



Release Configuration

Version 18.1.3

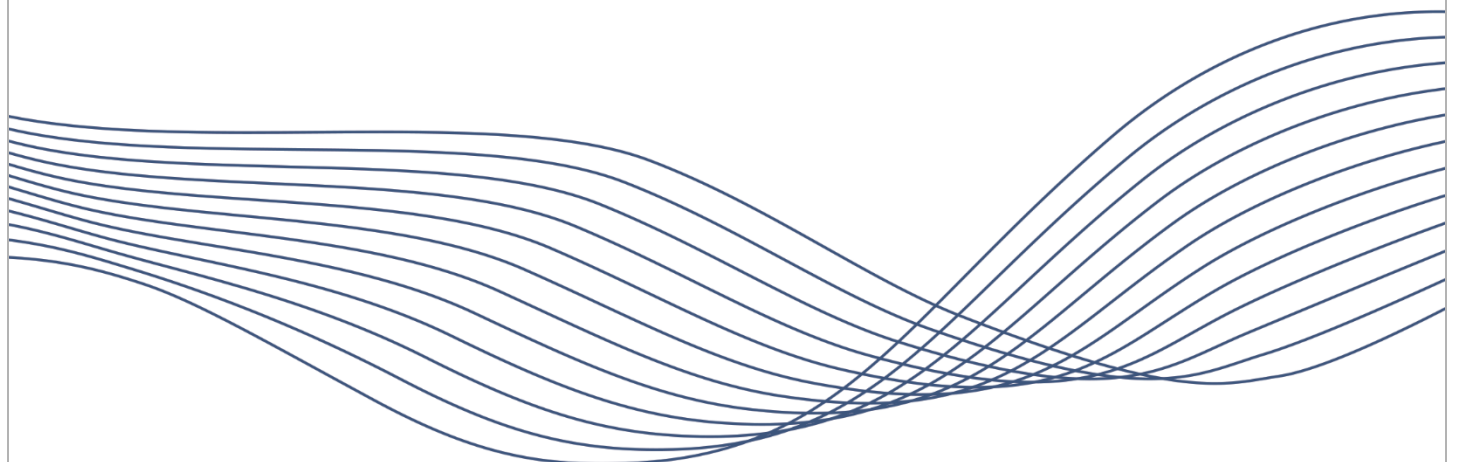




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1. Getting Started

1.1 Introduction

This document is the Release Configuration Sheet (RCS) for LORENZ eValidator 18.1.3.

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

This guide 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 the issues tracked under [LORENZ Help Desk](#) to allow every customer to identify items fixed on their behalf.

1.3 Where this software should 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 also with the LORENZ Automator.

1.4 Installing into a validated environment

According to the implemented change control procedures, (re-)validation steps will be required when putting the application into operational use. This depends on the validation policy implemented at each customer site.

LORENZ strongly suggests performing Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) based on a Validation Plan (VP). In addition, a thorough risk analysis and risk controlling should be performed.

The eValidator does not store or modify any electronic records for electronic submissions. However, due to the importance of correctness for the validation results, LORENZ recommends (re-)validating the product.



Note for validated environments: The software validation recommendations given in in this document only apply for customers upgrading from an existing version. All other customers should consider performing a full validation according to the policy defined in the organization.

1.4.1 Installation Qualification (IQ)

Both the setup package and the software binaries have been signed electronically to comply with the new security guidelines on Windows Vista, Windows Server 2008, Windows Server 2012, Windows Server 2016, and Windows 7, 8, or 10. The LORENZ certificate has been issued by GlobalSign (www.globalsign.com). If you need additional details about the certificate used, please contact LORENZ support.

Please only install LORENZ Automator software that has a genuine electronic signature issued to LORENZ Bridge Software GmbH. The signature will be shown upon installation.

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\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\Automator` 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 18.1.3, using the following distribution channels:

- HTTP download upon request

2.2 Product Documentation

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

Automator Documentation	Content
User Guide for LORENZ eValidator	This document describes how to use the LORENZ eValidator. It has not been updated for the 18.1.3 version. The 18.1.1 guide version is included with this release.
Functional Specification (FSP)	This document outlines the desired features and behavior of the system. It has not been updated for the 18.1.3 version. The 18.1.2 version is included with this release.
Release Configuration Sheet (RCS)	This document is the RCS. The RCS outlines the changes in LORENZ eValidator in this release.

Table 1: Product Documentation

2.3 Target Platform Information

The application has been tested and certified for the following operating system platforms:

- Microsoft Windows 7 and Windows 7 SP1 (32 and 64 Bit)
- Microsoft Windows 8 (32 and 64 Bit)
- Microsoft Windows 8.1 (32 and 64 Bit)
- Microsoft Windows 10
- Microsoft Windows Server 2008 R2 (incl. SP1)
- Microsoft Windows Server 2012
- Microsoft Windows Server 2012 R2
- Microsoft Windows Server 2016

Please Note:

The application setup requires Microsoft Windows Installer 3.1 or higher, which will not be installed automatically if not already existing on the target computer. All components are native Microsoft .NET 4.6.2 assemblies. Therefore, the .NET 4.6.2 runtime is required to use



the applications. The setup will not automatically install the .NET framework if not already present on the target computer. You need to do this manually before you start the installation of the eValidator.

2.4 Hardware requirements information

Minimum system

- 1 GHz processor
- 1 GB RAM
- 100 GB HDD

Recommended system

- 2 GHz processor with 2 or more cores or a multi-processor system
- 4 GB RAM
- 100 GB HDD

2.5 Release compatibility information

There are no compatibility issues for eValidator 18.1.3 related to previous versions. It can be used side by side with the docuBridge client.

This version will automatically replace an existing previous version of LORENZ eValidator 5.x found on the computer when you install LORENZ eValidator 18.1.3. Any version before LORENZ eValidator 5.0 will not be removed or upgraded by the eValidator setup. If you want to remove such a previous version, you need to uninstall it manually via the Add/Remove Programs dialog in the Control Panel or by re-running the setup program that installed the version.

The setup will install the eValidator only. Since version 5.8.1, the LORENZ Automator is now a self-contained product, which needs to be installed separately.

2.5.1 Foundation compatibility

This table shows the compatibility of the user management in eValidator webPanel to use the LORENZ Foundation system for user authentication and user authorization. No changes have been made to the eValidator webPanel in the 18.1.2 and 18.1.3 releases.

eValidator Release	Foundation Release	Compatibility
eValidator webPanel 18.1.1	1.0.0.0	Supported
eValidator webPanel 18.1.1	1.1.0.0	Certified
eValidator webPanel 18.1.1	1.2.0.0	Certified



eValidator Release	Foundation Release	Compatibility
eValidator webPanel 18.1.1	18.1.0.0	Certified
eValidator webPanel 18.1.1	18.1.1.0	Certified

Table 2: eValidator-LORENZ Foundation Compatibility



3. Installation Procedure Overview

3.1 Introduction

This section of the Release Configuration Sheet lists specific considerations for the installation of this release of the eValidator.

3.2 Software Installation Package

The distribution contains the software setup for eValidator 18.1.3. The setup can be used for both new and upgrade installations.

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 during installation, it will be updated.

3.2.1 eValidator Workstation

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; 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 non-eCTD submissions (NeeS and VNeedS). For details about the predefined validation rules for non-eCTD submissions, please refer to the user guide or the Functional Specification (FSP).

3.2.2 eValidator configPanel

This tool can be used by administrators to configure the LORENZ eValidator system. It will only be installed if the Workflow Service feature has been selected. The eValidator configPanel provides the following features and functions:

- Comprehensive configuration settings management
- License management
- Log file examination
- Start and stop the Workflow Service
- Detailed version information
- System configuration validation
- Importing and exporting system snapshots



3.3 Setup

Prior to installing eValidator, please unzip the distribution files to a temporary directory. If you have received the product on a CD or DVD, please copy the files to a temporary location on a hard disk and remove the “read-only” flags of these files before you continue.

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 during installation, it will be updated.

3.4 License Types

For the LORENZ eValidator different license types are available:

3.4.1 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.
- Using the LORENZ eValidator Batch Processing application is not supported.
- Only English localization is available.
- 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 on first start of the software. Only reinstalling the software will allow re-selecting the profile.
- You cannot validate submissions on a server operating system such as Microsoft Windows Server 2008, 2012, or 2016.
- 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”.
- You cannot use the automated profile update feature.

3.4.2 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 <http://www.lorenz.cc/eSolutions/eValidator>.

3.4.3 eValidator Enterprise license

This license does not have the functional limitations of the eValidator Basic or eValidator ONE license. Please note that the available extended profiles may depend on the modules you purchased. Additional features (e.g. the webPanel) can be purchased separately for this license type. For detailed information please contact LORENZ sales or talk to your LORENZ representative.

3.4.4 New/Update Installation

There are two different setup packages available:

3.4.4.1 Standard LORENZ setup, compressed

This setup consists files: setup.msi. Start the setup.msi to install the software.

3.4.4.2 Standard LORENZ setup, unpacked

This setup consists of multiple files, including a setup.msi. Start the setup.msi to install the software. You can customize this package before deploying it on your site. For example, you can add the license serial number to the **system.config** file in the package before deploying the package.

While it does not matter which setup (compressed or unpacked) you are using to update an existing previous product version or to install it for the first time, you must use the same setup if you want to uninstall or modify it later. Otherwise, uninstalling it will not work and when trying to modify an installation you would end up with two copies of the product installed.

Before installing LORENZ eValidator, please unzip the distribution file to a temporary directory. If you have received the product on a CD or DVD, please copy the files to a temporary location on a hard disk and remove the file's "read-only" flags before you continue.

Since the release 18.1, new versions of "BfArM eValidator" or "AGES eValidator" are no longer available. Please change to the standard product "LORENZ eValidator" instead.

If you currently have "BfArM eValidator" or "AGES eValidator" installed and you want to upgrade to "LORENZ eValidator", you must uninstall the current version before you can start installing the other package.

Now follow these steps to perform the installation:

1. In case Windows Installer or Microsoft .NET 4.6.2 runtime 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. Navigate to the setup folder **Setup LORENZ eValidator**.



3. Start the file **setup.msi**.
4. Acknowledge the confirmation dialogs and follow the instructions on the screen. Completing the installation of these components might require restarting the computer.
5. The eValidator installation wizard will be started. On Windows 7, Windows 8, Windows 10, Windows Server 2008, 2012, and 2016, you will get a User Access Control confirmation message showing the publisher's identity, similar to the example in the following picture:

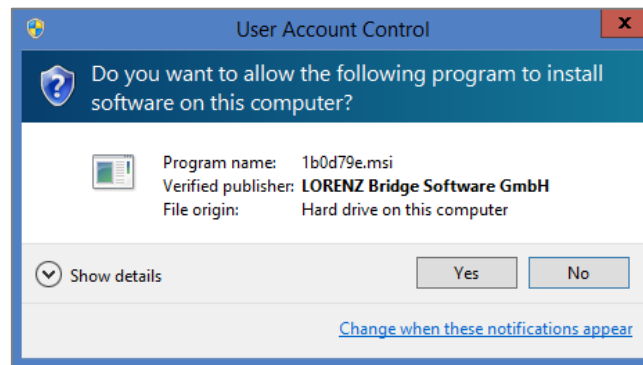


Image 1: Publisher's Identity Confirmation Dialog

6. To protect you from fraud through tampered software packages, please acknowledge this 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.
8. A new desktop shortcut (LORENZ eValidator) and a new start menu item will be created (LORENZ Life Sciences\eValidator). Both shortcuts can be used to start the application.
9. Start the eValidator. You will now be asked to select a profile for validation.

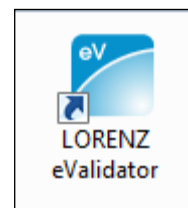




Image 2: Validation Profile Selection Dialog

Profiles contain collections of validation rules and settings for a specific validation scope (e.g. submitting an application to the FDA or to Health Canada).

The LORENZ eValidator installs a set of different profiles you can choose from. However, with the Basic license, a profile once chosen cannot be changed without reinstalling the



software. This applies to all users on a single computer (i.e. the profile chosen by the user who ran the application first will be applied to all other users as well and cannot be changed without reinstalling the software). The Enterprise version and the eValidator ONE versions do not have this limitation. To choose a profile, double-click the corresponding line or select the line and click the OK button. The profile will be loaded. The next time you start the LORENZ eValidator, you will not be prompted for the profile again; it will be loaded automatically.

3.4.4.3 LORENZ eValidator webPanel

You can still use the 18.1.1 version of the LORENZ eValidator webPanel. No changes have been made to the webPanel in this release.



4. Changes since the last Product Release

The following list of changes includes an impact analysis representing the product development team's view of the risk associated with each item.

4.1 eValidator Workstation: Changes in Release 18.1.3

4.1.1 Priority CRITICAL

4.1.1.1 EVA-1987 – EU eCTD / NeeS / VNeS Validation Criteria

Description

- **EU eCTD validation criteria 7.1** must be used starting September 2018, replacing the previous version 6.1. The LORENZ eValidator already has provided the corresponding validation profiles since release 18.1. With the release 18.1.3, the validation criteria 7.1 will be set as the standard, when using automatic format detection, and when validating using the docuBridge publishing feature. The profiles for validation criteria 6.1 have been moved to the Expired folder.
- **EU NeeS validation criteria 4.3** must be used starting September 2018, replacing the previous version 4.1. The LORENZ eValidator already has provided the corresponding validation profiles since release 18.1. With the release 18.1.3, the validation criteria 4.1 will be set as the standard, when using automatic format detection, and when validating using the docuBridge publishing feature. The profiles for validation criteria 4.1 have been moved to the Expired folder.
- **EU VNeS validation criteria 2.6** must be used starting September 2018, replacing the previous version 2.5b. The LORENZ eValidator already has provided the corresponding validation profiles since release 18.1. With the release 18.1.3, the validation criteria 2.6 will be set as the standard, when using automatic format detection, and when validating using the docuBridge publishing feature. The profiles for validation criteria 2.5b have been moved to the Expired folder.

Ticket Evaluation	
Priority	Critical
Type	Feature



Item	Change Impact
Profiles	<p>EU eCTD - Validation Crit. 7.1 NeeS - Validation Crit. 4.3: EU eCTD Validation Criteria 7.1 EU eCTD Validation Criteria 7.1 EXTENDED EU NeeS Validation Criteria 4.3 EU NeeS Validation Criteria 4.3, EXTENDED</p> <p>EU VNeS - Validation Criteria 2.6: VNeS 2.6, immunological VNeS 2.6, MRL VNeS 2.6, pharmaceutical VNeS 2.6, single file</p>
Configuration Files	Changed
Program Code	No changes
Documentation	No changes.

Validation Impact	Description
IQ	n/a
OQ	<p>Check that EU eCTD M1 v3.0.2 - Validation Crit. 6.1 NeeS - Validation Crit. 4.1 is no longer listed in the profile selection dialog. It can however still be loaded from the "Expired" folder when necessary (Enterprise license required).</p> <p>Check that EU VNeS - Validation Criteria 2.5b is no longer listed in the profile selection dialog. It can however still be loaded from the "Expired" folder when necessary (Enterprise license required).</p>
PQ	<p>Check that the EU eCTD Validation Criteria 7.1 profile is now the standard profile for EU eCTD that will be used with the auto-detect feature and also when validating from docuBridge.</p> <p>Check that the EU NeeS Validation Criteria 4.3 profile is now the standard profile for EU NeeS that will be used with the auto-detect feature and also when validating from docuBridge.</p> <p>Check that the VNeS 2.6 profiles are now the standard profiles for EU VNeS that will be used when validating from docuBridge.</p>



4.1.1.2 EVA-1993 – US eCTD, Rule 5030

Description

When validating multiple US eCTD submissions with the eValidator Workstation, the examination values for 5030 were not reset properly between the validations (unless the Workstation was between the validations). This could lead to incorrect validation results for the submissions (except for the first one validated).

The problem only affected the eValidator Workstation. Validating through the eValidator webPanel, eValidator Batch application, or from docuBridge was not affected.

These problems have now been resolved.

Ticket Evaluation	
Priority	Critical
Type	Bug

Item	Change Impact
Profiles	US eCTD - Val. Crit. 3.7 5030
	US eCTD - Val. Crit. 3.7, EXTENDED 5030
Configuration Files	No changes
Program Code	No changes
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	n/a
PQ	Customers with US eCTD submissions using the eValidator Workstation: Please verify that subsequent validations (different submissions) with the Workstation will no longer show inconclusive results for 5030, caused by not properly reset examination values from previous validations.



4.1.2 Priority MAJOR

4.1.2.1 EVA-1995 – User Settings and License Key after Upgrade

Description

After upgrading to eValidator 18.1, 18.1.1, or 18.1.2, all user specific application settings were reset. For example, the user had to re-enter the license key, the report path was reset to its default location, and also the most recently used profile was not loaded automatically.

The problem affected the eValidator Workstation and the eValidator Batch application, but not the eValidator webPanel and also not the validation from docuBridge.

This has now been resolved.

Ticket Evaluation	
Priority	Major
Type	Bug

Item	Change Impact
Profiles	No changes
Configuration Files	No changes
Program Code	Changed
Documentation	No changes

Validation Impact	Description
IQ	n/a
OQ	After installing the version 18.1.3, please verify that the user specific settings are still available in the eValidator Workstation or the eValidator Batch application (e.g. the license key, the report path, and the last used profile).
PQ	n/a

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