU eCTD validation criteria v8.2 is available in eValidator desktop client, eValidator webAccess, and LORENZ Job Management.</p> |



4.1.15 EU NeeS

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|---------------|
| EVA-6564 | Minor | Bug | EU NeeS Validation Criteria 4.3 Validation Rule 2.BP1 Rule 2.BP1 reported a false positive when the application sequence was validated from a network share directly, without an additional folder above the application folder. E.g. validating a sequence placed at a path like <code>\\server\app\0000</code> returned a false positive, while <code>\\server\apps\app\0000</code> returned the correct results. | eV-FSP-3002-5 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> EU NeeS Validation Criteria 4.3 EU NeeS Validation Criteria 4.3, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6564: Verify that rule 2.BP1 returns correct results when validating a sequence located on a network share. |



4.1.16 EU eCTD 4.0

| Ticket Number | Priority | Type | Description | FSP Reference |
|-----------------------|----------|---------|--|----------------|
| EVA-6638 | Critical | Feature | <p>EU eCTD 4.0 Validation Criteria 1.0 Validation Rule eCTD4-076</p> <p>The validation under rule eCTD4-076 caused false positives for eCTD 4.0 for document reuse from other applications. To avoid this, the configuration has been set to database mode by default (through the “r_submission_cache” setting).</p> <p>Please note that such scenarios are not supported in the eValidator Desktop Client, but only when the eValidator is installed in a server environment.</p> | eV-FSP-3002-51 |
| EVA-7003 | Major | Feature | <p>EU eCTD 4.0 Validation Criteria 1.0 Validation Rule eCTD4-076</p> <p>When a context of use references a document from another application through the application UUID (as specified in ICH IG, section 8.1.1), a false negative will be reported by eCTD4-76 stating that the document was not found. This has now been resolved.</p> <p>Please note that you must have previously validated the application sequence from the 3.2 or 4.0 format application that defined the document. Otherwise, the eValidator will not know the document. This requires the eValidator server components (with the cache database) to work. With the eValidator desktop client in standalone-mode, cross-application document reuse will not be supported.</p> | eV-FSP-3002-51 |
| EVA-7001 | Major | Bug | <p>EU eCTD 4.0 Validation Criteria 1.0 Validation Rule EU-eCTD4-043</p> <p>A CoU in section 1.3.1 referencing a document that has been defined in another sequence or in another application did always trigger EU-eCTD4-043 (about a missing language attribute for the document definition). This has been resolved now, for documents defined in another sequence or application, EU-eCTD-043 will be ignored.</p> | eV-FSP-3002-51 |
| EVA-6988, EVA-6704 | Major | Bug | <p>EU eCTD 4.0 Validation Criteria 1.0 Validation Rules eCTD4-025, eCTD4-026</p> <p>The validation rules listed above reported false positives or were missing errors when using forward compatibility mode (i.e. using a context of use to replace a leaf from a 3.2 sequence). This was caused by incomplete configuration</p> | eV-FSP-3002-51 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|-------|--|----------------|
| | | | settings for the EU eCTD 4.0 module. The missing settings have now been added, and some additional corrections in the program code were made. | |
| EVA-6859 | Major | Bug | EU eCTD 4.0 Validation Criteria 1.0 Validation Rule eCTD4-EU-071 The folder names in M2-M5 were checked against the EU naming rules from eCTD 3.2. This has been changed now, the names will be checked against the naming rules according to ICH eCTD 4.0 IG. | eV-FSP-3002-51 |
| EVA-6913 | Minor | Bug | EU eCTD 4.0 Validation Criteria 1.0 Validation Rule eCTD4-076 Incorrect results could be reported if the sha256.txt that contains the checksum for the submissionunit.xml did not exist. This has been resolved now. | eV-FSP-3002-51 |
| EVA-4266 | Major | Story | EU eCTD 4.0 Validation Criteria 1.0 A new profile has been added for the validation of EU eCTD 4.0 submissions, using validation criteria version 1.0. <div style="background-color: #e6f2ff; padding: 5px;"> This update was already available with the regulatory update package 1.16.7. </div> | eV-FSP-3002-51 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> EU eCTD 4.0 Validation Criteria 1.0 |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6638: Verify that rule eCTD4-076 does not report false positives in cross-application document reuse scenarios. |



| Validation Impact | Description |
|-------------------|--|
| | <p>EVA-7003: Try document reuse via application UUID pattern as described in ICH IG, section 8.1.1. No error should be reported by eCTD4-076 if the document was defined in the other application and the sequence that defined it has been validated already.</p> <p>EVA-7001: Verify rule EU-eCTD4-043 will never report a finding for a CoU in section 1.3.1 for documents defined in another sequence or application.</p> <p>EVA-6988, EVA-6704: With forward compatibility mode, verify that errors reported by eCTD4-025 and eCTD4-026 are not false positives.</p> <p>EVA-6859: Verify the folder name check in rule eCTD4-EU-071 is executed according to the ICH eCTD 4.0 IG naming rules.</p> <p>EVA-6913: Under normal scenarios the sha256.txt should exist. If it does not, verify that the validation under rule eCTD4-076 reports correct results.</p> <p>EVA-4266: Verify that the validation profile for EU eCTD 4.0 validation criteria v1.0 is available in eValidator desktop client, eValidator webAccess, and LORENZ Job Management.</p> |



4.1.17 GCC eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|-----------------------------------|
| EVA-6540 | Major | Bug | GCC eCTD Validation Criteria 1.2 & 1.4 (Extended Profile) Validation Rules M1_LC1, M1_LC2, M1_LC3, M1_LC4, M1_LC5, M1_LC6, ICH_LC1, ICH_LC2, ICH_LC3, ICH_LC4, ICH_LC5, ICH_LC6 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-14, eV-FSP-3002-15 |
| EVA-6315 | Minor | Feature | GCC eCTD Validation Criteria 1.2 & 1.4 An administrative information section has been added to the reports for GCC eCTD validation. The section shows the information from the gc-envelope section for all countries listed in gc-regional.xml. | eV-FSP-3002-16 eV-FSP-3002-17 |
| EVA-7015 | Minor | Bug | GCC eCTD Validation Criteria 1.2 & 1.4 Validation Rule 13 Rule 13 will now report an error when the stylesheet ich-stf-stylesheet-2-3.xsl is found and the submission is for KW-MOH. Due to the tool used for validation by the KW-MOH, the v2.3 stylesheet is not accepted by them. Additionally, the util folder content will now also be checked under rule 13. This check was previously only available for the extended profile under Files_006. | eV-FSP-3002-16 eV-FSP-3002-17 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • GCC eCTD - Validation Criteria 1.2 • GCC eCTD - Validation Criteria 1.2 EXTENDED • GCC eCTD - Validation Criteria 1.4 • GCC eCTD - Validation Criteria 1.4 EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |



| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6315: Verify the correct data as entered in the gc-envelope is displayed in the administrative information section.</p> <p>EVA-7015: Verify an error is reported under rule 13 if the stylesheet ich-stf-stylesheet-2-3.xsl is present in the current application and the submission is for Kuwait.</p> <p>Verify the util folder content will be checked under rule 13.</p> |



4.1.18 JP eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|----------------|
| EVA-5972 | Major | Bug | JP eCTD 3.2 Validation Criteria 1.0 Rule Cover-01 Rule Cover-01 was not executed when the validation was started from Job Management or eValidator webAccess. This issue has been resolved now. | eV-FSP-3002-28 |
| EVA-6285 | Minor | Bug | JP eCTD 3.2 Validation Criteria 1.0 With docuBridge test publishing, the validation result for sequences other than the initial one was incorrect because the content from previous sequences located in the publishing pool could not be processed correctly. This issue has been resolved now. This update was already available with the regulatory update package 1.16.4. | eV-FSP-3002-29 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> JP (PDMA) – eCTD 3.2, Validation Criteria 1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-5972: Verify rule Cover-01 is executed when validating using Job Management or eValidator webAccess. Please note that Cover-01 will not be executed when validation was triggered from docuBridge Publishing. This is intentional. EVA-6285: When validating a sequence other than the initial one, verify that the validation results are identical between the test publishing pool and the publishing pool. |



4.1.19 JP eCTD 4.0

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|-----------------------------|
| EVA-6913 | Minor | Bug | JP eCTD 4.0, Validation Criteria 1.6.0.0 Validation Rule JP-eCTD4-126 Incorrect results could be reported if the sha256.txt that contains the checksum for the submissionunit.xml did not exist. This has been resolved now. | eV-FSP-3002-29 |
| EVA-6457 | Critical | Bug | JP eCTD 4.0, Validation Criteria 1.6.0.0 Validation Rule PDF-46 The check for JavaScript caused the validation under rule PDF-46 to fail for AES-256 encrypted PDFs. In these cases, a finding that the "document could not be opened" was reported. This issue has been resolved now. This update was already available with the specific releases 24.2.0.02 & 25.2.0.01. | eV-FSP-3002-29, eV-FSP-6055 |
| EVA-6431 | Major | Feature | JP eCTD 4.0 Validation Criteria 1.6.0.0 Validation rule JP-eCTD4-151 Implementation for JP-eCTD4-151 has been added to the profile. This will check for contextOfUse elements with study documents where the study group order keyword or the indication keyword (if applicable) differ from what has been specified for the first dataset submitted for the study. Furthermore, it will report an error if multiple sponsor-defined keyword code/codeSystem combinations (ich-keyword-type-8) have been used for the same study (based on the study ID and the section number). This update was already available with the regulatory update package 1.16.3. | eV-FSP-3002-29 |
| EVA-6487 | Major | Feature | JP eCTD 4.0 Validation Criteria 1.6.0.0 Implementation Package 1.6.0.1 The new controlled vocabulary files contained in the implementation package 1.6.0.1 have been added to the eValidator configuration: <ul style="list-style-type: none"> · JP_CL14-terminology(tabulation).gc_v20.xml · JP_CL15-terminology(analysis).gc_v11.xml The validation criteria version has not changed, therefore the header in the validation profile still shows 1.6.0.0. | eV-FSP-3002-29 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|---|----------------|
| | | | This update was already available with the regulatory update package 1.16.3. | |
| EVA-6426 | Major | Bug | <p>JP eCTD 4.0 Validation Criteria 1.6.0.0 Validation rules JP-eCTD4-010, JP-eCTD4-011, JP-eCTD4-012, and JP-eCTD4-013</p> <p>Elements contextOfUse with status active but without a document reference could previously cause false positives for JP-eCTD4-010, JP-eCTD4-011, JP-eCTD4-012, and JP-eCTD4-013. This issue has been resolved now.</p> <p>This update was already available with the regulatory update package 1.16.1.</p> | eV-FSP-3002-29 |
| | | | | |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> Japan (PMDA) - eCTD 4.0 |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6913: Under normal scenarios the sha256.txt should exist. If it does not, verify that the validation under rule JP-eCTD4-126 reports correct results.</p> <p>EVA-6457: Verify that documents with AES-256 encryption are no longer reported as "Document could not be opened" under PDF-46.</p> <p>EVA-6431: Verify that JP-eCTD4-151 has been implemented now (i.e., the placeholder message "Check not Implemented" no longer appears for this rule).</p> |



| Validation Impact | Description |
|-------------------|---|
| | <p>Verify that the deviations described above will be reported.</p> <p>EVA-6487: Verify that the new codes and codeSystem versions listed in</p> <ul style="list-style-type: none">· JP_CL14-terminology(tabulation).gc_v20.xml· JP_CL15-terminology(analysis).gc_v11.xml <p>can be used in the submissionunit.xml without triggering errors.</p> <p>EVA-6426: Verify that JP-eCTD4-010, JP-eCTD4-011, JP-eCTD4-012, and JP-eCTD4-013 do not report warnings when contextofUse elements with status active have been provided without a document reference. Only JP-eCTD4-121 should report warnings for those elements.</p> |



4.1.20 JO eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6540 | Major | Bug | JO eCTD Validation Criteria 1.1 (Extended Profile) Validation Rules M1_LC1, M1_LC2, M1_LC3, M1_LC4, M1_LC5, M1_LC6, ICH_LC1, ICH_LC2, ICH_LC3, ICH_LC4, ICH_LC5, ICH_LC6 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-19 |
| EVA-6313 | Minor | Feature | JO eCTD Validation Criteria 1.1 An administrative information section has been added to the reports for Jordan eCTD validation. The section shows the information from the jo-envelope section in jo-regional.xml. | eV-FSP-3002-19 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> JO eCTD - Validation Criteria 1.1 JO eCTD - Validation Criteria 1.1 EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool. |



| Validation Impact | Description |
|-------------------|--|
| | EVA-6313: Verify the correct data as entered in the jo-envelope is displayed in the administrative information section. |



4.1.21 KR eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6314 | Minor | Feature | KR eCTD Validation Criteria 1.0 An administrative information section has been added to the reports for South Korean eCTD validation. The section shows the information from the admin section in kr-regional.xml. | eV-FSP-3002-34 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> KR eCTD - Validation Criteria v1.0 KR eCTD - Validation Criteria v1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6314: Verify the correct data as entered in the admin section is displayed in the administrative information section. |



4.1.22 KSA NeeS

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|---|----------------------------------|
| EVA-6564 | Minor | Bug | KSA NeeS Validation Criteria 1.2 and 1.4 Validation Rule 4.4 Rule 4.4 reported a false positive when the application sequence was validated from a network share directly, without an additional folder above the application folder. E.g. validating a sequence placed at a path like \\server\app\0000 returned a false positive, while \\server\apps\app\0000 returned the correct results. | eV-FSP-3002-14 eV-FSP-3002-15 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • KSA NeeS - Validation Criteria 1.2 • KSA NeeS - Validation Criteria 1.2 EXTENDED • KSA NeeS - Validation Criteria 1.4 • KSA NeeS - Validation Criteria 1.4 EXTENDED |
| Configuration Files | No changes |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6564: Verify that rule 4.4 returns correct results when validating a sequence located on a network share. |



4.1.23 MD5/SHA256 Proofreader

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|---|----------------|
| EVA-6951 | Major | Bug | MD5/SHA256 Verification & MD5/SHA256 Proofreading and Correction When opening the MD5/SHA256 Proofreader profile binder in the desktop client, the profile "MD5/SHA256 Proofreading and Correction" was always preselected. This issue has been resolved, the "MD5/SHA256 Verification" profile has now been set as the default. | eV-FSP-3002-37 |
| EVA-6407 | Minor | Bug | MD5/SHA256 Verification & MD5/SHA256 Proofreading and Correction The MD5/SHA256 Verification and the proofreading and correction profiles have been adapted to not contact the US FDA Servers when validating the us-regional.xml. Before, this could lead to the request being blocked and the validation reporting an error. This issue has been resolved now. <div style="background-color: #e0f2f1; padding: 5px; border: 1px solid #c8e6c9;"> This update was already available with the regulatory update package 1.16.1. </div> | eV-FSP-3002-37 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> MD5/SHA256 Verification MD5/SHA256 Proofreading and Correction |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6951: When using the MD5/SHA256 Proofreader, verify that the "MD5/SHA256 Verification" profile is preselected. |



| Validation Impact | Description |
|-------------------|--|
| | EVA-6407: Verify running the MD5/SHA256 verification and the proofreading and correction profiles works for US eCTD 3.2 submissions. No errors about the us-regional.xml not being loadable should be reported. Also, no such errors should appear in the log file. |



4.1.24 PDF Document Validation (US FDA Requirements)

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|-----------------------------|
| EVA-6457 | Critical | Bug | <p>PDF QC - US FDA (Multiple Documents) PDF QC - US FDA (Single Document) Validation Rule G08</p> <p>The check for JavaScript caused the validation under rule G08 to fail for AES-256 encrypted PDFs. In these cases, a finding that the "document could not be opened" was reported. This issue has been resolved now.</p> <p>This update was already available with the specific releases 24.2.0.02 & 25.2.0.01.</p> | eV-FSP-3023, eV-FSP-6055 |
| EVA-6611 | Minor | Bug | <p>PDF QC - US FDA (Multiple Documents) PDF QC - US FDA (Single Document)</p> <p>The PDF QC profile will now also automatically save results to the database. Prerequisite for saving results to the database is enabled in the configuration.</p> <p>This update was already available with the regulatory update package 1.16.6.</p> | eV-FSP-3023 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> PDF QC - US FDA (Multiple Documents) PDF QC - US FDA (Single Document) |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6457:</p> <p>Verify that documents with AES-256 encryption are no longer reported as "Document could not be opened" under G08.</p> |



| Validation Impact | Description |
|-------------------|---|
| | EVA-6611: For eV FIVE and dB built-in installations, verify that results of the PDF QC validation will be saved to the database if the configuration setting is enabled. |



4.1.25 RS NeeS

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6564 | Minor | Bug | RS NeeS Validation Criteria 1.0 Validation Rule 2.BP1 Rule 2.BP1 reported a false positive when the application sequence was validated from a network share directly, without an additional folder above the application folder. E.g. validating a sequence placed at a path like \\server\app\0000 returned a false positive, while \\server\apps\app\0000 returned the correct results. | eV-FSP-3002-47 |
| EVA-6508 | Major | Feature | RS NeeS Validation Criteria 1.0 New profiles have been added for the validation of Serbian NeeS format, using validation criteria version 1.0. <div>This update was already available with the regulatory update package 1.16.4.</div> | eV-FSP-3002-47 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> RS NeeS – Validation Criteria 1.0 RS NeeS – Validation Criteria 1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6564: Verify that rule 2.BP1 returns correct results when validating a sequence located on a network share. EVA-6508: Verify that the validation profile for RS NeeS validation criteria v1.0 is available in eValidator desktop client, eValidator webAccess, and LORENZ Job Management. |



4.1.26 SG eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6540 | Major | Bug | SG eCTD Validation Criteria 1.0 Validation Rules 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 4.5.5, 4.5.6, 4.5.7, 4.5.8 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-36 |
| EVA-6551 | Major | Feature | SG eCTD Validation Criteria 1.0 Validation Rule 5.2.5 For the verification of categories and file-tags, the eValidator will now use valid-values.xml version 6 as released by ICH. This update was already available with the regulatory update package 1.16.4. | eV-FSP-3002-36 |
| EVA-6312 | Minor | Feature | SG eCTD Validation Criteria 1.0 An administrative information section has been added to the reports for Singapore eCTD validation. The section shows the information from the sg-envelope section in sg-regional.xml. This update was already available with the regulatory update package 1.16.4. | eV-FSP-3002-36 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> SG eCTD – Validation Criteria 1.0 SG eCTD – Validation Criteria 1.0, Extended |
| Configuration Files | Changed |
| Program Code | Changed |



| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6551: Verify that the new file-tags from valid-values.xml version 6 can now be used in STFs.</p> <p>EVA-6312: Verify the correct data as entered in the sg-envelope is displayed in the administrative information section.</p> |



4.1.27 TH eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6540 | Major | Bug | TH eCTD Validation Criteria 1.0 Validation Results 17.17, M1_LC1, M1_LC2, M1_LC3, M1_LC4, M1_LC5, M1_LC6, ICH_LC1, ICH_LC2, ICH_LC3, ICH_LC4, ICH_LC5, ICH_LC6 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-25 |
| EVA-6318 | Minor | Feature | TH eCTD Validation Criteria 1.0 An administrative information section has been added to the reports for Thai eCTD validation. The section shows the information from the envelope section in th-regional.xml. | eV-FSP-3002-25 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> TH eCTD - Validation Criteria 1.0 TH eCTD - Validation Criteria 1.0 EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ/OQ/PQ | EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool. EVA-6318: Verify the correct data as entered in the envelope is displayed in the administrative information section. |



4.1.28 TN eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6540 | Major | Bug | TN eCTD Validation Criteria 1.1 Validation Results 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.5.10, 4.5.6, 4.5.7, 4.5.8, 4.5.9 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-43 |
| EVA-6829 | Major | Feature | TN eCTD Validation Criteria 1.1 Validation Rule 2.1.8 Rule 2.1.8 did not report an error about a wrong initial sequence under the following conditions: <ul style="list-style-type: none"> • The initial sequence is not 0001 • Submission type is not baseline • A folder xxxx-workingdocuments exists, where xxxx is a 4-digit number that is lower than the number of the sequence being validated) | eV-FSP-3002-43 |
| EVA-6826 | Major | Feature | TN eCTD Validation Criteria 1.1 The following controlled vocabulary files have been updated by ANMPS: <ul style="list-style-type: none"> • document-matrix.xml • submission-type-matrix.xml • submission-lead-matrix.xml These CVs have now been updated inside the eValidator configuration to be used when running validations offline. | eV-FSP-3002-43 |
| EVA-6835 | Major | Bug | TN eCTD Validation Criteria 1.1 Validation Rule 4.5.3 Rule 4.5.3 should trigger only for leaf references in modified-file attributes that cannot be found or resolved. However, the profile also reported error(s) when the physical files referenced by those leaf IDs did not exist. This | eV-FSP-3002-43 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|---|---------------|
| | | | additional check is not in scope of the validation rule and has now been removed. | |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> TN eCTD Validation Criteria 1.1 TN eCTD Validation Criteria 1.1, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6829: Review your submissions for the conditions listed above and re-validate if required.</p> <p>EVA-6826: Verify that the latest versions of the CV files mentioned in the description are used when running validations using the Tunesian eCTD/eSubmission profile in offline mode.</p> <p>EVA-6835: Verify rule 4.5.3 does not report errors for referenced content files that could not be found (but only if the leaf IDs could not be resolved).</p> |



4.1.29 TN eSubmission

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6826 | Major | Feature | TN eSubmission Validation Criteria 1.1 (ANMPS, with trigger file) The following controlled vocabulary files have been updated by ANMPS: <ul style="list-style-type: none"> document-matrix.xml submission-type-matrix.xml submission-lead-matrix.xml These CVs have now been updated inside the eValidator configuration to be used when running validations offline. | eV-FSP-3002-44 |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> TN eSubmission - Validation Criteria 1.1 (ANMPS, with trigger file) |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6826: Verify that the latest versions of the CV files mentioned in the description are used when running validations using the Tunesian eCTD/eSubmission profile in offline mode. |



4.1.30 TW eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6540 | Major | Bug | TW eCTD Validation Criteria eCTD-V-R1 Validation Result K12, M1_LC1, M1_LC2, M1_LC3, M1_LC4, M1_LC5, M1_LC6, ICH_LC1, ICH_LC2, ICH_LC3, ICH_LC4, ICH_LC5, ICH_LC6 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-26 |
| EVA-6584 | Major | Feature | TW eCTD Validation Criteria eCTD-V-R1 TW eCTD Validation Criteria eCTD-V-R2 The Taiwan eCTD Validation Criteria Version 1.0 (eCTD-V-R1) is still accepted after July 1, 2025. Therefore, the validation profile for Version 1.0 has been added to the list of active profiles again. Also, the expiration warning has been removed from version 1.0 and a warning has been added to version 2.0 that this version has been withdrawn. <div>This update was already available with the regulatory update package 1.16.5.</div> | eV-FSP-3002-26 |
| EVA-6465 | Major | Feature | TW eCTD Validation Criteria eCTD-V-R2 New profiles have been added for the TW eCTD validation criteria related to the update for the TW eCTD specification (eCTD-R2). <div>This update was already available with the regulatory update package 1.16.3.</div> | eV-FSP-3002-26 |

| Change Impact | Description |
|---------------|-------------|
|---------------|-------------|



| | |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> Taiwan eCTD 1.0 - Validation Criteria eCTD-V-R1 Taiwan eCTD 1.0 - Validation Criteria eCTD-V-R1, EXTENDED Taiwan eCTD 2.0 - Validation Criteria eCTD-V-R2 Taiwan eCTD 2.0 - Validation Criteria eCTD-V-R2, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6584: Verify that the TW-eCTD-V-R1 profile is available in the list of active profiles in the eValidator Desktop Clients, eValidator webAccess and Job Management. Verify that no expiration warning will be displayed when using the TW-eCTD-V-R1 profile, but when using the TW-eCTD-V-R2 profile. LORENZ advises against usage of the TW-eCTD-V-R2 profile, as it has been withdrawn by the Taiwan agency.</p> <p>EVA-6465: TW eCTD-V-R2 has been withdrawn by the TW agency. Please see EVA-6584.</p> |



4.1.31 UA eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6540 | Major | Bug | UA eCTD Validation Criteria 1.0 Validation Result 11.12 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-35 |
| EVA-6628 | Major | Feature | UA eCTD 1.0 Validation Criteria 1.0 Validation Rules UA.1.2 A verification of the signature issuer has been added to rule UA1.2. Note that this enhancement does not offer a proper signature chain validation but informs if the signature uses the correct standard (PAdES) but was not issued by one of the trusted authorities. | eV-FSP-3002-35 |
| EVA-6570 | Minor | Bug | UA eCTD Validation Criteria 1.0 (Preflight Profile) Validation Rule UA1.2 Rule UA1.2 has been deactivated in preflight validation because it would generate false positives for missing documents. Please note that the preflight profiles are used with the preflight publishing feature from LORENZ docuBridge only. <div style="background-color: #e0f2f7; padding: 5px;"> This update was already available with the regulatory update package 1.16.5. </div> | eV-FSP-3002-35 |

| Change Impact | Description |
|---------------|--|
| Profiles | <ul style="list-style-type: none"> • UA eCTD – Validation Criteria 1.0 • UA eCTD – Validation Criteria 1.0, EXTENDED • UA eCTD – Validation Criteria 1.0, PREFLIGHT |



| | |
|---------------------|---------|
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6628: Verify rule UA1.2 will now inform if a form, annex or letter file was not signed using a signature that has been issued by one of the trusted authorities (https://czo.gov.ua/en/certificates). When executing validation rule UA1.2, the validation profiles will access the LORENZ server to check for updated information about trusted authorities. When access to the LORENZ server (https://support.lorenz.cc/files/ev5/configupdate/ua/uasignatureIssuers.xml) fails or validation is executed in offline mode, the information will be retrieved from the configuration files installed with the LORENZ eValidator.</p> <p>EVA-6570: When using preflight validation, verify that rule UA1.2 is not executed.</p> |



4.1.32 US eCTD (M1 v2.5, DTD v3.3)

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|---------------|
| EVA-6540 | Major | Bug | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 (Extended Profile)</p> <p>Validation Results A_M1_LC1, A_M1_LC2, A_M1_LC3, A_M1_LC4, A_M1_LC5, A_M1_LC6, ICH_LC1, ICH_LC2, ICH_LC2_STF, ICH_LC3, ICH_LC4, ICH_LC5, ICH_LC6</p> <p>This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool.</p> | eV-FSP-3002-1 |
| EVA-6778 | Major | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rules 1544 & 2043</p> <p>Rules 1544 & 2043 have been changed to only compare company-name and id against previous sequence but not also against the initial sequence.</p> | eV-FSP-3002-1 |
| EVA-6745 | Major | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 1255</p> <p>Rule 1255 has been updated to check the file extensions according to the latest file format specification (v9.3) released by USFDA: https://www.fda.gov/media/85816/download?attachment.</p> | eV-FSP-3002-1 |
| EVA-6606 | Major | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 1153</p> <p>Following changes were done to the validation under rule 1153:</p> <ul style="list-style-type: none"> • Rule 1153 will no longer trigger when the physical file (the content file) referenced through the modified-file leaf ID does not exist. • 1153 will now trigger when modified-file references a leaf in a different application. • When using offline mode for validation, FDA has observed a significant performance degradation when processing 1153 with us-regional.xml having | eV-FSP-3002-1 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|--------------------|----------|---------|--|------------------------------|
| | | | <p>multiple leaf elements with delete or replace operations. This has been resolved now.</p> <ul style="list-style-type: none"> The results for 1153 will no longer be written into sub reports but directly into the main report. | |
| EVA-6560, EVA-6849 | Major | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4</p> <p>When docuBridge built-in validation is used all contained application sequences in a grouped submissions will now automatically be validated after publishing the primary application. This functionality was previously only available for eValidator FIVE customers through Job Management, eValidator webAccess or the Batch Processing application.</p> <p>Additionally, the controller profile that was needed to validate all secondary applications contained in a grouped submission has been removed from LORENZ Job Management. Starting the validation for a primary application in a grouped submission will now automatically trigger validation for all contained sequences of the group.</p> | eV-FSP-3002-1 eV-FSP-6031 |
| EVA-6841 | Minor | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4</p> <p>The display name of the profile for validating secondary applications in grouped submissions has been changed from "US eCTD - Val. Crit. 4.4 (CDER), Grouped Child Application" to "US eCTD - Val. Crit. 4.4 (CDER) - Grouped Secondary Application".</p> | eV-FSP-3002-1 |
| EVA-6660 | Minor | Bug | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 (EXTENDED Profile only) Validation Rule A_M1_015, A_M1_015a</p> <p>Rule A_M1_015 has been changed to exclude Ad/Promo submissions (submission type fdast8) from the check.</p> <p>To handle Ad/Promo submission, rule A_M1_015a has been added to report missing contact types: tech, promo reg (fdaact2, fdaact4).</p> | eV-FSP-3002-1 |
| EVA-5875 | Major | Bug | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 2034</p> <p>Submission type Promotional Labeling Advertising (fdast8) is accepted for application type EUA (fdaat6) and will no longer trigger an error under 2034.</p> | eV-FSP-3002-1 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|---------------|
| | | | This update was already available with the regulatory update package 1.16.3. | |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • US eCTD - Val. Crit. 4.4 (CDER) • US eCTD - Val. Crit. 4.4 (CDER), EXTENDED • US eCTD - Val. Crit. 4.4 (CBER) • US eCTD - Val. Crit. 4.4 (CBER), EXTENDED • US eCTD - Val. Crit. 4.4 (CDER) - Grouped Secondary Application • US eCTD - Val. Crit. 4.4 (CDER) - Grouped Secondary Application, EXTENDED • US eCTD - Val. Crit. 4.4 (CBER) - Grouped Secondary Application • US eCTD - Val. Crit. 4.4 (CBER) - Grouped Secondary Application, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6778: Verify that rules 1544 & 2043 no longer report a finding if the company-name and id have changed in comparison to the previous sequence only (the initial sequence will not be checked anymore if it is not the direct predecessor sequence).</p> <p>EVA-6745: Verify that Rule 1255 checks for file extensions according to the latest specification for file format types released by USFDA.</p> |



| Validation Impact | Description |
|-------------------|---|
| | <p>EVA-6606: Verify the changes listed in the description are now applied for rule 1153.</p> <p>EVA-6560, EVA-6849: Verify all sequences in a grouped application are validated automatically when using docuBridge built-in validation or when starting the validation from LORENZ Job Management. Verify the Controller profile for US eCTD 3.2 grouped submission validation has been removed from LORENZ Job Management.</p> <p>EVA-6841: Verify the profiles for validating grouped applications are displayed as "US eCTD - Val. Crit. 4.4 (CDER/CBER) - Grouped Secondary Application" in the reports.</p> <p>EVA-6660: Verify rule A_M1_015 is no longer applied to Ad/Promo submissions and instead rule A_M1_015a is executed and reports applicable missing contact types.</p> <p>EVA-5875: Verify that 2024 will not trigger an error when Promotional Label Advertising is used as submission type for an EUA.</p> |



4.1.33 US eCTD 4.0

| Ticket Number | Priority | Type | Description | FSP Reference |
|-----------------------|----------|---------|--|------------------------------|
| EVA-6638 | Critical | Feature | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule eCTD4-076 <p>The validation under rule eCTD4-076 caused false positives for eCTD 4.0 for document reuse from other applications. To avoid this, the configuration has been set to database mode by default (through the "r_submission_cache" setting).</p> <p>Please note that such scenarios are not supported in the eValidator Desktop Client, but only when the eValidator is installed in a server environment.</p> | eV-FSP-3002-2 |
| EVA-6710 | Major | Feature | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rules eCTD4-046 <p>Improvements for document processing have been made to avoid false positives related to duplicate document definitions: When update mode is specified for a document definition, the document.reference.@value will now be ignored if the document ID was known (please see ICH IG, section 9.2.17.2).</p> | eV-FSP-3002-2 |
| EVA-6746 | Major | Feature | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule US-eCTD4-527 <p>File formats will now be accepted or reported by rule US-eCTD4-527 based on the version 9.3 of the US FDA File Format specification: https://www.fda.gov/media/85816/download?attachment.</p> | eV-FSP-3002-2 |
| EVA-6561, EVA-6850 | Major | Feature | US FDA eCTD 4.0 Validation Criteria 1.4 <p>The controller profile that was needed to validate all secondary applications contained in a grouped submission has been removed from LORENZ Job Management. Starting the validation for a primary application in a grouped submission will now automatically trigger validation for all contained sequences of the group (for both primary and secondary applications).</p> <p>When docuBridge built-in validation is used, all contained application sequences in a grouped submissions will now automatically be validated after publishing the primary application. This functionality was previously only available for eValidator FIVE customers through Job Management, eValidator webAccess or the Batch Processing application.</p> | eV-FSP-6031 eV-FSP-3002-2 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|-------------------------------|
| | | | Note that as of now publishing of US eCTD 4.0 grouped submissions is not supported from docuBridge. | |
| EVA-6995 | Major | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Contact Information When the contact name details “part” and “qualifier” where missing, the contact name was not listed in the report under “Administrative Information”. This has now been resolved. | eV-FSP-3002-2 eV-FSP-14001 |
| EVA-6787 | Major | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule US-eCTD4-559 When the current sequence was 0 and/or any non-numeric sequence folders existed in the application path, it could happen that the rule US-eCTD4-559 ran into an endless loop. This has been resolved now. | eV-FSP-3002-2 |
| EVA-6711 | Major | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule eCTD4-082 Rule eCTD4-082 has been adapted to also exempt documents with text/@updateMode="R". Previously only documents with title/@updateMode="R" were exempted. | eV-FSP-3002-2 |
| EVA-6641 | Major | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule eCTD4-076 Rule eCTD4-076 did not report an error if the referenced document was defined in a CDER submission but the current application is for CBER or vice versa. This issue has now been resolved. | eV-FSP-3002-2 |
| EVA-7021 | Minor | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule US-eCTD4-524 For the combination of submission type “Report” and submission unit type “Annual Report”, rule US-eCTD4-524 did not report a warning when the regulatory contact was missing. This issue has now been resolved. | eV-FSP-3002-2 |
| EVA-6913 | Minor | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule eCTD4-076 Incorrect results could be reported if the sha256.txt that contains the checksum for the submissionunit.xml did not exist. This has been resolved now. | eV-FSP-3002-2 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|-------------------------------------|----------|---------|---|---------------|
| EVA-6451 | Major | Feature | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule eCTD4-076 Rule eCTD4-076 has been improved to also show the Context of Use IDs where the references to the unknown documents were found. This update was already available with the regulatory update package 1.16.6. | eV-FSP-3002-2 |
| EVA-5655 | Major | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rules US-eCTD4-519 and US-eCTD-554 Rules US-eCTD4-519 and US-eCTD4-554 did previously not report findings for IND applications with studies in M5 when the studies do not comply with these rules. This has been resolved now. This update was already available with the regulatory update package 1.16.6. | eV-FSP-3002-2 |
| EVA-5360 | Major | Bug | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule eCTD4-519 Rule US-eCTD4-519 did incorrectly recognize two studies with the same Study ID in section 5.3.5.3 or 5.3.5.4 as the same, even though the indication keyword codes were different. This update was already available with the regulatory update package 1.16.6. | eV-FSP-3002-2 |
| EVA-6449 | Major | Feature | US FDA eCTD 4.0 Validation Criteria 1.4 Validation Rule eCTD4-026 Rule eCTD4-026 will now not only list the referenced Context of Use ID but also the referencing Context of Use ID. This update was already available with the regulatory update package 1.16.6. | eV-FSP-3002-2 |
| EVA-5795, EVA-6452, EVA-6448, | Minor | Feature | US FDA eCTD 4.0 Validation Criteria 1.4 Submissions using forward compatibility are not yet | eV-FSP-3002-2 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|--|----------|------|---|---------------|
| EVA-6447, EVA-6443, EVA-5798, EVA-5692, EVA-6450 | | | <p>accepted by US FDA. However, customers who want to prepare for that can already test it. It is possible to configure the validation to support forward compatibility mode.</p> <p>For this, please open the file Profile_US_eCTD.settings from the folder C:\ProgramData\Lorenz Life Sciences\validator\Repositories\ProfileParameters. Add the following line to the file and save the file: <setting name="p_allow_forward_compatibility">true</setting></p> <p>This update was already available with the regulatory update package 1.16.6.</p> | |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> US - eCTD 4.0 |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ/PQ | <p>EVA-6638: Verify that rule eCTD4-076 does not report false positives in cross-application document reuse scenarios.</p> <p>EVA-6710: The verify that eCTD4-046 will not be triggered indicating a duplicate document identifier when you used both update mode and document.reference.@value in a document definition for an already existing document identifier. Please make sure you never add a new document with both update mode and reference.@value specified because this will cause issues in later sequences when the document is reused.</p> <p>EVA-6746: Verify rule US-eCTD4-527 allows usage of the file formats following version 9.3 of the US FDA File Format specification.</p> <p>EVA-6561, EVA-6850: Verify all sequences in a grouped application are validated automatically when</p> |



| Validation Impact | Description |
|-------------------|--|
| | <p>using docuBridge built-in validation or starting the validation from LORENZ Job Management. Verify the Controller profile for US eCTD 4.0 grouped submission validation has been removed from LORENZ Job Management.</p> <p>EVA-6995: Verify that contact names are correctly displayed under “Administrative Information” in the report, even when the contact name details “part” and “qualifier” are missing.</p> <p>EVA-6787: Verify that for sequence 0 folder or non-numeric folders in the app life cycle, the rule US-eCTD4-559 does not loop endlessly.</p> <p>EVA-6641: Verify rule eCTD4-076 reports an error if the referenced document was defined in a CDER submission but the current application is for CBER or vice versa.</p> <p>EVA-6711: Verify documents with text/@updateMode="R" are exempted from rule eCTD4-082.</p> <p>EVA-7021: Verify that rule US-eCTD4-524 reports a warning for missing contacts in Report / Annual Report submissions.</p> <p>EVA-6913: Under normal scenarios the sha256.txt should exist. If it does not, verify that the validation under rule eCTD4-076 reports correct results.</p> <p>EVA-6451: Verify Context of Use IDs are displayed under eCTD4-076 if unknown document references are found.</p> <p>EVA-5655: When validating IND applications, verify rules US-eCTD4-519 and US-eCTD4-554 will now consider studies in M5.</p> <p>EVA-5360: Verify that rule US-eCTD4-519 does not report a warning when two studies with the same Study ID but different indication keywords are used in section 5.3.5.3 or 5.3.5.4.</p> |



| Validation Impact | Description |
|-------------------|---|
| | <p>EVA-6449: Verify that also the referencing Context of Use ID is listed under eCTD4-026.</p> <p>EVA-5795, EVA-6452, EVA-6448, EVA-6447, EVA-6443, EVA-5798, EVA-5692, EVA-6450: When you want to test validation of submissions using forward compatibility follow the steps above to enable forward compatibility mode. Verify submissions using forwards compatibility are validated as expected.</p> |



4.1.34 WHO PQT eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6540 | Major | Bug | WHO PQT eCTD Validation Criteria 1.1 Validation Results C.12 This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool. | eV-FSP-3002-48 |
| EVA-6317 | Minor | Feature | WHO PQT eCTD Validation Criteria 1.1 An administrative information section has been added to the reports for WHO PQT eCTD validation. The section shows the information from the whopqth-envelope section in whopqth-regional.xml. | eV-FSP-3002-48 |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> WHO PQT eCTD - Validation Criteria 1.1 WHO PQT eCTD - Validation Criteria 1.1, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool. EVA-6317: Verify the correct data as entered in the whopqth-envelope is displayed in the administrative information section. |



4.1.35 ZA eCTD

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------|
| EVA-6540 | Major | Bug | <p>ZA eCTD Validation Criteria 3.1 Validation Results 3.5.6, 3.5.7, 3.5.8, 3.5.9, 3.5.10, 4.5.6, 4.5.7, 4.5.8, 4.5.9</p> <p>This applies to docuBridge Test Publishing only An issue was resolved for validations executed through docuBridge test publishing: The system incorrectly used previous sequence data from the test publishing pool instead of the publishing pool when both contained the same previous sequence(s). This could lead to incorrect results in the rules mentioned above. The logic has been corrected to ensure that data is consistently taken from the publishing pool.</p> | eV-FSP-3002-20 |
| EVA-6614 | Major | Feature | <p>ZA eCTD Validation Criteria 3.1.1 Validation Rule 4.7.11d</p> <p>The submission type matrix has been updated by SAHPRA in July 2025. When validating a sequence, the latest version of the document matrix will be downloaded automatically by the validation profile.</p> <p>However, for offline validation (and when the SAHPRA website could not be accessed) a copy of this file is available in the eValidator configuration folder (and will automatically be used in those cases). This copy has now been updated to the latest version.</p> <p>Please note that LORENZ strongly recommends to always run the validation in online mode. This will ensure that the latest version of the SAHPRA matrices and controlled vocabulary files will be applied.</p> <p>This update was already available with the regulatory update package 1.16.5.</p> | eV-FSP-3002-20 |
| EVA-6542 | Major | Feature | <p>ZA eCTD Validation Criteria 3.1.1</p> <p>The following controlled vocabulary files have been updated by SAHPRA:</p> <ul style="list-style-type: none"> • application-type.xml • contact-type.xml • document-matrix.xml • evaluation-path.xml | eV-FSP-3002-20 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|---|---------------|
| | | | <ul style="list-style-type: none"> sequence-type.xml submission-lead.xml submission-type.xml <p>These CVs have been updated inside the eValidator configuration to be used when running validations offline.</p> <p>This update was already available with the regulatory update package 1.16.4.</p> | |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> ZA eCTD - Validation Criteria 3.1.1 ZA eCTD - Validation Criteria 3.1.1 EXTENDED ZA eCTD - Validation Criteria 3.1.1 PREFLIGHT |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| PQ | <p>EVA-6540: For the validation run after test publishing, verify that rules executing a deep life cycle check use correct previous sequence data from the publishing pool (if it exists) instead of the test publishing pool.</p> <p>EVA-6614: Verify that the latest document matrix version as published by SAHPRA is available in the configuration folder C:\ProgramData\Lorenz Life Sciences\eValidator\DTD\regional-za-3.1\cv.</p> <p>EVA-6542: Verify that the latest versions of the CV files mentioned in the description are used when running validations using the South African eCTD profile in offline mode.</p> |



4.1.36 ZA eSubmission

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|----------------|
| EVA-6614 | Major | Feature | <p>ZA eSubmission Validation Criteria 3.1.1 (SAHPRA, with trigger file) Validation Rule 4.7.11d</p> <p>The submission type matrix has been updated by SAHPRA in July 2025. When validating a sequence, the latest version of the document matrix will be downloaded automatically by the validation profile.</p> <p>However, for offline validation (and when the SAHPRA website could not be accessed) a copy of this file is available in the eValidator configuration folder (and will automatically be used in those cases). This copy has now been updated to the latest version.</p> <p>Please note that LORENZ strongly recommends to always run the validation in online mode. This will ensure that the latest version of the SAHPRA matrices and controlled vocabulary files will be applied.</p> <p>This change only applies to the ZA eSubmission - Validation Criteria 3.1.1 (SAHPRA, with trigger file) profile.</p> <p>This update was already available with the regulatory update package 1.16.5.</p> | eV-FSP-3002-21 |
| EVA-6542 | Major | Feature | <p>ZA eSubmission Validation Criteria 3.1.1</p> <p>The following controlled vocabulary files have been updated by SAHPRA:</p> <ul style="list-style-type: none"> • application-type.xml • contact-type.xml • document-matrix.xml • evaluation-path.xml • sequence-type.xml • submission-lead.xml • submission-type.xml <p>These CVs have been updated inside the eValidator configuration to be used when running validations offline.</p> | eV-FSP-3002-21 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|--|---------------|
| | | | This update was already available with the regulatory update package 1.16.4. | |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • ZA eSubmission - Validation Criteria 3.1.1 • ZA eSubmission - Validation Criteria 3.1.1 (SAHPRA, with trigger file) • ZA eSubmission - Validation Criteria 3.1.1, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| PQ | <p>EVA-6614: Verify that the latest document matrix version as published by SAHPRA is available in the configuration folder C:\ProgramData\Lorenz Life Sciences\eValidator\DTD\regional-za-3.1\cv.</p> <p>EVA-6542: Verify that the latest versions of the CV files mentioned in the description are used when running validations using the South African eSubmission profile in offline mode.</p> |



4.1.37 Expired Profiles

| Ticket Number | Priority | Type | Description | FSP Reference |
|------------------------------------|----------|-------|--|---|
| EVA-6958, EVA-6604, EVA-6486 | Minor | Story | <p>The following expired profiles (incl. extended versions) have been moved to the Expired folder:</p> <ul style="list-style-type: none"> • AU eCTD 3.1 • CN eSubmission v1.0 • CA eCTD 5.2 • CA Non-eCTD 5.2 <p>This update was already available with previous regulatory update packages.</p> | eV-FSP-3002-22, eV-FSP-3002-13, eV-FSP-3002-7, eV-FSP-3002-8 |

| Change Impact | Description |
|---------------------|----------------------------|
| Profiles | See profiles listed above. |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| PQ | <p>EVA-6958, EVA-6604, EVA-6486:</p> <p>eValidator Desktop Client: Verify that the profiles listed above are no longer listed in the profile selection dialog but can be loaded from the Expired folder (eV FIVE license required).</p> <p>eValidator Server: Verify that the latest versions of the profiles listed above are now the default used when validating submissions in Job Management, eValidator webAccess, or through docuBridge Publishing.</p> |



4.2 Reports and Style Sheets

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|--|
| EVA-6621 | Major | Feature | In compliance with Section 508 and WCAG requirements, the HTML reports created by eValidator can now be navigated using the keyboard. | eV-FSP-12043 eV-FSP-2033 |
| EVA-5275 | Minor | Feature | <p>If a different location for previous sequences has been configured, the previous sequences location is now shown in the report, under General Information.</p> <p>For further information on how to set a different previous sequences location please refer to the eValidator User Guide and eValidator webAccess User Guide.</p> | eV-FSP-2010 eV-FSP-6059 eV-FSP-12025 eV-FSP-10007 |
| EVA-7013 | Minor | Bug | <p>A PDF report could not be generated if the validated submission sequence contained invalid envelope data (or envelope data was missing completely).</p> <p>A PDF report could not be generated if the validated submission sequence was validated with the profile for a different format or region (profile did not match the sequence region).</p> <p>These issues applied to the following profiles: AU eCTD, BA eCTD, CH eCTD, EU eCTD 3.2, GC eCTD, JO eCTD, KR eCTD, SG eCTD, TH eCTD, TN eCTD, TW eCTD, UA eCTD, US eCTD 3.2, WA eCTD, WHO eCTD, ZA eCTD</p> <p>The issues have now been resolved.</p> | eV-FSP-5019 |
| EVA-6899 | Minor | Bug | When database reporting was used, the report header description was not written to the report. This issue has now been resolved. | eV-FSP-14003 |
| EVA-6484 | Minor | Bug | <p>Running the Sequence Statistics profile with eValidator 23.1.x* did not show the eValidator logo in the report header. This has now been resolved.</p> <p>Please note: The same issue applies to the RUP installation reports when using eValidator 23.1.x*. It will also be resolved with RUP 1.16.3. But the effect will only be visible with the next RUP after 1.16.3.</p> <p>* That is 23.1, 23.1.1, or 23.1.1.01</p> <p>This update was already available with the regulatory update package 1.16.3.</p> | eV-FSP-5026 |



| Change Impact | Description |
|---------------------|-------------|
| Profiles | All |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ/OQ/PQ | <p>EVA-6621: Verify that the HTML reports generated by eValidator can be fully navigated using only the keyboard.</p> <p>EVA-5275: Verify that when a different location for previous sequences is configured, this location is correctly displayed in the report under General Information.</p> <p>EVA-7013: Verify that even with an invalid regional backbone the PDF reports can be generated.</p> <p>EVA-6899: Verify that when database reporting is used, the report header description is correctly written and displayed in the generated report.</p> <p>EVA-6484: Verify that the eValidator logo is displayed in the validation report for the Sequence Statistics profile when using eValidator version 23.1 or 23.1.1 or 23.1.1.01.</p> |



4.3 eValidator Desktop Client & Batch Processing Application

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|--|
| EVA-7036 | Major | Feature | Legacy report styles have been decommissioned. Therefore, the option to use “old” style reports is no longer available in the eValidator Desktop Client and Batch Processing Application. | eV-FSP-10007 eV-FSP-2028 eV-FSP-5002 eV-FSP-5003 eV-FSP-5011 |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | All |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ/OQ/PQ | EVA-7036: Verify that the option to select or generate legacy (“old” style) reports is no longer available in the eValidator Desktop Client and Batch Processing Application, and that only the current report styles can be used. |



4.4 Setup and System Configuration

| Ticket Number | Priority | Type | Description | FSP Reference |
|--------------------|----------|---------|--|---------------|
| EVA-6783, EVA-6632 | Major | Feature | <p>The logging configuration has been updated in preparation for cloud container deployments.</p> <ul style="list-style-type: none"> In the LORENZ configPanel, it is now only possible to specify the log file directory where log files are stored. The log level configuration has been moved to the new page, "Logging Configuration – Application Log," in the LORENZ adminPanel. On this page, you can set the general log level or configure detailed log levels for specific components by adding categories. <p>Note: Be cautious when setting the log level to DEBUG or TRACE, as this can create very large log files with impact on system performance.</p> <p>Please refer to the LORENZ Foundation Administrator Guide for more information.</p> | eV-FSP-1020 |
| EVA-6741 | Major | Feature | <p>The configuration package export and import in the LORENZ configPanel has been redesigned and improved.</p> <p>With this change, it is now possible to backup and restore the following eValidator configuration items:</p> <ul style="list-style-type: none"> system.config AutoDetectMappings.xml definitions.xml Custom Profiles <p>For further information, please refer to the LORENZ Foundation Administrator Guide.</p> | eV-FSP-4014 |
| EVA-6659 | Major | Bug | <p>The eValidator Desktop Client now requires .NET Core 8.0.x Runtime, ASP.NET Core 8.0.x and Windows Desktop Runtime 8.0.x to be installed. These components can be downloaded and installed from the Microsoft website (before or after installation). Otherwise, you will be prompted to download and install the components during the first start of eValidator Desktop.</p> <p>For your convenience, we have provided a bundle with the client setup package of these components that you can use without downloading them: dotnetruntimes.exe.</p> | eV-FSP-1004 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|---|---------------|
| EVA-6415 | Minor | Bug | The eValidator Submission Cache schema was updated to version 25.2. Ensure to upgrade the database schema after installation. | eV-FSP-14003 |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | All |
| Configuration Files | No changes |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ/OQ | <p>EVA-6783, EVA-6632: Verify that in the configPanel, only the log file directory can be specified, and that log level configuration is no longer available there. Verify that in the adminPanel, under Logging Configuration – Application Log the general log level can be set. Confirm that log files are generated correctly according to the defined settings.</p> <p>EVA-6741: Confirm that after restoring a configuration package, all settings and profiles are correctly reapplied and the system operates as expected.</p> <p>EVA-6659: Make sure .NET Core 8.0.x Runtime, ASP.NET Core 8.0.x and Windows Desktop Runtime 8.0.x are installed when the Desktop Client shall be used on the system.</p> <p>EVA-6415: Upgrade the database schema version of the eValidator Submission Cache to 25.2.</p> |



4.5 eValidator webAccess (Submission Validation)

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|--|---------------|
| EVA-6739 | Major | Bug | It could happen that duplicate entries were written to the eValidator Database when rules were activated/deactivated through eValidator webAccess. This could lead to issues when the database scheme version was upgraded to 24.1 or higher. This issue has now been resolved. | eV-FSP-14003 |
| LSC-969 | Major | Bug | An issue was identified where entering date values via keyboard resulted in incorrect entries by displaying the wrong day first. This happened when the user's system time zone greatly differed from the primary time zone setting—by 10-12 hours. As a result, the UI incorrectly applied a time zone offset. The problem has now been resolved. | eV-FSP-3031 |
| EVA-6630 | Minor | Feature | The way the eValidator webAccess application processes background refreshes has been improved. With this change, the following issues have been resolved: interface flickering, unintended loss of focus, and tooltips opening inadvertently. | eV-FSP-12009 |
| EVA-6406 | Minor | Bug | In some cases, when trying to change a validation name, the newly entered name was reverted automatically due to a background refresh operation. This issue has been resolved now. | eV-FSP-12025 |
| EVA-6359 | Minor | Bug | In the validation list, no tooltip was shown long validation names that could not be displayed fully. This issue has been resolved now. | eV-FSP-12006 |
| LSC-843 | Minor | Bug | In right-click menus, the focus was fixed on the first element. This lead to issues while trying to navigate through submenu elements, trying to open one of the submenus using the keyboard. This issue has been resolved now. | eV-FSP-12043 |
| LSC-103 | Minor | Feature | <p>New alternative shortcut keys have been introduced to enhance accessibility and usability of the Focus Manager:</p> <ul style="list-style-type: none"> • Alt + P: Move focus to the previous element • Alt + N: Move focus to the next element <p>These shortcuts address several limitations of the previous Shift + Left/Right combination:</p> | eV-FSP-12043 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|----------------------------|
| | | | <ul style="list-style-type: none"> The Focus Manager can now be activated even when a screen reader is active, as screen readers often override arrow key shortcuts. The shortcuts now work when the focus is inside a table, where arrow keys are used for table navigation. They provide a consistent and reliable way to navigate between elements across different contexts. | |
| LSC-880 | Minor | Bug | An issue that caused the text in dropdowns where multiple items could be selected to be white on white background when light theme was used or black on black background when dark theme was used has been resolved. This issue occurred when the contrast setting was set to medium or high, and only for selected items in a dropdown list. | eV-FSP-12043 |
| LSC-914 | Minor | Bug | Child rows of a grouped entry in tables could falsely be displayed when the parent row is collapsed. This issue has been resolved now. | eV-FSP-20012, eV-FSP-12015 |
| LSC-917 | Minor | Feature | <p>This release adds improvements to better meet accessibility standards outlined in WCAG 2.2. LORENZ web applications now support more WCAG Level A and AA criteria, making them easier to use for people with disabilities.</p> <p>Key enhancements made in this release:</p> <ul style="list-style-type: none"> WCAG Level A Compliance Improvements <ul style="list-style-type: none"> Keyboard Navigation Enhancements: Ensured all interactive elements are accessible via keyboard navigation. Bypass repetitive content blocks: Added Focus Manager to the Storage Manager dialog shown in Job Management and eValidator webAccess. Alternative Text for Images: Implemented missing alt attributes for non-decorative images. WCAG Level AA Compliance Enhancements <ul style="list-style-type: none"> Status Messages: Status messages are generated automatically to ensure assistive technologies like screen readers can announce them. | eV-FSP-12043 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|------------------|----------|---------|--|---------------|
| LSC-885 | Minor | Feature | <p>The Notification Center has been improved by adding detailed preference settings to increase usability, as well as a deactivation option. The new feature allows users to choose the kind of notifications that they want to receive if the feature is active, and admins to deactivate notifications for their organization.</p> <p>The UNC can be disabled by admins using the new configPanel option "Disable User Notifications globally".</p> <p>To opt-out of certain notification categories, users can now click the new button at the top right of the Notification dropdown menu to open the capability list, containing the categories and sub-categories for deactivation. For identification purposes, notifications now contain a chip informing the user about the associated category.</p> <p>All categories are toggled on by default. The set preference is persisted between sessions. If a toggled-off capability/category in the Opt-out List is later toggled on in order to view notifications, those notifications are immediately visible in the UI upon Save.</p> <p>Note: For opting-purposes, the former topic "You were mentioned" has been renamed to "Mentions".</p> | eV-FSP-20020 |
| LSC-962 | Minor | Bug | An issue that prevented the focus manager from being activated after a row or cell in a table was selected has been resolved. | eV-FSP-12043 |
| LSC-861, LSC-836 | Minor | Bug | Density settings were improved to work reliably throughout the LORENZ suite. | eV-FSP-12043 |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | n/a |
| Configuration Files | Not changed |
| Program Code | Changed |



| Validation Impact | Description |
|-------------------|--|
| IQ/OQ/PQ | <p>EVA-6739: If you ran into issues with the database upgrade because of duplicate entries before, verify that the issue no longer exists.</p> <p>LSC-969: Verify that entering date values via keyboard correctly displays and saves the intended date, regardless of differences between the user's system time zone and the primary time zone setting.</p> <p>EVA-6630: Verify that the eValidator webAccess application processes background refreshes smoothly, without interface flickering, unintended loss of focus, or unintended tooltip activation during normal operation.</p> <p>EVA-6406: Verify that when changing a validation name, the newly entered name is retained and not reverted.</p> <p>EVA-6359: Verify that tooltips are displayed for long validation names in the validation list when the full name cannot be shown, ensuring the complete text is accessible to the user.</p> <p>LSC-843: Verify that in right-click menus, keyboard navigation functions correctly and focus can move between submenu elements without being fixed on the first item. Confirm that submenus can be opened and accessed using the keyboard.</p> <p>LSC-103: Verify that the new shortcut keys Alt + P and Alt + N in the Focus Manager correctly move focus to the previous and next elements. Confirm that these shortcuts function reliably with screen readers active, within tables, and across different interface contexts.</p> <p>LSC-880: Verify that in dropdown lists with multiple selectable items, the text color contrasts correctly with the background in both light and dark themes when the contrast setting is set to medium or high.</p> <p>LSC-914: Verify that in tables with grouped entries, child rows remain hidden when the parent row is collapsed. Confirm that child rows are only displayed when the parent row is expanded.</p> <p>LSC-917: Customers have this included this in their PQ, should add verification steps for WCAG Level A and AA items mentioned.</p> <p>LSC-885: Verify that administrators can globally disable user notifications using the new "Disable User Notifications globally" option in the configPanel.</p> |



| Validation Impact | Description |
|-------------------|---|
| | <p>Verify that users can manage notification preferences through the capability list, enabling or disabling specific categories and sub-categories, and that these settings persist between sessions.</p> <p>LSC-962: Verify that the Focus Manager can be activated after selecting a row or cell in a table.</p> <p>LSC-861, LSC-836: Confirm that changes to density are applied uniformly to all relevant interface components.</p> |



4.6 LORENZ Job Management

| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|------|---|---------------|
| EVA-6888 | Major | Bug | The description for the Validation Templates Reload has been updated in LORENZ Job Management. A validation templates reload is required, whenever profiles have been added or changed/updated. | eV-FSP-20016 |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | All |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ/OQ/PQ | EVA-6888: If the text was mentioned in the PQ scripts, update them to reflect the description change. |



4.7 Other Items

| Ticket Number | Priority | Type | Description | FSP Reference |
|------------------------------|----------|---------|---|--|
| EVA-6282, EVA-5612 | Critical | Feature | <p>As part of our ongoing modernization efforts, the product has been migrated from .NET Framework to .NET 8. This significant update lays the foundation for future cross-platform support, including Linux installations.</p> <p>Platform Updates:</p> <ul style="list-style-type: none"> The application now runs on .NET Core 8.0.x Runtime and ASP.NET Core 8.0.x. Desktop clients are now based on the Windows Desktop Runtime 8.0.x. The migration also prepares the system for future deployment on Linux environments, offering greater flexibility for diverse infrastructures. <p>Application and Console Changes:</p> <ul style="list-style-type: none"> The former eValidator Console has been replaced by the JobWorkerConsole, enabling more reliable and scalable background processing. The PowerShell Console has been removed to simplify configuration and reduce system dependencies. <p>Functional Enhancements:</p> <ul style="list-style-type: none"> PDF Engine Upgraded: The internal PDF engine has been modernized to deliver better performance, improved compatibility, and more consistent output quality. | eV-FSP-4010 eV-FSP-7001 eV-FSP-7013 eV-FSP-10004 eV-FSP-11001, eV-FSP-11002 eV-FSP-1004 eV-FSP-1005 eV-FSP-1007 eV-FSP-1009 eV-FSP-1013 eV-FSP-1015 eV-FSP-2014 eV-FSP-5016 eV-FSP-6033 eV-FSP-6051 eV-FSP-6054 eV-FSP-7001-7013 eV-FSP-10002 |
| EVA-6501, EVA-6619, EVA-7011 | Major | Feature | <p>In the dialog to install RUPs in LORENZ Job Management and eValidator Desktop Client it is now possible to select a specific RUP version that shall be installed. This allows for a more flexible RUP installation or even rollback in cases of errors with a newer RUP version. Please note that the RUP version 1.17.1 will be the first RUP version you can roll back to.</p> | eV-FSP-4007 eV-FSP-2005 |



| Ticket Number | Priority | Type | Description | FSP Reference |
|---------------|----------|---------|---|---------------|
| | | | For further information, refer to the LORENZ eValidator Administrator Guide. | |
| EVA-6655 | Major | Bug | If the auto-detect feature was used multiple times on the same system in parallel (e.g. from webAccess, Job Management), it could happen that the AutoDetectConfig.xml file was locked, which then led to issues with further use of the auto-detect feature. This issue has been resolved now. | eV-FSP-12007 |
| EVA-7035 | Major | Feature | The database migration tool that was delivered with the 23.1 release onward has been decommissioned with this release. | - |
| EVA-6667 | Critical | Story | <p>The previously used version of 7-Zip (18.1) contained known security vulnerabilities. To ensure the highest level of security, the tool has been updated to the latest available version (24.09).</p> <p>This update closes the vulnerabilities and ensures the continued safe use of 7-Zip within the system.</p> <p>This update was already available with the specific release 25.2.0.02.</p> | - |
| EVA-6499 | Critical | Bug | <p>In certain scenarios validating PDFs containing compressed streams could cause the eValidator to crash. This issue has been resolved now.</p> <p>This update was already available with the specific release 25.2.0.01.</p> | eV-FSP-6055 |
| EVA-6701 | Minor | Story | <p>The obsolete and potentially vulnerable SQLite 3.13.0 component has been removed, as it was no longer in use. There is no impact on functionality: SQLite is still available in the latest version through an internal function.</p> <p>This update was already available with the specific release 25.2.0.02.</p> | eV-FSP-14002 |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | n/a |
| Configuration Files | Changed |



| | |
|--------------|---------|
| Program Code | Changed |
|--------------|---------|

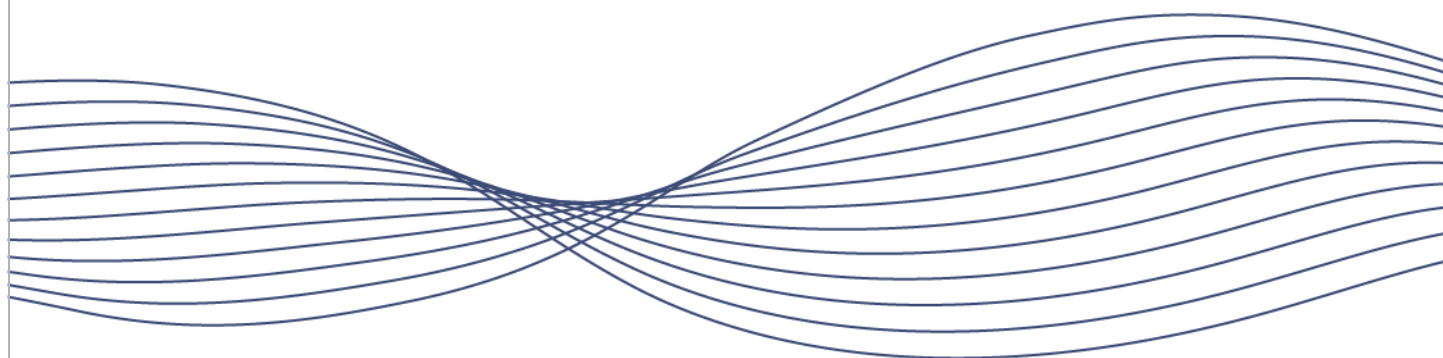
| Validation Impact | Description |
|-------------------|--|
| IQ/OQ/PQ | <p>EVA-6282: The migration of the product from .NET Framework to .NET 8 represents a major architectural change affecting both the application platform and several functional components. This change impacts core runtime environments, deployment structures, and internal processing behavior. As such, a complete revalidation of the system is strongly recommended to ensure compliance, reliability, and performance under the new framework.</p> <p>EVA-6501, EVA-6619, EVA-7011: <u>Please note that the following steps will only be available starting with Regulatory Update Package version 1.17.1.</u></p> <p>eValidator Basic & ONE: In the Desktop Client, verify you can select a specific RUP version from the Manage/Update dialog.</p> <p>eValidator FIVE & docuBridge built-in: Verify you can use the RUP version selection through the eValidator Configuration Update (RUP) rup dialog in Job Management.</p> <p>EVA-6655: Verify that auto-detecting the right profile for validation works correctly when it is used multiple times in parallel on the same system.</p> <p>EVA-7035: n/a</p> <p>EVA-6667, EVA-6701: Verify the updated components are present, no re-validation of business processes is required.</p> <p>EVA-6499: In case you experienced this issue before, re-validate the submission that caused the crash and verify the validation completes.</p> |



4.8 Known Issues

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|--|
| EVA-5081 | Minor | Bug | An issue has been identified that causes the validation to get stuck on execution when the first PDF check rule in an extended validation profile has been disabled manually. To avoid this issue, ensure that the first PDF check rule is always enabled. |
| EVA-7043 | Minor | Bug | An issue has been detected where the final results are not displayed correctly in the profile pane for validations triggered from eValidator webAccess. However, after validation finished the report is available and can be reviewed. |

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