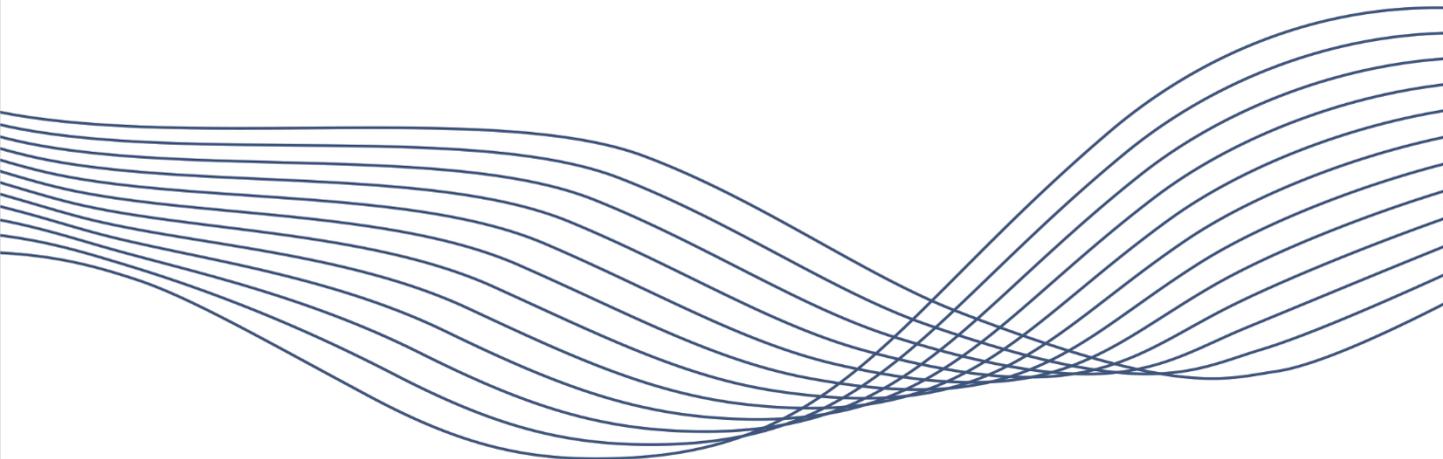




Functional Specification

eValidator 23.2



October 2023

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1. Notes

In this document, “LORENZ” has been used for the LORENZ Life Sciences Group.

Instead of the official and complete product name LORENZ eValidator throughout this document the term eValidator will be used frequently - always denoting the LORENZ eValidator product.

The Quality Management System (which LBS and LAS have committed to) states that the **Functional Specification (FSP)** is a description of the product to be supplied in terms of the functions it will perform and the facilities required to meet the user requirements.

This document may be part of the quotation specification and the release deliverables, although it shall not be used as the specification against which the system will be tested (PRP is used instead).

Note that the FSP is **not** a User Guide but a reference document for validation purposes. That is, the FSP does not contain design-specific items (e.g., button colors).



2. Introduction

The **LORENZ eValidator** application allows verifying and validating electronic submissions based on configured check options and dynamic verification rules. Validation results will be created as XML reports, HTML reports, and (optionally) PDF reports; adequate XSL style sheets for viewing the report content in a web browser are also provided.

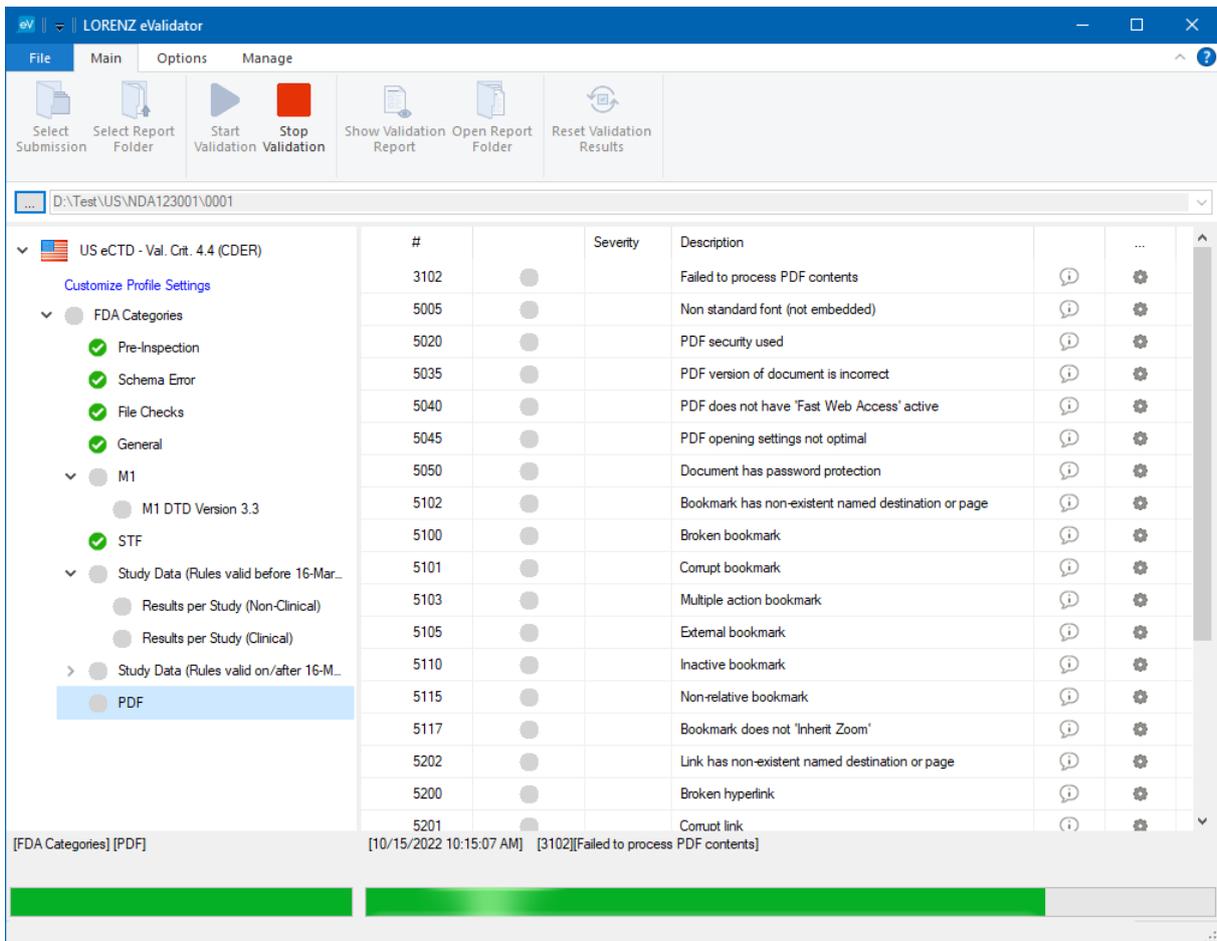


Figure 1: LORENZ eValidator Desktop Client User Interface



The next figure shows the overall system component diagram for LORENZ eValidator, including desktop clients and profiles. Components in blue color will be installed as part of the eValidator installation. Components in grey color are provided by LORENZ Foundation or LORENZ Automator.

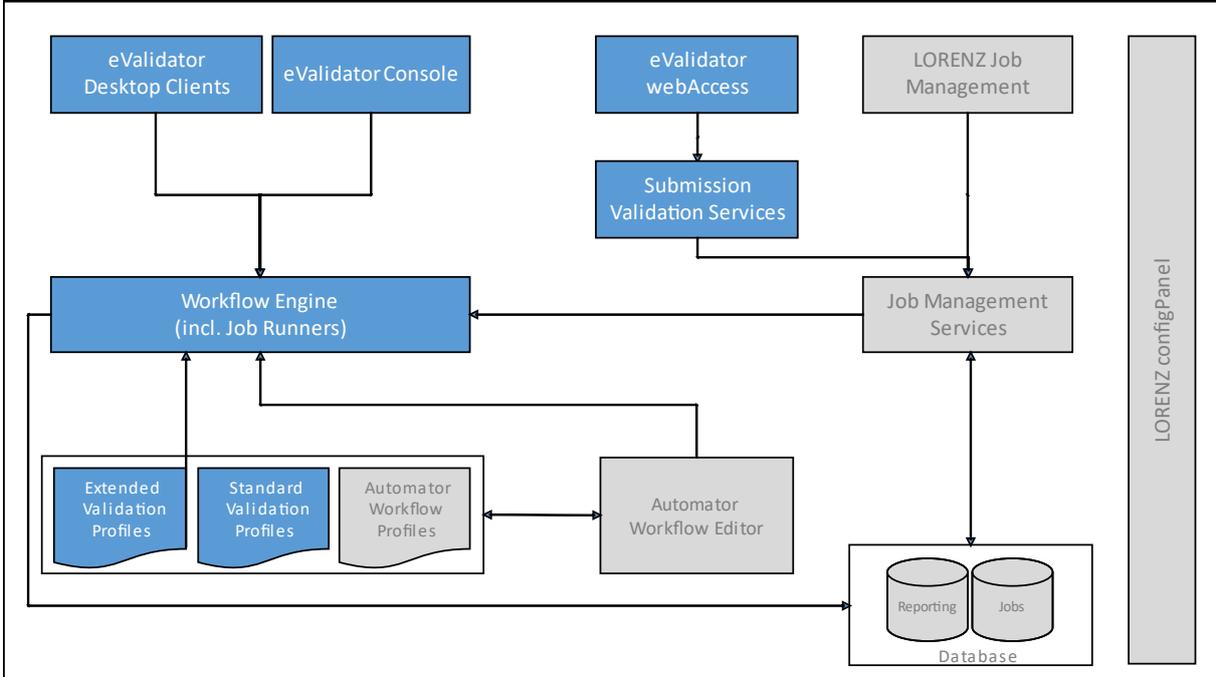


Figure 2: LORENZ eValidator Components



3. Product History

3.1 LORENZ eValidator 23.2

The LORENZ eValidator 23.2 release includes the following important new or updated features:

- Support for ECOWAS eCTD and eSubmission Validation Criteria 1.0
- Support for SG eCTD Validation Criteria 0.9
- New validation profiles for EU VNeeds Validation Criteria 3.1
- New validation profiles for JP eCTD 4.0 Validation Criteria 1.5.0.1
- Functionality to store validation results in database is now enabled in all active profiles by default. Enabling the feature via configPanel is required. A profile to purge validation results from the database is available in the LORENZ Job Management.
- Subreports can now be embedded into the main report and no longer need to be created in separate files.
- Improvements for eValidator webAccess.

3.2 Previous Versions

3.2.1 LORENZ eValidator 23.1

The LORENZ eValidator 23.1 release includes the following important new or updated features:

- eValidator webPanel has been removed. Jobs are now controlled through LORENZ Job Management.
- eValidator configPanel has been removed. All remaining eValidator settings are now integrated in LORENZ configPanel.
- eValidator Server is now using LORENZ RIM license.

3.2.2 LORENZ eValidator 22.2

The LORENZ eValidator 22.2 release includes the following important new or updated features:

- Support for US eCTD 4.0 Validation Criteria 1.2
- Support for JP eCTD 4.0 Validation Criteria 1.4.0.1
- Updates for several regional profiles (e.g., US eCTD, CN eCTD, CA eCTD, EU eCTD, ZA eCTD)
- Improvements for eValidator webAccess
- Renamed eValidator Enterprise to eValidator FIVE

3.2.3 LORENZ eValidator 22.1

The LORENZ eValidator 22.1 release includes the following important new or updated features:



- Improved System validation
- Added US eCTD 4.0 profile (for FDA pilot)
- Updates for several regional profiles (e.g., EU VNeS, US eCTD, CN eCTD)
- New report style is now the default for all validations

3.2.4 LORENZ eValidator 21.2

The LORENZ eValidator 21.2 release includes the following important new or updated features:

- New validation profiles for Swissmedic eDok
- Updates for several regional profiles (e.g., US, EU, ZA)
- Improvements for eValidator webAccess (e.g., US Grouped Submissions)

3.2.5 LORENZ eValidator 21.1

The LORENZ eValidator 21.1 release includes the following important new or updated features:

- New validation profiles for US eCTD validation criteria 3.9
- New validation profiles for TW eCTD validation criteria 0.6 (preview)
- Updates for several regional profiles (e.g., CH, US, CA, EU, ZA)
- New: eValidator webAccess
- New Setups for “eValidator Client” and “eValidator” Server installations

3.2.6 LORENZ eValidator 20.2

The LORENZ eValidator 20.2 release includes the following important new or updated features:

- New validation profiles for CA HC eCTD and Non-eCTD validation criteria 5.0
- New validation profiles for CA HC REP CO (Company) XML
- Updates for several regional profiles (e.g., CH, US, CA, EU, ZA)
- Validation reports in PDF format, as a configurable option

3.2.7 LORENZ eValidator 20.1.1

The LORENZ eValidator 20.1.1 release includes the following important new or updated features:

- New validation profile for Jordan eCTD v1.1
- New validation profile for ZA eSubmission
- Updates for several regional profiles (e.g. AU, CH, US, CA, EU, ZA)



3.2.8 LORENZ eValidator 20.1

The LORENZ eValidator 20.1 release includes the following important new or updated features:

- The LORENZ eValidator now uses .Net 4.7.2 as a prerequisite
- Advertisement in eValidator Client, Basic license
- Updates for several regional profiles (e.g. AU, US, CA, EU)
- New CH 1.5 eCTD validation profiles
- Improvements for the Regulatory Update installation feature

3.2.9 LORENZ eValidator 19.2.1

The LORENZ eValidator 19.2.1 release includes the following important new or updated features:

- Several updates for US eCTD, CN eCTD, AU eCTD, ZA eCTD, PDF QC
- Improvements for date/time format in reports

3.2.10 LORENZ eValidator 19.2

The LORENZ eValidator 19.2 release includes the following important new or updated features:

- Multiple updates for US eCTD, CA eCTD, CN eCTD, CH eCTD, AU eCTD, JO eCTD, TH eCTD, EU eCTD, GCC eCTD, US CDRH eCopy
- License handling for eValidator ONE changed
- Database migration tool added
- Setup has been optimized (only one setup type for eValidator, and one for webPanel)

3.2.11 LORENZ eValidator 19.1.1

The LORENZ eValidator 19.1.1 release includes the following important new or updated features:

- Updates for US eCTD, CA eCTD, EU eCTD, ZA eCTD, AU eCTD/NeeS
- Improvements for eValidatorConsole and JobWorkerConsole

3.2.12 LORENZ eValidator 19.1

The LORENZ eValidator 19.1 release includes the following important new or updated features:

- New Profile for US FDA eCTD validation criteria 3.8
- New Profile for CN CDE eCTD validation criteria 0.2
- Updates for CA eCTD, EU eCTD, ZA eCTD, AU NeeS
- Re-designed PDF QC Profile (now using PDFIUM)



- Improved update feature (regulatory update packages)
- Improved support for high-resolution displays

3.2.13 LORENZ eValidator 18.2.1

The LORENZ eValidator 18.2.1 release includes the following new or updated features:

- New Profile for Health Canada eCTD validation criteria 4.4
- New Profile for Health Canada non-eCTD validation criteria 4.4
- New Profile for Jordan eCTD
- New Profile for Swissmedic eCTD validation criteria 1.4
- Updates for US eCTD, EU eCTD, GCC eCTD, JP eCTD, ZA eCTD, EU NeeS, AU NeeS

3.2.14 LORENZ eValidator 18.2

The LORENZ eValidator 18.2 release includes the following new or updated features:

- Customized profile mappings can be preserved (freeze mappings)
- New configuration option to always use extended profiles
- Automatic profile switching when current profile has expired
- Validate SAS XPORT files is now supported
- PDF Analysis now supports getting PDF bookmarks status (expanded/collapsed)
- PDF Analysis now supports complete page size validation
- Report folder name change (milliseconds)
- Using docuBridge as tracking repository

3.2.15 LORENZ eValidator 18.1.2

The LORENZ eValidator 18.1.2 release includes the following new or updated features:

- New US eCTD profiles for validation criteria 3.7
- Improvements for Load Balancing (eValidator webPanel)

3.2.16 LORENZ eValidator 18.1.1

The LORENZ eValidator 18.1.1 release includes the following new or updated features:

- Updates for US eCTD profiles
- Updates for AU eCTD and NeeS profiles
- Improvements for Load Balancing (eValidator webPanel)

3.2.17 LORENZ eValidator 18.1

The LORENZ eValidator 18.1 release includes the following new or updated features:

- Support for EU eCTD validation criteria 7.1



- Support for EU NeeS validation criteria 4.3
- Support for EU VNeS validation criteria 2.6
- Updates for CA eCTD extended profile
- Updates for US eCTD profiles
- Updates for JP eCTD profile
- Updates for PDF QC profile
- Improvements for Load Balancing (eValidator webPanel)
- Single sign-on authentication (eValidator webPanel)
- Stylesheet improvements for US eCTD and PDF QC reports
- Manual/Automatic Configuration Update also for BASIC and ONE

3.2.18 LORENZ eValidator 5.10.1

The LORENZ eValidator 5.10.1 release includes the following new or updated features:

- Support for CA eCTD validation criteria 4.3
- Updates for US eCTD profiles
- Updates for JP eCTD profile
- Updates for ZA eCTD profiles
- Updates for AU eCTD and NeeS profiles

3.2.19 LORENZ eValidator 5.10

The LORENZ eValidator 5.10 release includes the following new or updated features:

- Support for AU eCTD validation criteria 3.1
- Support for AU NeeS validation criteria 3.1
- New Batch Processing application
- Using .Net framework 4.6.2

3.2.20 LORENZ eValidator 5.9.2

- Support for HC Non-eCTD Validation Criteria 4.2

3.2.21 LORENZ eValidator 5.9.1

The LORENZ eValidator 5.9.1 release includes the following new or updated features:

- Support for US FDA eCTD validation criteria v3.6
- Support for EU VNeS validation criteria v2.5b
- PDF QC Profiles

3.2.22 LORENZ eValidator 5.9

The LORENZ eValidator 5.9 release includes the following new or updated features:



- Support for US FDA eCTD validation criteria v3.5.1, and new file format specification v2.0
- Support for offline validation (without Internet access)
- Improved web proxy support
- Automatic profile updates

3.2.23 LORENZ eValidator 5.8.2

The LORENZ eValidator 5.8.2 release includes the following new or updated features:

- Support for Health Canada eCTD validation criteria v4.2.

3.2.24 LORENZ eValidator 5.8.1

The LORENZ eValidator 5.8.1 release includes the following new or updated features:

- MCC (South Africa) M1 v2.1 and Validation Criteria v2.0.
- US FDA eCTD Validation Criteria v3.3: Improved support for validation of US eCTD submissions in the eValidator webPanel (grouped Submissions, Application Reports, High Error Reports)
- Workflow Extension for processing SAS XPT files without third-party software
- eValidator webPanel: LORENZ Foundation integration

3.2.25 LORENZ eValidator 5.8

The LORENZ eValidator 5.8 release includes the following new or updated features:

- New setup for LORENZ eValidator
- LORENZ eValidator and LORENZ Automator are now separate products.
- Profile Editor has been removed (it is now available with LORENZ Automator)
- New user interface for eValidator desktop client application (Windows 8 and Windows 10 compliant)
- Support for web proxies to allow validation in environments with restricted internet access
- Improved support for validation of US submissions: New validation report style, Application Reports, High Error Reports

3.2.26 LORENZ eValidator 5.7.1

The LORENZ eValidator 5.7.1 release added the following new feature:

- Validation: Support for EU M1 v3.0.1, Validation criteria v6.1

3.2.27 LORENZ eValidator 5.7

The LORENZ eValidator 5.7 release added the following new or improved features:



- Validation: Support for EU M1 v3.0, Validation criteria v6.1
- Validation: Support for EU NeeS validation criteria v4.1
- Validation: Support for Health Canada's eCTD validation criteria v4.1
- Workflow Editor: Bookmarks
- Workflow Editor: Log view for preflight
- Workflow Editor: Improved action methods for PowerShell, database access, docuBridge access, XML processing

3.2.28 LORENZ eValidator 5.6.1.04

The LORENZ eValidator 5.6.1.04 release added the following new feature:

- Validation: Preliminary support for Health Canada's eCTD validation criteria v4.1

Hint: Specific releases 5.6.1.02 and 5.6.1.03 did not add or change any functions or features (just bug fixes).

3.2.29 LORENZ eValidator 5.6.1.01

The LORENZ eValidator 5.6.1.01 release added the following new features (for a complete list, please refer to the Release Configuration Sheet):

- Validation: Support for Thai FDA eCTD validation criteria v1.0
- Validation: Support for VNeS validation criteria v2.4

3.2.30 LORENZ eValidator 5.6.1

The LORENZ eValidator 5.6.1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Validation: Support for GCC eCTD validation criteria v1.4
- Validation: Support for KSA NeeS validation criteria v1.4
- Automator Workflow Profile Editor: Debug/Preflight function
- Automator Workflow Profile Editor: Improvements for Extension methods
- webPanel enhancements

3.2.31 LORENZ eValidator 5.6

The LORENZ eValidator 5.6 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Validation: Support for CH eCTD v1.3
- Validation: Support for GCC eCTD v1.4 (DTD v1.1, validation criteria v1.3)
- New webPanel
- Optional new stylesheet for validation and automation reports
- Automator Workflow Profile Editor: New features and functions, e.g., docuBridge and eSubmission Gateway modules, IMAP support, etc.



- The .Net framework 4.5 is now required to run the application.

3.2.32 LORENZ eValidator 5.5.1

The LORENZ eValidator 5.5.1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Validation: Support for VNeS version 2.3
- Validation: Support for CA eCTD validation criteria 4.0
- Updates for Validation profiles: US eCTD, AU eCTD, EU eCTD, GCC eCTD, BIH NeS
- Updated PDF engine for better performance
- Automator Workflow Profile Editor: New features and functions, e.g., SOAP and REST calls, workflow references, embedded custom data, processing PDF XFA data, improved condition handling, etc.

3.2.33 LORENZ eValidator 5.5

The LORENZ eValidator 5.5 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Validation: Updated CA eCTD profile
- Validation: Updated AU eCTD profile (Validation Criteria 3.0)
- Validation: Updated AU NeS profile (Validation Criteria 3.0)
- Validation: Improvements and corrections for PDF analysis
- Validation: Check references in dataset definition files (define.xml)
- webPanel: Job list export
- webPanel: Support File/folder browser in user dialogs
- webPanel / Batch Service: Support for ORACLE 11 and 12
- Automator Workflow Profile Editor: New features and functions, e.g., job management, database queries, text file processing

3.2.34 LORENZ eValidator 5.4.1

The LORENZ eValidator 5.4.1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Validation: Updated CA eCTD profile
- Validation: PDF/A no longer raises warnings in the reports (eV5-532)
- Validation: Corrections to ALMBIH and FDA CDRH eCOPY profiles
- Validation: New rule in FDA eCTD extended profile, to raise a warning if links to other documents do not open in a new window
- webPanel: Support for user dialog at job startup
- Automator Workflow Profile Editor: New features and functions, improved handling
- Automator Workflow Profile Editor now replaces the legacy Profile Editor



3.2.35 LORENZ eValidator 5.4

The LORENZ eValidator 5.4 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Support for TH eCTD M1 Schema 0.91 and validation criteria v0.91
- Support for TH eCTD M1 Schema 0.92 and validation criteria v0.92
- Support for ALMBIH NeeS v1.0 and validation criteria v1.0
- Updated profile for FDA CDRH eCopy device submissions
- New editor for validation profiles and Automator workflow profiles

3.2.36 LORENZ eValidator 5.3.1

The LORENZ eValidator 5.3.1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Support for AU eCTD M1 Schema 0.90 and Validation Criteria v0.90
- Support for AU NeeS 1.0 and Validation Criteria v1.0

3.2.37 LORENZ eValidator 5.3

The LORENZ eValidator 5.3 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- New configuration editor for eValidator FIVE version LORENZ Automator configPanel
- Support for US eCTD M1 DTD 3.3 and Validation Criteria v3.1
- Preflight profiles with reduced validation sets
- MD5 Proofreading and correction profile
- New setup for webPanel
- Improved filter handling for webPanel
- Improved load-balancing for multi-server installations

3.2.38 LORENZ eValidator 5.2.1

The LORENZ eValidator 5.2.1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Advanced load balancing for the eValidator Batch Service – now supporting different profile sets on each server
- Enhanced Baseline Optimized Validation for PDF Analysis
- Updated JP eCTD profile (PMDA)
- Option to copy the report ZIP to the application folder

3.2.39 LORENZ eValidator 5.2

The LORENZ eValidator 5.2 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):



- Support for AU (TGA) NeeS (provisional)
- Support for FDA eCTD Validation Criteria 3.0 and M1 version 2.2 (DTD v3.2)
- Support for multiple Batch Services in load balancing scenarios
- Improved setups (harmonized with docuBridge setup approach)

3.2.40 LORENZ eValidator 5.1.2

The LORENZ eValidator 5.1.2 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Support for VNeS 2.2
- Baseline Optimized Validation
- Improved folder browsing in eValidator webPanel for folders with a large amount of content
- Additional options for server-side folder access with eValidator webPanel/Batch Service

3.2.41 LORENZ eValidator 5.1 SP1

The LORENZ eValidator 5.1 SP1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Support for EU eCTD M1 v2.0 validation (criteria version 5.0)
- Support for CA validation criteria 3.0
- Support for CDRH eCopy validation
- Provisional support for MCC ZA eCTD 1.0 validation
- LORENZ eValidator webPanel: Support for job priorities
- LORENZ eValidator webPanel: User interface improvements
- LORENZ eValidator webPanel: Flexible resume dialogs
- Validation reports now with list of referenced and list of missing sequences Significant performance improvements in PDF analysis

3.2.42 LORENZ eValidator 5.1 / HF1

The LORENZ eValidator 5.1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Supports the GCC NeeS 1.2 validation criteria
- Supports the US M1 v.2 0 (DTD 3.0)
- Preliminary support for GCC eCTD 1.2 validation criteria
- LORENZ eValidator webPanel: Support for job annotations
- LORENZ eValidator webPanel: Supporting searches for combined results
- LORENZ eValidator webPanel: Links to PDF documents can now be URLs
- Support for profile specific style sheets
- Validation of CDISC define.xml files in US submissions



- New PowerShell host applications

3.2.43 LORENZ eValidator 5.0 SP1

The LORENZ eValidator 5.0 SP1 release added the following new or enhanced features (for a complete list, please refer to the Release Configuration Sheet):

- Automatic submission pre-examination to find the best matching profile
- The Profile Editor has been improved significantly
- Supports the GCC NeeS 1.0 validation criteria
- Preliminary support for GCC eCTD 1.0 validation criteria
- New system component: LORENZ eValidator webPanel
- New system component: LORENZ eValidator Batch Service
- Improved font rendering in main program
- PDF Analysis can now detect PDF/A documents
- PDF Analysis can now detect certificate secured documents

3.2.44 LORENZ eValidator 5.0

Apart from a new interface, the eValidator 5.0 was completely redesigned from the ground up to incorporate the knowledge gathered from literally thousands of users around the world, including agencies. Here are the key features and functions for version 5.0:

- Validation criteria published by the agencies are now addressed more closely than before. Wherever possible the exact same granularity, numbering and names as in the official documents are being used.
- Supports the official CA eCTD 1.0 validation criteria
- Supports the official EU eCTD 3.1 validation criteria
- Supports the official EU NeeS 2.1 validation criteria
- Supports the official US eCTD 1.0 validation criteria
- Supports the official US eCTD 2.1 validation criteria
- Supports the official CH eCTD 1.1 validation criteria
- Supports JP eCTD 1.0 validation
- Supports VNeS 2.1
- Flexible severity levels and associated colors for validation findings
- Full command line support
- Full PowerShell scripting support
- Protected profiles
- Alternative application folders for previous sequences

3.2.45 LORENZ eValidator 3.1 SP1

The LORENZ eValidator 3.1 release added the following new or enhanced features:

- Support for the new EU eCTD validation criteria (3.1)



- Support for the new EU NeeS validation criteria (2.1)
- Support for the new FDA eCTD validation criteria (2.0)
- Better support for very large submissions
- EU profile harmonization (BfArM and AGES profiles now replaced by general EU profile)

3.2.46 LORENZ eValidator 3.1

The LORENZ eValidator 3.1 release added the following new or enhanced features:

- Alternative application folders for previous sequences
- New summary report (professional version)
- New program logo and icons
- Protected profiles
- Anchor points in reports
- Hardware bound licenses

3.2.47 LORENZ eValidator 3.0 SP1 HF5

The LORENZ eValidator 3.0 SP1 HF5 release added the following new or enhanced features:

- Additional profiles for Polish agency
- In all pre-defined (default) profiles (signed electronically by LORENZ), the severities can no longer be changed.
- NeeS: Guidance 2.0 support
- CH M1 version 1.1 support
- Reused files in eCTD will be detected automatically (in the same sequence only)
- Rules with severity "Ignore" will be hidden in the eValidator rule lists.

3.2.48 LORENZ eValidator 3.0 SP1 HF2, HF3, and HF4

The LORENZ eValidator 3.0 SP1 HF2 to HF4 releases added the following new or enhanced features:

- Additional profiles for BfArM and AGES
- Default profile no longer usable for validation
- NeeS: Adherence to naming conventions now has "warning" severity
- NeeS / eCTD: For EU the path lengths will be calculated excluding application name
- NeeS: Rule severities changed to "information" for "m1-toc.exists", "m2-toc.exists", "m3-toc.exists", "m4-toc.exists", "m5-toc.exists"

3.2.49 LORENZ eValidator 3.0 SP1 HF1

The LORENZ eValidator 3.0 SP1 HF1 release provides the following new or enhanced features:



- Support for Swissmedic M1 1.0 specification
- Compliance with the Swissmedic validation rules (version 1.0)

3.2.50 LORENZ eValidator 3.0 SP1

The LORENZ eValidator 3.0 SP1 release the following new or enhanced features:

- New licensing technology (same as for docuBridge 5)
- Easier unlocking the software with Basic license
- Support for EU 1.4 specification
- Compliance with the EU 1.3 validation rules (version 2.1)
- Compliance with NeeS validation rules (version 1.0)
- User Interface and reporting customizations for BfArM

3.2.51 LORENZ eValidator 3.0

The LORENZ eValidator 3.0 release provides the following new or enhanced features:

- New product name LORENZ eValidator
- New GUI (WPF)
- Separation of GUI and validation engine (eValidatorCore.dll)
- New licensing
- New report style
- Support for Non-eCTD submissions
- Compliance with the EU 1.3 validation rules

3.2.52 eCTDValidator 2.2

The eCTDValidator 2.2 release provides the following new or enhanced features:

- New rule functions for life cycle analysis: CheckValueHistory and CheckElementHistory
- Improved support for Japan Regional 1.0: the rule function Cumulative Completeness in Life Cycle is now capable of checking all relevant life cycle patterns. The use of the standard life cycle pattern checking rules " Detect Life Cycle Pattern:..." is now obsolete for JP submissions.
- Improved support for Japan Regional 1.0: submission number and m1 section content is now checked over life cycle to ensure that administrative information is maintained in subsequent submissions.
- For PDF validation results, the number of violations identified for documents with forbidden PDF versions, is now printed in the main report.
- For referenced files and LMC analysis, the number of violations is now printed in the main report.



3.2.53 eCTDValidator 2.1

The eCTDValidator 2.1 release provides a number of significant enhancements and new features:

- Enhanced PDF protection analysis and verification of the document's initial view
- Support for Japan Regional 1.0
- Experimental support for ICH 3.3.3 (2.1 HF2: the 3.3.3 draft has been withdrawn and therefore the eCTD Validator release will no longer support it).
- Deep scans for life cycle patterns
- Separate configuration files for standard settings (validate.xml) and custom settings (CustomRulesAndOptions.xml)
- New configuration file location (CommonAppData folder)
- Enhanced localization support for custom rules
- Report results can be provided as HTML files in addition to the XML files.

3.2.54 eCTDValidator 2.0 SP1

The eCTDValidator 2.0 SP1 release provides a number of significant enhancements and new features:

- New profile description report
- Report header and report description fields
- License technology for docuBridge integrated usage
- New custom rules for EU and US regional backbones

3.2.55 eCTDValidator 2.0

This is first official eCTDValidator version (which is 2.0) to be shipped as an independent product. So far, the validator has been shipped as part of the docuBridge client installations only. Starting with eCTDValidator 2.0, a new validator application with a lot of essential new features and functions becomes available.

The eCTDValidator may be used to check eCTD applications for:

- Adherence to ICH backbone specifications
- Adherence to regional requirements
- Adherence to STF specifications
- File and folder structure problems
- PDF hyperlink problems, PDF bookmark problems
- PDF protection / optimization
- Many more constraints and options
- The eCTDValidator provides a flexible report output:
- All results provided as XML files
- Standard stylesheets shipping with eCTDValidator
- Stylesheets may be replaced or customized



- Report content with hyperlinks to sub-reports Other essential features:
- The eCTDValidator provides a very simple but powerful user interface. It is a native
- .NET application
- Has runtime language switching
- Powerful Configuration editor available (separate license required)
- Uses a new licensing technology
- Full encryption of program and configuration files supported
- Internals based on legacy eCTDValidator shipped with docuBridge 3.6 (prior to SP3)



4. Functional Specification

4.1 General Features

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-2	<p>The eValidator desktop client application allows electronic submission validation based on both Backbone DTDs/Schemas (ICH) and on regional DTDs/Schemas provided by local authorities. Validation for Study Tagging Files (STF) is also supported.</p> <p>To validate an eCTD submission, the sequence folder must be selected.</p>	eValidator5-FSP-1001
EVA-3	<p>The eValidator desktop client supports processing non-eCTD applications according to the NeeS guidance: To validate a NeeS submission, the sequence folder must be selected.</p>	eValidator5-FSP-1002
EVA-7	<p>The eValidator desktop client supports processing VNeedS applications</p>	eValidator5-FSP-1003



<p>EVA-9 EVA-11 EVA-15 EVA-84 EVA-320 EVA-324 EVA-332 EVA-1063 EVA-1687 EVA-1774 EVA-2005 EVA-1776 EVA-2442 EVA-2697 EVA-2673</p>	<p>The eValidator desktop client application is a standalone client application based on .Net 4.7.2 (no other .Net versions are required). The eValidator user interface is fully separated from the validation engine and the validation rules (profiles and configuration files).</p> <p>A setup package is provided with the eValidator. This setup automatically checks for prerequisites (e.g., Windows Installer, .Net framework 4.7.2). Installation of those prerequisites must be completed by the user before</p> <p>Setups can be configured to raise warnings upon installation through the eValidator client application, asking the user to read the corresponding Release Configuration Sheet before proceeding with the update.</p> <p>The setup content can be customized before rolling it out on a site (e.g., adding the license serial number to the system.config configuration file).</p> <p>Application shortcuts on the desktop and in the Windows start menu will be created.</p> <p>When installing a software update (i.e., a new version replaces an older version), the setup will preserve any user specific changes made to the configuration files and merge them into the new configuration files. The configuration merging as part of the eValidator setup supports a list for application settings that should not be preserved but deleted if the new setup comes with updated values.</p> <p>Merged settings:</p> <ul style="list-style-type: none"> • Profile • Binder • Report • application • culture • recent_profiles • report_compress • report_keep_xml • report_create_date_time_folder • show_red_green_blindness_helper • config_key_report_copyziptoapp • offline_validation • prompt_before_starting_triggered_profile • use_baseline_optimization • use_auto_detection • report_use_old_stylesheet 	<p>eValidator5-FSP-1004</p>
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Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-18 EVA-19 EVA-183 EVA-338	<p>The eValidator desktop client uses a secure and flexible licensing mechanism (EZIRIZ). Without an appropriate license, none of the advanced features can be used (but basic features only).</p> <p>The setup will automatically install Basic license files for the eValidator.</p> <p>License can be bound to hardware code like the approach taken in docuBridge 5.x.</p> <p>The operating system version will not be evaluated as part of the hardware code.</p> <p>Licenses use serial numbers for activation. Restrictions for Basic license:</p> <ul style="list-style-type: none"> • Cannot be used on a server operating system • Does not allow on the fly profile loading. Only one profile can be selected when the software is used for the first time. Switching profile requires re-installing the software. • Does not allow using the command line interface for bulk validation. • Does not allow parallel execution of checks in a validation process • Does not allow script extensions • Does not allow profile modifications • Does not generate the raw format XML reports • Does not generate the summary report • Does not allow changing the report header information • Does not allow using unprotected (unsigned) profiles • Does not allow using the Batch Processing application <p>Version 5.1: The license management has been redesigned to allow finer granularity for licensed features. The License Management dialog in the workstation reflects this.</p>	eValidator5-FSP-1005



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-10 EVA-378 EVA-379 EVA-597 EVA-1991	<p>(eValidator FIVE version only)</p> <p>A command line interface is available to</p> <ul style="list-style-type: none"> • Select the application folder and sequence • Select the report path • Select the profile • Automatically run a validation when the program has been started • Show/Hide user interface when running a validation • Automatically close the program when validation is finished • Compress report files (ZIP archive) • Copy ZIP report to application folder • Create or omit date time report folder • Specify an alternative sequence folder location for previous eCTD sequences in a life cycle. By default, this folder will only be used if the previous sequences are not present in the application folder. Through configuration the system can be instructed to always use the alternative folder – and to ignore any previous sequence folder in the main application folder. • Specify the language for user interface and reports • Configure the number of threads to be used when running a profile that is enabled for parallel execution. • Toggle thread information display in user interface • Suppress confirmation messages • Keep the Xml report files • Specify an initial sequence number for eCTD <p>Set the main window width and height Furthermore, all general profile settings can be provided as command line switches. For a detailed command line switches reference please refer to the LORENZ eValidator User Guide.</p>	eValidator5-FSP-1006
EVA-12	The eValidator profiles can be extended with custom rules based on PowerShell scripts.	eValidator5-FSP-1007
EVA-13	The eValidator allows running multiple instances in parallel in the same Windows session.	eValidator5-FSP-1008



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-14	The eValidator application supports parallel execution of checks in a single validation process. This is a licensable option. The number of parallel threads/tasks can be configured. The user can turn multithreading off even if the profile has parallel execution configured for one or more groups. The opposite is not true: when the profile is not configured for parallel execution the user cannot force this through the user interface or command line parameters.	eValidator5-FSP-1009
EVA-17 EVA-1407 EVA-1977	The eValidator application user interface is fully localizable. For the Basic version, only English language is available. The eValidator FIVE version includes English, German, and French. Other languages can be added upon request. This also applies to the eValidator Batch Processing client application.	eValidator5-FSP-1010
EVA-5 EVA-8	The eValidator supports custom validations. Custom validation is based on a user-defined compilation of validation rules (checks), not necessarily related to a specific submission format. Examples: <ul style="list-style-type: none"> • Validation of XML files only (submission index files or any other kind of XML files) • Validation of partial submissions (specific modules only) • Validation of custom file/folder structures • Validation of PDF files 	eValidator5-FSP-1012
EVA-271	(eValidator FIVE version only) The eValidator automatically determines the optimal number of parallel threads for a validation based on the processor infrastructure. Intel Hyper-Threading is ignored in the formula.	eValidator5-FSP-1013
EVA-1186	Supported Operating Systems are: <ul style="list-style-type: none"> • Microsoft Windows 10 • Microsoft Windows Server 2012 R2 • Microsoft Windows Server 2016 • Microsoft Windows Server 2019 • Microsoft Windows Server 2022 	eValidator5-FSP-1014
EVA-2089	The LORENZ eValidator can also be used on Windows systems when the FIPS mode is enabled. For this, specific configuration files have been added to the program files.	eValidator5-FSP-1015



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-2085	All executables are digitally signed by LORENZ. To avoid delayed startup in case of Internet connection problems, signature verification has been disabled for program startup.	eValidator5-FSP-1016
EVA-2173	The eValidator client application supports high-resolution displays with magnification settings above 100%.	eValidator5-FSP-1017
EVA-2352	Activating an eValidator ONE License: <ol style="list-style-type: none"> 1. Open the Manage menu tab. 2. Click on the Manage License symbol. 3. Click on the eValidator ONE button. 4. You will be guided to a LORENZ web site where you need to enter your LORENZ ID credentials 5. Select the license you have purchased already. 6. The license will then be sent to you via email. 7. Click the Select... button to locate and load the license file that was sent to you by LORENZ. 8. Enter or paste the serial number for this license in the Serial Number text field. 9. Click the Apply button. You will now see the confirmation message that the license has been activated. 	eValidator5-FSP-1018
EVA-2746 EVA-2939	Starting with version 21.1, two setup packages exist: <ul style="list-style-type: none"> • eValidator Client • eValidator Server <p>The eValidator Client setup cannot be installed over an existing eValidator Server installation.</p>	eValidator5-FSP-1019



4.2 User Interface

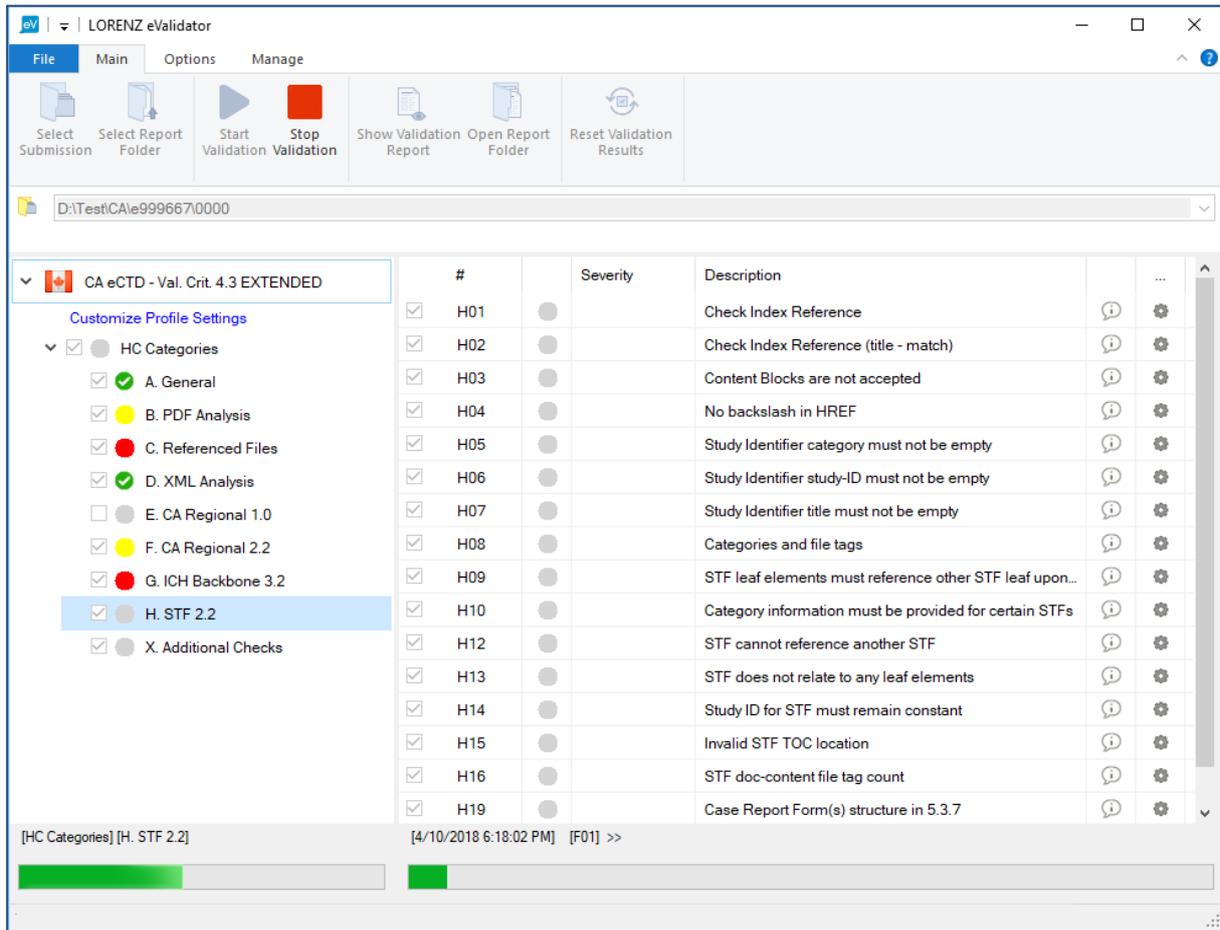


Figure 3: LORENZ eValidator Desktop Client

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-71 EVA-147 EVA-2555	<p>The user interface main window is divided into the following sections:</p> <ul style="list-style-type: none"> • Ribbon menu • Tree view pane showing structure of the active profile(s). • Text field and browser button for application (dossier) path • Rules pane (showing the rules for the selected node in the profile tree). The rule descriptions will be displayed using multiple lines if necessary. 	eValidator5-FSP-2001



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-58 EVA-59 EVA-70 EVA-1680	<p>The user interface (main window) uses a tabbed ribbon style menu. There are three tabs available: Main, Options, Manage.</p> <p>Like Windows Explorer, the ribbon menu has a quick access toolbar, where the user can customize which menu buttons shall be listed. The current settings will be saved in the user's configuration file and restored upon next application start.</p>	eValidator5-FSP-2002
EVA-70 EVA-108 EVA-374	<p>The ribbon menu tab Main provides the following features:</p> <ul style="list-style-type: none"> • Selecting the application to validate • Starting the validation (also possible through the CTRL+Enter key combination) • Canceling the validation • Viewing the validation report • Resetting the user interface to clear the validation results (Reset Validation Results). 	eValidator5-FSP-2003
EVA-58 EVA-378 EVA-380	<p>The ribbon menu tab Options provides the following features:</p> <ul style="list-style-type: none"> • Select report folder • Setting report options: compress to ZIP, copy ZIP to application folder, auto detect, confirm profile switch • Search for rules in the current profile, based on rule number or title text • Additional options through a separate dialog (baseline optimization, XML reports, report style, initial sequence number, alternative previous sequences path) <p>Note: The alternative folder for previous sequences can also be specified as a command line parameter and in the user specific configuration file. See the user guide for details.</p>	eValidator5-FSP-2004



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-59 EVA-69 EVA-117	<p>The ribbon menu tab Manage provides the following features:</p> <ul style="list-style-type: none"> • Changing language for UI/reports • Change the license • Show user guide (can also be opened from the About dialog by pressing the F1 key) • Show support contact information • Check for program updates • Show quick information about the program About) 	eValidator5-FSP-2005
EVA-54	<p>The application folder can be selected through folder browser dialog or through drag and drop from Windows Explorer.</p>	eValidator5-FSP-2006
EVA-55	<p>The profile can be selected through a profile browser dialog in the ribbon system menu. The profile browser dialog shows profile binders only, while the profiles themselves can be selected through the Custom Profiles hyperlink.</p> <p>The Open Profile dialog will replace all currently loaded profiles with the newly selected one(s).</p> <p>Profile binders can be removed from the browser dialog through a special attribute.</p>	eValidator5-FSP-2007
EVA-56	<p>Note: This feature is no longer available with version 5.8. You can change the Binder files in a text editor to customize the profiles to be loaded.</p>	eValidator5-FSP-2008
EVA-57	<p>When a validation is completed or aborted, the user interface provides the following features on the home tab of the ribbon:</p> <ul style="list-style-type: none"> • Reset the profile view (removing all result information but preserving the report files) • View the main report • Open the report folder in Windows Explorer • Show failed checks only (toggle) • Start the validation again 	eValidator5-FSP-2009



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-36 EVA-1320	<p>(eValidator FIVE version only)</p> <p>The eValidator application supports more than one application folder for an eCTD submission (i.e., the current sequence may be in a different folder than the previous sequences). The user can configure this through the user interface. This can either be the path to the application where the older sequences are stored, or the top-level folder where all the applications with their older sequences are stored. For the latter, it is assumed that the application number for the current sequence and the previous sequences is the same (otherwise the older sequences could not be found).</p> <p>This setting will be saved in the user specific configuration file.</p>	eValidator5-FSP-2010
EVA-38 EVA-364	<p>The validation results will be shown in the user interface.</p> <p>These results will be removed (reset) when a new profile or a new application has been selected.</p>	eValidator5-FSP-2011
EVA-42	<p>The validation process can be aborted by the user at any time. Hence the validation process will never block the Windows session or the user interface executable (i.e., the executable will still respond to user actions while a validation is running).</p>	eValidator5-FSP-2012
EVA-45	<p>For an eCTD application, the initial sequence is configurable through the user interface. For example, when the user validates sequence 0010 and the initial sequence is 0004, the eValidator must be made aware that the initial sequence is not 0000. Some life cycle operations need to know about the initial sequence.</p>	eValidator5-FSP-2013
EVA-48	<p>The rules in a group are sortable (in the user interface application) by several criteria: rule number, rule title, rule severity.</p> <p>This feature is no longer available since version 5.8.</p>	eValidator5-FSP-2014
EVA-49	<p>When a validation is complete the user can filter the results view in the user interface application to show</p> <ul style="list-style-type: none"> • All rules -OR- • Only the failed rules (by selecting or unselecting severities). 	eValidator5-FSP-2015



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-53	<p>The eValidator updates the status of the profile items (groups, rules) while running a validation. This allows it to preview the status before completion and then decide whether to proceed or abort. Upon cancelation (Abort Validation), the user can decide whether the (incomplete) report files shall be preserved or deleted. In case the user chooses to keep them, the report files will have an indication that the validation process has been aborted before completion. The profile view will not be reset in this case so that the user can still check the results of the aborted validation in the main window.</p>	eValidator5-FSP-2016
EVA-51 EVA-60	<p>The following settings will be read from the user's configuration file when starting the user interface application:</p> <ul style="list-style-type: none"> • Last used application folder • Last used profile • Last used report path • Create date time folder for reports • Keep xml reports • Compress reports to zip (currently this is the only option to get a single file reporting result) • Number of threads to use • Alternative sequence path • Prompt user to save changes in protected profiles 	eValidator5-FSP-2017
EVA-61	<p>The profile settings will be handled as follows.</p> <ul style="list-style-type: none"> • General profile settings (not related to a rule or group) can be viewed and edited in user interface on the Profile Settings dialog. If a setting is editable or not depends on its status in the profile (attribute "license_level"). • For each rule inside a group, the rule name (normally the rule number) and a rule short text will be shown in the Rules Settings dialog. A more comprehensive rule help can be viewed in the Rule Description dialog. • Rule parameters, which allow modification (attribute "enable_user_edit") can be viewed and edited on the Rule Settings pane when selecting a rule. 	eValidator5-FSP-2018



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-62	When selecting multiple rules in the rules pane, the user can change the rule status (enabled/disabled) for one of the selected rules and the change will be applied to the entire selection.	eValidator5-FSP-2019
EVA-63	License information will be shown in the user interface main window (status bar at the bottom of the window).	eValidator5-FSP-2020
EVA-64	<p>When running a validation, the UI main window shows progress information:</p> <ul style="list-style-type: none"> • Progress bar for overall progress (triggered by progress anchor points in the profile). • Progress bar for step progress (i.e., the progress for the children of an anchor point). • Status text information for both overall and step progress. 	eValidator5-FSP-2021
EVA-65	It is possible to run multiple parallel instances of the eValidator using the same profile file.	eValidator5-FSP-2022
EVA-66	<p>(eValidator version)</p> <p>The eValidator allows saving profiles. Changes made to a loaded profile in the user interface will be saved properly (unless the settings are not to be saved because of the license or other restrictions). When closing a profile or closing the program the user should be prompted to save the profile if any changes were made (prof version only).</p> <p>Switching between profiles from the same loaded profile binder without closing them will not prompt the user to save the changes.</p>	eValidator5-FSP-2023
EVA-67 EVA-4220	<p>(eValidator FIVE version)</p> <p>The eValidator user interface allows enabling /disabling groups and rules. When disabling a group in the tree view, all its children will be made inaccessible. This means the group can no longer be expanded and all its children are invisible to the user until the group is enabled again.</p> <p>Optionally, the extended profiles can be locked to prevent any changes.</p>	eValidator5-FSP-2024
EVA-67	While running a validation, all group and rule settings are locked.	eValidator5-FSP-2025



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-68	When starting a validation, the eValidator user interface indicates a possible mismatch between selected profile and selected application content (e.g., US profile loaded, and application contains EU sequence). This is accomplished through a pre-analysis of the sequence content.	eValidator5-FSP-2026
EVA-426	The font family for the user interface components can be specified in the configuration file (system.config), which allows language specific font usage (e.g., for Asian culture settings).	eValidator5-FSP-2027
EVA-511 EVA-3552	For validation reports, the eValidator desktop client allows using the “old” style layout instead of the new style layout. Release 22.1: The new style (formerly used for US eCTD validation reports) is the default.	eValidator5-FSP-2028
EVA-1317	The 10 most recently used application (dossier) paths are being preserved in the configuration file and can be accessed through a dropdown-list.	eValidator5-FSP-2029
EVA-1317	<p>The eValidator Workstation allows increasing and decreasing the font size for the main window and all dependent dialog windows (except for the font in the Ribbon menu, which is controlled by Windows standard settings).</p> <p>Increase font size: Hold CTRL key down and scroll the mouse wheel upwards; or press CTRL and + (on the number pad).</p> <p>Decrease font size: Hold CTRL key down and scroll the mouse wheel downwards; or press CTRL and - (on the number pad).</p> <p>Feature has been removed with EVA-2173 (support for high-resolution displays).</p>	eValidator5-FSP-2030
EVA-1317	The available keyboard shortcuts are listed in the About dialog, which can be accessed from the ribbon menu or by pressing F1.	eValidator5-FSP-2031
EVA-1317	The eValidator desktop client supports Windows DPI settings higher than 100%.	eValidator5-FSP-2032



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-1317	The eValidator desktop client is section 508 compliant (refers to accessibility guidelines).	eValidator5-FSP-2033
EVA-1559 EVA-1725 EVA-1998 EVA-2534	<p>For error analysis, the eValidator desktop client can be configured to write log files (using the Log4Net logging framework). When the application has been started already, logging can be turned on through CTRL+F7 and turned off through CTRL+F8. Both keyboard shortcuts will change the logging status temporarily only, i.e., the changes will not be written to the configuration file.</p> <p>If necessary, a log level "Trace" exists that can be used to write all details, including every single Action step into the log files. Only with this level, the Action condition expression evaluations will be logged.</p>	eValidator5-FSP-2034
EVA-2493	<p>The eValidator client application will show advertisement pictures when starting the program and when starting a validation.</p> <p>The pictures will be selected randomly from a configured picture set that will be installed with the eValidator.</p> <p>Clicking into the pictures will open a web page that has been configured for the corresponding picture. This is the only scenario where Internet access will be used.</p> <p>A countdown timer will be displayed to indicate how long the picture will be displayed. The duration can be configured.</p> <p>The advertisements will only be shown with a Basic license, and for a ONE or an eValidator FIVE license that has not been activated yet.</p>	eValidator5-FSP-2035



4.3 Validation Profiles

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-21 EVA-258	<p>Profiles are configurable containers (in Xml format) for validation rules and settings. There can be protected and unprotected profiles. A profile is called a protected profile if its electronic signature is valid (LORENZ signature or customer signature as provided through a LORENZ web service).</p> <p>Protected profiles cannot be modified in the eValidator desktop client.</p> <p>Even if a rule has its parameters set as “editing allowed”, this will not be possible in a protected profile.</p>	eValidator5-FSP-3001
EVA-25, EVA-26, EVA-27, EVA-28, EVA-29, EVA-32, EVA-99, EVA-185, EVA-213, EVA-242, EVA-4, EVA-231, EVA-277, EVA-281, EVA-282, EVA-283, EVA-316, EVA-318, EVA-294, EVA-340, EVA-351, EVA-352, EVA-376, EVA-407, EVA-414, EVA-425, EVA-34, EVA-35, EVA-462, EVA-489, EVA-493, EVA-494, EVA-556, EVA-557, EVA-694, EVA-757 EVA-702, EVA-998, EVA-1145, EVA-1202, EVA-1175, EVA-1196, EVA-1257, EVA-1150, EVA-1203, EVA-1232,	<p>Standard profiles are included in the eValidator package for the following specifications (additional profiles may be available on the LORENZ web site or in the eValidator setup package).</p> <p>The following list only contains the profiles for currently active or upcoming versions of validation criteria and specifications. Expired versions of the profiles can be found in the “Expired” subfolder of the “Profiles” folder.</p> <p>The US validation criteria v4.4 for eCTD</p> <p>The US validation criteria v1.2 for eCTD 4.0</p> <p>The EU validation criteria v6.1 for eCTD</p> <p>The EU validation criteria v7.1 for eCTD</p> <p>The EU validation criteria v4.3 for NeeS</p> <p>The EU validation criteria v3.1 for VNeedS</p> <p>The CA validation criteria v5.1 for eCTD</p> <p>The CA validation criteria v5.1 for Non-eCTD (including a profile for Non-eCTD without REP files)</p> <p>The CH validation criteria v1.4, v1.5 for eCTD</p> <p>The CN validation criteria v1.0 for eCTD</p> <p>The CN validation criteria v1.1 for eCTD</p> <p>The GCC/KSA validation criteria v1.2 for NeeS</p> <p>The GCC/KSA validation criteria v1.4 for NeeS</p> <p>The GCC eCTD specification v1.2</p> <p>The GCC eCTD specification v1.5 (validation criteria v1.4)</p> <p>The GCC VNeedS specification v4.1</p>	eValidator5-FSP-3002



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-1308, EVA-1391, EVA-1392, EVA-1427, EVA-1448, EVA-1550, EVA-1552, EVA-1556, EVA-1573, EVA-1612, EVA-1644, EVA-1660, EVA-1667, EVA-1756, EVA-1575, EVA-1758, EVA-1759, EVA-1802, EVA-1850, EVA-1899, EVA-1921, EVA-1941, EVA-2064, EVA-2079, EVA-2080, EVA-2088, EVA-2172, EVA-2147, EVA-2218, EVA-2273, EVA-2482, EVA-2467, EVA-2596, EVA-2603, EVA-2669, EVA-2698, EVA-2958, EVA-2927, EVA-2843, EVA-3132, EVA-3399, EVA-3517, EVA-3532, EVA-3763, EVA-3533, EVA-3803, EVA-3839, EVA-3893, EVA-3577, EVA-1833, EVA-3892, EVA-4394, EVA-4335, EVA-4746, EVA-4486, EVA-4913	The Jordan eCTD validation criteria set v1.1 The MCC ZA eCTD validation criteria v2.1 set for eCTD The MCC ZA eSubmission validation criteria The AU TGA eCTD validation criteria v3.1 set for eCTD The AU TGA NeeS validation criteria set v3.1 The Thai FDA eCTD validation criteria set 1.0 The Taiwan FDA eCTD validation criteria eCTD-V-R1 FDA CDRH eCopy specification The JP eCTD 1.0 specification (PMDA) The ALMBIH NeeS 1.0 validation criteria set 1.0 The ECOWAS eCTD validation criteria v1.0 The ECOWAS eSubmission validation criteria v1.0 MD5 Verification and Proofreading/Correction (the latter requires an eValidator FIVE license). Statistical Information Profile for eCTD submissions “Preflight” profiles for all eCTD profiles listed above (with a reduced rule set each – focusing on backbones, and on the total path length check). Available on request: JP eCTD 4.0 (validation criteria 1.4.0.1)	
EVA-25 EVA-26 EVA-27 EVA-28	The rules in the standard validation profiles directly reflect the corresponding criteria from the official set (including the number, the severity, and the description).	eValidator5-FSP-3003



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-29 EVA-32		
EVA-22 EVA-50	Starting with version 5.8, the Profile Editor is now part of the LORENZ Automator product. The LORENZ eValidator no longer contains an Editor.	eValidator5-FSP-3004
EVA-23	Rules in a validation profile can be grouped. A group of rules can depend on other groups of rules, which define the order of execution (in addition to a WBS code assigned to the group. WBS = work breakdown structure, like the principles known from workflow of project management tasks	eValidator5-FSP-3005
EVA-24	A validation rule can depend on other rules of the same group, which defines the order of execution inside the group (in addition to the step number assigned to the rule).	eValidator5-FSP-3006
EVA-33	(For eValidator FIVE license with advanced features) The PMDA (Japan) validation criteria set (v1.0) for eCTD is addressed directly in a dedicated profile (only as long as the criterion set is in use by the PMDA).	eValidator5-FSP-3007
EVA-37	The severity level enumerations are configurable (e.g. Error/Warning or P/F/Best Practice or High/Medium/Low) alongside with the corresponding color coding in the report.	eValidator5-FSP-3008
EVA-43	Any rule related to file and folder checking supports an exclusion list (as a general profile setting or as a parameter to the rule). This also applies to files examined in PDF analysis: An exclusion list specified for the very first rule in PDF analysis will automatically be applied to all other rules in the group. Alternatively, the user can select one or more rules and define the exclusion list for them. Changing rule parameters is not possible with the Basic version.	eValidator5-FSP-3009
EVA-55	A profile binder is a container for profiles. One or more profiles for the same context can be grouped in a binder (e.g., eCTD and NeeS for EU or US criteria 1.0 and US criteria 2.2 for US).	eValidator5-FSP-3010



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-46 EVA-83 EVA-93	<p>eCTD: In addition to the criteria sets published by the agencies, every standard profile includes one or more rules for application detection. These rules will report all identified backbones (and regionals) alongside their checksums (optional). As an option, the available previous sequences can also be examined.</p> <p>Backbone types or backbone versions not valid for the current profile will also be listed by the rules but marked as inappropriate.</p> <p>Through the Profile Editor other (older) backbone versions than the ones officially supported by the agency criteria can be enabled.</p> <p>The application detection (aka application identification) rules can also check for transition errors, where a previous sequence in the application is using a higher backbone version than the current sequence.</p>	eValidator5-FSP-3011
EVA-135 EVA-1676 EVA-1682 EVA-1853 EVA-2022 EVA-2023 EVA-2038 EVA-3095	<p>(eValidator FIVE version only)</p> <p>The eValidator supports automatic format detection and profile assignment for applications, both in the engine and in the user interface. With this feature the user does not need to choose the actual profile manually. The eValidator will assign it automatically based on the pre-examination results for the submission.</p> <p>The default profiles for the individual submission formats (“mappings”) are specified in the AutoDetectMappings.xml file, in the Profiles folder. The mappings can be customized there if required. Customizations can be configured to be preserved (“freezing”) during a software upgrade or configuration update. When a profile name has been “frozen” in the mappings file, and the corresponding profile has been moved to the Expired folder by a subsequent software update, the eValidator will still load it from the new location.</p> <p>In the eValidator desktop client, the automatic format detection is deactivated if the currently selected profile is a profile for PDF QC validation or eCTD MD5 proofreading.</p> <p>For US eCTD submissions published with docuBridge 21.1 or later, the eValidator can determine the FDA Center (and hence the appropriate profile) from the embedded comment (center:cber, center:cder).</p>	eValidator5-FSP-3012



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-134 EVA-1635 EVA-1654	<p>The eValidator supports encrypted profiles. Encrypted profiles are used for additional profiles that can be purchased through the LORENZ web site.</p> <p>When saving changes to an encrypted profile, the updated profile will always be encrypted again.</p> <p>With a Basic license, encrypted profiles can be loaded if the profile does not require a specific license. Saving encrypted profiles is not possible with a Basic license.</p>	eValidator5-FSP-3013
EVA-478	<p>Expired validation profiles (profiles for expired criteria or DTD/Schema versions) are being preserved and can be loaded manually from the Expired subfolder of the Profiles folder. Profiles in this folder have an additional warning in the report, indicating that the profile is outdated.</p> <p>C:\ProgramData\LORENZ Life Sciences\ eValidator\ Profiles\Expired</p>	eValidator5-FSP-3018
EVA-1315	<p>LORENZ implements validation profiles using the following approach:</p> <ul style="list-style-type: none"> • First, an extended profile will be implemented. Either as a new profile or updating an existing one. • Then, a profile generation tool will create the standard profile and the preflight profile from this extended profile. The tool uses a control file, which contains instructions, which portions (rules etc.) of the extended shall be removed or disabled when preparing the standard or preflight profiles. <p>Through this automated approach, LORENZ minimizes the risk of errors by eliminating the need to manually apply and duplicate the changes to all required profile “flavors”.</p>	eValidator5-FSP-3019
EVA-1486 EVA-1501 EVA-1671 EVA-1949 EVA-3089 EVA-2890	<p>The study data standards defined by the US FDA will be checked in the US eCTD validation profiles (rule numbers 1734 to 1737).</p> <p>The checks apply to studies with a study start date (in TS.xpt) after 17-Dec-2016 (NDA/ANDA/BLA) or after 17-Dec-2017 (IND). The eValidator will retrieve the start date from the TS.xpt files.</p> <p>The variables that will be checked for the study start</p>	eValidator5-FSP-3020



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>date are: STSTDTC (non-clinical studies) and SSTDTC (clinical studies).</p> <p>The checks use a “current view” file generated from the information in the folder structure. This file is being used to verify that one and only one version of the TS:xpt file exists (and, if applicable, also of DM.xpt, define.xml, ADSL.xpt).</p> <p>Alternatively, the current view file can be generated using a tracking system instead of the folder structure. An implementation exists to use docuBridge as the tracking system.</p> <p>For the trial summary files ts.xpt, the eValidator will tolerate additional or incomplete content at the end (which violates the format specification), if the necessary information could be retrieved (study start date for the study of interest).</p>	
EVA-1495	<p>The eValidator desktop client “remembers” the most recently used profile and will reload it automatically with the next start of the program. If in the meantime, a software update has been applied and the previously used profile has now been moved to the “Expired” folder, the eValidator will also try loading the profile from there. If it can be loaded from there, the user will get an information about its expired status.</p>	eValidator5-FSP-3021
EVA-1534	<p>For the validation of US eCTD submissions, the corresponding profiles are based on the published FDA validation criteria.</p> <p>Furthermore, the profiles also consider the latest versions of the file format specification document, and the FDA PDF specification document.</p>	eValidator5-FSP-3022
EVA-1629 EVA-1634 EVA-1568 EVA-1790 EVA-1791 EVA-1985 EVA-1999	<p>For the validation of PDF documents, outside of submission context, dedicated profiles exist (PDF QC). These profiles can validate one selected PDF document or all PDF documents in a selected folder structure.</p> <p>The PDF QC (USFDA) profiles include all PDF checks from the US FDA eCTD validation criteria plus the following checks from the FDA PDF specification:</p> <ul style="list-style-type: none"> • Video/Audio/3D content not allowed • Page size constraints (all pages in a document) 	eValidator5-FSP-3023



Ref. Numbers	Specification Text and Comments	FSP Codes
	<ul style="list-style-type: none"> • Bookmarks and hyperlinks required for documents with more than 4 pages • Bookmarks and hyperlinks must open a new window when referencing external documents <p>Additional checks also included:</p> <ul style="list-style-type: none"> • Detection of Reference XObjects • Detection of any JavaScript used in documents • Total number of hyperlinks/bookmarks <p>The PDF QC profiles allow customization: for certain rules, the parameters can be modified and saved in a user-specific configuration file. This allows customization without modifying the actual profile files. When loading a PDF QC profile, the eValidator desktop client also looks for external profile parameter files and merges the values from those files into the loaded profile.</p>	
EVA-2021	For auto detect and for validation from docuBridge, the eValidator can be configured to use the extended versions of the mapped profiles, when available.	eValidator5-FSP-3024
EVA-1982	For auto detect and for validation from docuBridge, the eValidator can be configured to automatically switch to a newer profile version if the mapped current profile has expired.	eValidator5-FSP-3025
EVA-1820	For the validation of Swissmedic eDok submissions, the corresponding profiles are based on the published Swiss Medic documentation was added.	eValidator5-FSP-3026
EVA-1833 EVA-4070	<p>A statistical information profile is available for eCTD sequences. This profile will create a report with information about the sequence content:</p> <ul style="list-style-type: none"> • Number of files and total size per file type • Number of life cycle operations • Hyperlinking statistics by CTD section • Documents without any hyperlinks to other documents in the sequence • Documents that are not referenced by any other documents in the sequence 	eValidator5-FSP-3027



Ref. Numbers	Specification Text and Comments	FSP Codes
	To use the profile, an eValidator FIVE license is required.	
EVA-2733	For EU eCTD submissions, the extended profile can detect and report empty eAFs (blank forms).	eValidator5-FSP-3028
EVA-3015	Translations exist for the profile description texts and the profile binder description texts: German, French, Japanese, Simplified Chinese.	eValidator5-FSP-3029
EVA-3926	Deprecated profile versions for US eCTD validations have been removed from the "Expired" folder. The only versions preserved are: Profile v4.3: This is the most-recent expired version. Profile v3.9: This is the latest version that allows validating US DTD 2.01 submissions without reporting an error with 1463.	eValidator5-FSP-3030



4.4 Configuration Files

Configuration files for the LORENZ eValidator system are stored in a central location on the computer where the program has been installed. This refers to the sub-folder in the CommonAppData folder where the configuration data for the eValidator is stored: LORENZ Life Sciences\ eValidator .

The CommonAppData folder is the folder on a Microsoft Windows computer, where application data is stored that applies to all users on a given computer. The actual location depends on the operating system version and culture. For Windows Vista or Windows 7 and later Windows versions this folder is c:\ProgramData .

For the LORENZ eValidator, the following configuration folder structure is being created (please refer to the LORENZ eValidator User Guide for detailed information about the eValidator files and folders).

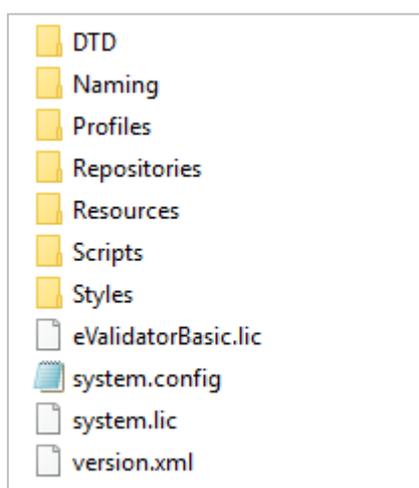


Figure 4: Configuration Folder Structure

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-44	The eValidator can write comprehensive processing information into a log file. This is a configurable option.	eValidator5-FSP-4001
EVA-45 EVA-1483	For an eCTD application, the initial sequence is configurable. For example, when the user validates sequence 0010 and the initial sequence is 0004, the eValidator must be made aware that the initial sequence is not 0000. Some life cycle operations need to know about the initial sequence. For US eCTD submissions, it is not necessary to specify an initial sequence number other than 0000 or 0001. The eValidator will automatically check if previous sequences exist to determine if the current one is the initial one. For other regions, this does not	eValidator5-FSP-4002



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>apply, because some agencies require that the initial sequence must be 0000.</p>	
EVA-60	<p>The following settings can be stored in the user's configuration file:</p> <ul style="list-style-type: none"> • Last used application folder • Last used profile • Last used report path • Create date time folder for reports • Keep xml reports • Compress reports to zip • Number of threads to use • Alternative sequence path • Prompt user to save changes in protected profiles <p>Note: The user's configuration is not located in the CommonAppData folder. Instead it will be created in the following folder:</p> <p>C:\Users\[USERNAME]\AppData\Local\LORENZ Life Sciences\eValidator</p> <p>This location applies to Windows 7, Windows 2008 Server, and later Windows versions.</p>	eValidator5-FSP-4003
EVA-1312	<p>Offline Validation:</p> <p>The eValidator desktop client and the eValidator webAccess can be configured to run validation in offline mode, even if the submission references a DTD through a web URL. Currently, this applies to US FDA submissions only.</p>	eValidator5-FSP-4004
EVA-1313 EVA-1504	<p>Web Proxies:</p> <p>The eValidator desktop client supports using web proxies for controlled Internet access. The user-specific proxy settings can be defined in a dialog in the eValidator desktop client,</p> <p>Proxy settings that are not user-specific can be defined in the configuration file (system.config).</p>	eValidator5-FSP-4005
EVA-1348 EVA-1853 EVA-2956	<p>Format Mappings</p> <p>In the AutoDetectMappings.xml file, format mappings can be specified, which will be used by other programs to map a format to a specific profile.</p>	eValidator5-FSP-4006



Ref. Numbers	Specification Text and Comments	FSP Codes
	For US eCTD, the mapping can be configured specific to the corresponding FDA center (CDER/CBER).	
EVA-1476 EVA-1808 EVA-2188 EVA-2201 EVA-2210 EVA-2457 EVA-2456 EVA-2673 EVA-3529	<p>Regulatory Update Packages (Profile/Configuration Update)</p> <p>The eValidator can be instructed to update its configuration base (profiles and other configuration files) without installing a new product version (i.e., without running the setup program). This feature is available in the eValidator desktop client and the LORENZ Job Management.</p> <p>The update feature can be configured to download the update packages from the LORENZ web server or from a different location (e.g., from a location in the network of the user). The latter requires that the user downloads the packages manually before. The actual update can then be performed without Internet access.</p> <p>In the system.config file (or through eV configPanel), the following modes can be configured for the update:</p> <ul style="list-style-type: none"> • automatic = Always check for and install updates when eV Workstation is started • manual = Install updates manually by clicking the menu button (this is the default mode) • forced = Automatically install available updates when starting the eV, without prompting the user • disabled = The update is disabled. <p>When checking for updates through the menu button, it will only check for product updates but not for configuration updates.</p> <p>When an update package is available, a link will be displayed in the status bar of the eValidator client application. Updates (both software and regulatory updates) can be installed directly from the eValidator client application.</p> <p>The eValidator client application will be restarted after a regulatory configuration package has been installed. The validation reports will show the installed regulatory update package version alongside the installed software version.</p> <p>For desktop clients, regulatory update packages can be configured to raise warnings upon installation, asking the user to read the corresponding Release</p>	eValidator5-FSP-4007



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>Configuration Sheet before proceeding with the update.</p> <p>The REST service URL for regulatory update packages is: https://support.lorenz.cc/evalidatorupdateservice.</p> <p>The download address for a regulatory update package is: https://support.lorenz.cc/files/ev5/regulatory_Updates/eValidatorConfigurationPackage_x.y.z.zip (x.y.z is the package version number, e.g., 1.8.2)</p>	
EVA-1579	<p>An optional setting can be specified in the global system.config (in ProgamData) that forces the eValidator desktop client application to delete the user-specific configuration file on next start of the eValidator.</p> <p>This is done through a combination of the application setting "delete_user_config" and the comparison of the "version" application setting: if the "delete_user_config" is set true and the versions in user config and global config differ, the user config shall be overwritten with the global config.</p> <p>Note: The license serial number (if any) will be restored in the user specific config file after replacing the file.</p>	eValidator5-FSP-4008
EVA-1629	<p>The eValidator profiles can be configured to be customizable. Through custom data embedded in the profile, the profile defined the parameters that shall be configurable through an external configuration file.</p> <p>It is up to the profile to generate those external configuration files when being loaded by the engine. Furthermore, the profile should merge new and existing parameter values. Additional information can be found in the Workflow Editor User Guide and in the Profile Reference Guide.</p> <p>The eValidator desktop client will read the custom data from profiles (if available) and write them into the user-specific configuration folder. In case the configuration file already exists, the eValidator desktop client will merge new and existing values. It will then provide the customizable parameters in the Rule Settings dialog.</p>	eValidator5-FSP-4009
EVA-2266	<p>For eValidatorConsole and JobWorkerConsole:</p> <p>If the report base folder (specified as configuration setting or through command line) does not exist, it will</p>	eValidator5-FSP-4010



Ref. Numbers	Specification Text and Comments	FSP Codes
	be created before starting the validation.	
EVA-2391	Access to application paths (submissions) can be restricted through a configuration setting.	eValidator5-FSP-4011
EVA-2387	For web browser applications allowed to open validation reports, a configuration setting exists (to grant access to certain browsers only if necessary).	eValidator5-FSP-4012
EVA-3384	Individual custom mappings at AutoDetectMappings.xml file will be preserved and not changed by regulatory updates.	eValidator5-FSP-4013



4.5 Validation Reports

The reports will show a TOC panel that shows a summary of the findings in a linked list. Clicking on a hyperlink will navigate the user to the corresponding **Details** section.

LORENZ eValidator - Sequence Validation Report
eCTD - US Regional

High:	1	Application name:	ind111111
Medium:	15	Profile:	US eCTD - Val. Crit. 3.6
Low:	9	User name:	jw
Information:	5	Date/time of execution (local time):	4/10/2018 6:49:09 PM

Table of Content

- Application Identification
- FDA Categories
 - High:1 | Medium:15 | Low:9 | Information:5
 - File Checks
 - High:0 | Medium:3 | Low:0 | Information:0
 - General
 - High:0 | Medium:0 | Low:7 | Information:0
 - M1
 - High:1 | Medium:2 | Low:2 | Information:5
 - M1 DTD Version 3.3
 - High:1 | Medium:2 | Low:2 | Information:5
 - STF
 - STF attributes (1357)
 - Study Data
 - Study Data Standards
 - PDF
 - High:0 | Medium:10 | Low:0 | Information:0

Administrative Information

Admin section item	Value
Applicant ID	123456677
Company Name	Good Medicine Company
Submission Description	Development Safety Update Report (DSUR) Grouped submission to Multiple IND Applications
Regulatory Contact	Michael Smith Business Telephone Number: 1-212-555-9876 Mobile Telephone Number: 1-212-555-6789 michael.smith@goodmedicine.com
Technical Contact	Mary Day Business Telephone Number: 1-212-555-0123 Mobile Telephone Number: 1-212-555-3210 mary.day@goodmedicine.com
Backbone Version	ICH: 3.2 US Regional: 3.3
Application Type	Investigational New Drug (IND)
Application containing files	true
Application number	111111
Sequence number	0001
Submission Type	Annual Report
Submission ID	0001

Figure 5: Validation Report with Table of Contents



Alternatively, classic (“old”) style reports can be used:

LORENZ eValidator

LORENZ eValidator - Application Validation Report
eCTD - US Regional

Application name	123456
Full path of application	g:\test\123456
Sequence	0000
Preceding sequences found in application path	n/a
Other sequences referenced	n/a
Missing referenced sequences	n/a
Profile	US eCTD - Val. Crit. 3.1, EXTENDED
Profile Path	C:\ProgramData\LORENZ Life Sciences\eValidator\Profiles\Profile_US_3-1_Extended.xml
Profile status	Not signed (not protected) - v1.7.7
User name	jw
License information	LORENZ Life Sciences / Corporate License
Date/time of execution (UTC)	21/08/2015 11:27:37
Date/time of execution (local time)	21/08/2015 13:27:37
Runtime (hh:mm:ss)	00:00:11
Total files	81
Total folders	60
Total size (MB)	3.77
Total PDF documents	52
Total PDF pages	296

Information	11
Low	23
Medium	153
High	1

Figure 6: LORENZ eValidator Validation Report



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-16 EVA-1752 EVA-1886	<p>The eValidator application provides comprehensive and flexible validation reports. Preferably, the validation results will be saved in HTML files. The application can be configured to create XML reports in addition to HTML reports. The folder path for creating the report files must be specified before starting a validation. The path can be set using the folder browser dialog (button on the right-hand side). There is always a main report file named eValidator5Report.html, which may reference one or more sub-reports (which will have a reference to the corresponding rule number in the header).</p> <p>Upon creation of the report file, the corresponding style sheets will be copied from the application path to the report path.</p> <p>Report path structure: <code>ccc\aaa\sss\ddd</code></p> <p><code>cccc</code> = custom path as selected by user</p> <p><code>aaaa</code> = name of submission checked</p> <p><code>ssss</code> = sequence number checked</p> <p><code>dddd</code> = yyyy-MM-dd—HH-mm-ss-fff (date and time of execution, with milliseconds precision).</p>	eValidator5-FSP-5001
EVA-16	<p>Only the main report and the summary report will be placed into the report folder root. All other files are placed in a subfolder named "files". Such a structure makes it easier for the user finding the report files to open and an optional zip container would be clearly arranged.</p>	eValidator5-FSP-5002
EVA-16	<p>When using the eValidator FIVE version, a summary report is created in addition to the main report. This summary report provides an overview of the findings per group/categories and has hyperlinks to directly navigate to the corresponding groups in the main report.</p> <p>Note: This does not apply for US eCTD validations.</p>	eValidator5-FSP-5003
EVA-16 EVA-278 EVA-285	<p>Validation reports include statistical information such as: total files, total size, total number of PDF pages, and validation runtime. The runtime is given as hh:mm:ss.</p> <p>Also included:</p> <ul style="list-style-type: none"> • Profile name, status, and path 	eValidator5-FSP-5004



Ref. Numbers	Specification Text and Comments	FSP Codes
	<ul style="list-style-type: none"> List of previous sequences found in application path. List of sequences referenced from the current sequence. List of missing referenced sequences. 	
EVA-16 EVA-63	License information will be shown in the report files.	eValidator5-FSP-5005
EVA-16	Validation reports use the same colors as in the user interface for highlighting findings (see picture below).	eValidator5-FSP-5006

Color coded findings:

● eCTD4-070
Required keywords for a Context of Use code attribute must be included
Problem/Issue:
A required keyword.code@code is not submitted for the Context of Use heading
Corrective Action:
The submission unit needs to be resubmitted with all required keywords for the Context of Use

● eCTD4-071 (2)
The Keyword Type must be valid for the Context of Use heading
Problem/Issue:
The Keyword code value(s) contextOfUse.code submitted for the Context of Use heading is (are) invalid for the eCTD heading
Corrective Action:
The submission unit needs to be resubmitted with valid keyword types for the Context of Use

Invalid keyword types provided

- Invalid keyword type 'us-form-type' in Context Of Use 'dd8dacba-b98f-59a0-9db2-3ba2769585da', section 'us_1.2'.
- Invalid keyword type 'us-form-type' in Context Of Use 'b98abe88-8c12-5a4a-8e24-afffb2acb7e9', section 'us_1.6.1'.

● eCTD4-072 (3)
On each Context of Use element, a valid Keyword Type shall only be used once
Problem/Issue:
The same Keyword type has been used more than once for the Context of Use element
Corrective Action:
The submission unit needs to be resubmitted with only one Keyword of the same Keyword type for each Context of Use

Keyword type has been used more than once

- Keyword type 'us-form-type' has been used more than once at Context Of Use 'f8fe3e00-f03a-5b74-a30c-3e6712b82a79', section 'us_1.1'.
- Keyword type 'us-form-type' has been used more than once at Context Of Use 'dd8dacba-b98f-59a0-9db2-3ba2769585da', section 'us_1.2'.

Figure 7: Color Coded Findings for US eCTD Validations



Color coded findings for validations using the old report style:

16.BP6	OK	All hyperlinks are set to "inherit zoom"
16.BP6	OK	All bookmarks are set to "inherit zoom"
16.BP7	Best Practice (16)	PDFs must have 'Fast Web View' active
<p>Please click here to open the sub-report(s):</p> <ul style="list-style-type: none"> files/eValidator5Report-ex1-cpv1.0-0000-PDF_FastWebAccess-0.html 		
16.BP8	OK	PDF Document Properties for the Initial View must be set for 'Page Layout = Default' and 'Magnification = Default'
16.BP9	OK	All PDF hyperlinks must be relative
16.BP10	OK	All PDF bookmarks must be relative
16.BP11	OK	The bookmarks pane should be visible if bookmarks are included within a PDF document

Figure 8: Color Coded Findings for non-US eCTDs

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-72	<p>(eValidator FIVE version)</p> <p>A profile content report is available:</p> <ul style="list-style-type: none"> Simple version 1: only the enabled and visible profile items shall be reported (with IDs, titles, descriptions) Simple version 2: all profile items shall be reported (with IDs, titles, descriptions) Extended version 1: only the enabled and visible profile items shall be reported (with IDs, titles, descriptions, rule implementations and parameters) Extended version 2: all profile items shall be reported (with IDs, titles, descriptions, rule implementations and parameters) <p>The user can request and view the report from the main window user interface (using the F10 key) and also through scripting. Customers are encouraged to use the profile content reports for the profiles included in the</p>	eValidator5-FSP-5007



Ref. Numbers	Specification Text and Comments	FSP Codes
	LORENZ eValidator package as an addendum to this Functional Specification document.	
EVA-73	<p>(eValidator FIVE version)</p> <p>A reference report for the eValidator extensions can be requested through the scripting interface. This report lists all implemented methods, which can be used to configure validation rules, with description texts and corresponding method parameters.</p> <p>This report may be used as a programmer's reference (API).</p>	eValidator5-FSP-5008
EVA-160	<p>(eValidator FIVE version)</p> <p>The eValidator allows using custom style sheets for the validation reports. This can be done through profile variables defined in the profile (refer to the Automator Workflow Editor user guide for further information).</p>	eValidator5-FSP-5009
EVA-511 EVA-1335 EVA-1346 EVA-1669	<p>In US eCTD validation reports, additional information is being provided from the admin section in the us-regional.xml file, including a summary of the applications in a grouped submission, and links to application forms and index files.</p> <p>Hyperlinks to sub-reports or other files are highlighted in blue.</p> <p>Other stylesheets are available in the "Styles" folder of the configuration directory, including a stylesheet for automation profiles.</p>	eValidator5-FSP-5010
EVA-1351 EVA-1916	<p>The names of the validation reports are: eVReport.html eVSummaryReport.html (for non-US eCTD validation only)</p> <p>Note: This has been changed with version 5.8 to reflect that the reports have been generated by the eValidator.</p> <p>Previously, the reports had different names. But with the new Automator product available, it became necessary to build the report names in a product specific way.</p> <p>The default report names can be changed in the system.config file (or through configPanel).</p> <p>For US eCTD and PDF QC related profiles, the default report names can be overridden through the p_report_name variable.</p>	eValidator5-FSP-5011



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-1663	Validation profiles can also create custom report files (as XML, HTML, or Excel) in addition to the actual validation reports.	eValidator5-FSP-5012
EVA-1818	Profiles can be configured to not create any report files (by setting the profile variable <code>p_create_report</code> to false). For the eValidator, this is only a theoretical option, because reports are vital in validation context.	eValidator5-FSP-5013
EVA-1839 EVA-1886	<p>Profiles can be configured to create a top-level report folder other than the standard timestamp folder.</p> <p>Through the variable <code>p_report_mode</code>, the top-level report folder can be configured to use the jobid as its name, or the ticks count value, or the date/time with milliseconds precision (the standard).</p> <p>Currently, none of the validation profiles use a top-level report folder other than the standard timestamp folder with milliseconds precision.</p>	eValidator5-FSP-5014
EVA-1848	When validating a US eCTD submission, the report will show a “(not applicable)” hint for all skipped checks (checks that were not executed because they were not applicable).	eValidator5-FSP-5015
EVA-1907	<p>For sub-reports, the report names are composed from the actual main report name (e.g., eVReport) and a variable part defined by the Activity that generates the sub-report.</p> <p>Starting with the 18.1.1 release, the application number and sequence are no longer part of the sub-report name.</p>	eValidator5-FSP-5016
EVA-2428	The date and time format used in the reports (especially in the header and in the statistics section) can be defined through a profile variable: <code>p_profile_default_datetime_format</code> .	eValidator5-FSP-5017
EVA-2473	The items in the sub-reports are sorted in alphabetical order.	eValidator5-FSP-5018
EVA-2601 EVA-4127	<p>Validation reports in PDF format</p> <p>As a configurable option, the Validator can generate single-file validation reports in PDF format, in addition to the HTML report (using similar styles as the corresponding HTML reports). These single-file reports</p>	eValidator5-FSP-5019



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>can be distributed or shared easily, as no other files are required.</p> <p>PDF reports are available for all eValidator applications (eValidator clients, eValidator Console, LORENZ Job Management, and eValidator webAccess)</p> <p>Through a configuration setting, rendering PDF reports can be disabled for specific profiles.</p>	
EVA-3069 EVA-3393	File/folder path information in the validation reports will be provided without the folders above the application folder. This is a configurable option.	eValidator5-FSP-5020
EVA-4243	Findings per validation rule will be listed using bullet points as shown in the sample picture below.	eValidator5-FSP-5021
EVA-4228	<p>For validation criteria, the rule number and the findings count are listed in the header line.</p> <p>In the next lines, the description text and further information (if applicable) will be provided, preserving any whitespaces used in the original sources.</p>	eValidator5-FSP-5022

● eCTD4-071 (2)

The Keyword Type must be valid for the Context of Use heading

Problem/Issue:
The Keyword code value(s) contextOfUse.code submitted for the Context of Use heading is (are) invalid for the eCTD heading

Corrective Action:
The submission unit needs to be resubmitted with valid keyword types for the Context of Use

Invalid keyword types provided

- Invalid keyword type 'us-form-type' in Context Of Use 'dd8dacba-b98f-59a0-9db2-3ba2769585da', section 'us_1.2'.
- Invalid keyword type 'us-form-type' in Context Of Use 'b98abe88-8c12-5a4a-8e24-afffb2acb7e9', section 'us_1.6.1'.

Figure 9: LORENZ eValidator webPanel

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-4741	<p>The following fields are always displayed in the general information section of automation job reports:</p> <ul style="list-style-type: none"> • Date/time of execution (local time for desktop clients, primary user time zone will be used for 	eValidator5-FSP-5023



Ref. Numbers	Specification Text and Comments	FSP Codes
	validations executed through eValidator webAccess or LORENZ Job Management) <ul style="list-style-type: none">• Date/time of execution (UTC)• Runtime (hh:mm:ss)• License information• Profile• Profile Path• Profile Status	
EVA-4620	Sub-reports can be embedded in the report.	eValidator5-FSP-5024



4.6 Extended Validation Features

Features listed in this section apply to the eValidator FIVE version only.

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-40	<p>There is an extended profile for each standard eCTD profile, which supports additional rules not covered by the official criteria set published by the agencies.</p> <p>Extended profiles are not protected and can be customized.</p>	eValidator5-FSP-6001
EVA-39 EVA-86 EVA-279 EVA-4207	<p>Deep Life Cycle Scanning</p> <p>The sequence of operations will be analyzed: when checking LCM semantics, the eValidator also checks the operational sequences for being valid, invalid, or not recommended. Currently the following six leaf life cycle patterns will be detected and reported:</p> <p>AppendOnAppend</p> <p>This refers to scenarios where an append operation is applied on an existing append leaf. Most authorities want the subsequent append to be applied on the original leaf instead. The pattern does not apply to STF nodes.</p> <p>AppendOnAppendSTF</p> <p>This refers to scenarios where an append operation for an STF leaf is not applied to the most recent (previous) version of this STF.</p> <p>MultipleDelete</p> <p>This refers to scenarios where a leaf is deleted more than once.</p> <p>OperationOnDeleted</p> <p>This refers to scenarios where an operation is being applied on a leaf, which has been deleted already. From a technical perspective, the MultipleDelete pattern is a sub-pattern of this pattern.</p> <p>BranchingAppend</p> <p>This refers to scenarios where an append operation is being applied on a leaf, which has already been replaced by another leaf.</p> <p>BranchingDelete</p> <p>This refers to scenarios where a delete operation is being applied on a leaf, which has already been</p>	eValidator5-FSP-6002



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>replaced by another leaf.</p> <p>BranchingReplace</p> <p>This refers to scenarios where a replace operation is being applied on a leaf, which has already been replaced by another leaf. For additional details about these patterns, please refer to the user guide.</p> <p>The output from the Deep Life Cycle checks can be limited to findings that affect the current sequence only.</p> <p>To improve performance when validating a submission from an application with many sequences, the deep life cycle checks will be skipped when the current sequence backbone files (index.xml, regional backbone file) have no leaf elements with operation attribute delete, replace, or append.</p>	
EVA-47	<p>The eValidator application supports direct invocation of rules from other authorized applications. An application is authorized if and only if its strong name is listed in the version.xml file.</p>	eValidator5-FSP-6003
EVA-75 EVA-222 EVA-272	<p>The eValidator can detect PDF portfolio documents and documents with attachments.</p> <p>It is also possible to check for specific attachment file types or file names,</p>	eValidator5-FSP-6004
EVA-76 EVA-218	<p>Reused Files</p> <p>The eValidator detects and handles file reuse scenarios (see ICH 3.2.2, Appendix 6).</p> <p>When publishing a submission using references, the eValidator will not consider those files having invalid name.</p> <p>Reused files will be handled properly within all contexts and scopes: Inside an index file, between index files in the same sequence, between sequences and even between different applications.</p> <p>Furthermore, the user will get a list of all reused files in the report (see new rule – File Reuse in the corresponding backbone sections).</p> <p>For reused files in node extensions, the whole xpath to the location can be printed instead of just the leaf ID (as in the other cases).</p>	eValidator5-FSP-6005



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-77	The eValidator supports the detection of leaf elements which append or replace previous content with the same content as before.	eValidator5-FSP-6006
EVA-78	The eValidator supports the detection of scenarios where more than one replace or delete operation for the same target document occurs in the same index file (same sequence).	eValidator5-FSP-6007
EVA-79 EVA-89 EVA-176 EVA-88 EVA-1648 EVA-1986	<p>For STF validation, it will be verified that the study attributes are filled, and the appropriate values are specified (STF 2.6, Page 8).</p> <p>The eValidator checks the study property element values.</p> <p>Category values and file-tag values will be checked against the definition in the valid-values.xml file. The eValidator is using the version of this file that is accepted by the corresponding authority (e.g. FDA, HC, TGA).</p> <p>Lorenz eValidator Lorenz eValidator also checks if a mandatory category element is missing (For the US, additional metadata is required for STFs in sections 4.2.3.1, 4.2.3.2, 4.2.3.4.1 & 5.3.5.1).</p> <p>eValidator FIVE version (US and CA profiles):</p> <p>When sequence B is modifying an STF (xml) file and the referenced modified-file is not an xml file (but a PDF file for example), the eValidator can report this as a finding.</p> <p>The eValidator checks the metadata (category grouping) according to the STF spec. chapter II.C.</p> <p>STFs usually need to have the XML file extension. For US validation, the eValidator will also check other file types for being STFs. Rule 1867 will then report the incorrect file names accordingly.</p> <p>The STF checks will also be executed for STFs with invalid names.</p>	eValidator5-FSP-6008
EVA-80	The eValidator can verify the values for any element or attribute in an eCTD index file. Verification includes checking for existence, empty values, and value syntax.	eValidator5-FSP-6009
EVA-81	Any security settings (access permission constraints) on files or folders can be detected and reported.	eValidator5-FSP-6010



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-82	There is a configuration option to specify files and folders that shall be ignored when checking files for being referenced in backbones.	eValidator5-FSP-6011
EVA-33	<p>The eValidator supports the following specific regulation for Japanese submissions:</p> <p>Leaf elements with an operation replace, delete, or append targeting a leaf in a previous sequence must not have the same leaf id as the leaf in the previous sequence.</p> <p>Furthermore, leaf ids must be unique throughout the whole life cycle except for the following condition: For leaf elements with an operation new the leaf id must be retained in all sequences if the operation did not change (identical leaf ids for copied leaf elements in later sequences).</p>	eValidator5-FSP-6012
EVA-33	The JP 1.0 specification includes checks for file attributes (Excel files read-only). The Validator allows checking files for any other Windows file attribute as well.	eValidator5-FSP-6013
EVA-87	When analyzing PDF documents for being optimized for web access, the eValidator both checks the "/Linearized" flag in the document and the total document size specified in this catalog dictionary.	eValidator5-FSP-6014
EVA-91	A special rule "Total number of hyperlinks" is available for the profiles (currently by default only in the extended CA profile). The purpose of this rule is to report the total number of hyperlinks in the submission without creating the corresponding sub reports.	eValidator5-FSP-6015
EVA-142	When no backbones or no acceptable backbones (according to allowed DTD versions) could be found, the Application Identification rule will report a finding.	eValidator5-FSP-6016
EVA-111 EVA-1824	<p>The eValidator supports extracting and creating ZIP containers through profile rules.</p> <p>When zipping a folder content, the top-level folder can optionally be included or not.</p>	eValidator5-FSP-6017
EVA-110	The eValidator can detect PDF/A documents.	eValidator5-FSP-6018
EVA-109	Cross-node operations	eValidator5-FSP-6019



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>The eValidator can find leaf operations on nodes with an original location different from the node location in the current sequence. For example: A leaf in m2-3-p-drug- product with a replace operation targeting a leaf in m2-6-3- pharmacology-tabulated-summary.</p>	
<p>EVA-125 EVA-417</p>	<p>CDISC (SDTM) define.xml</p> <p>SDTM: The data definition file (define.xml) describes the format and content of the submitted datasets. See http://www.cdisc.org/define-xml.</p> <p>The eValidator does not check the validity of these files.</p> <p>Update for release 5.3: The rule has been removed from the US eCTD profiles due to licensing issues.</p>	<p>eValidator5-FSP-6020</p>
<p>EVA-169</p>	<p>The eValidator checks the file names in section 1.3.1 (EU M1) according to "ema5240202007.pdf" [3 May 2011, EMA/524020/2007 rev.3, Patient Health Protection].</p>	<p>eValidator5-FSP-6021</p>
<p>EVA-309 EVA-368</p>	<p>The eValidator supports Baseline Optimized Validation.</p> <p>When running validations on the same application sequence several times using the same profile, the eValidator can benefit from the results of previous validations ("baselines") for content that has not changed in the meantime. For example, the MD5 checksum verification can be skipped for files that have not been changed.</p> <p>Furthermore, PDF analysis can be skipped automatically for files that did not change since the baseline validation. For such documents, it does not matter that any findings (errors, warnings etc.) in the previous validation reports will be imported into the current validation report.</p> <p>For additional information please refer to the user guide.</p>	<p>eValidator5-FSP-6022</p>
<p>EVA-339 EVA-3359</p>	<p>The eValidator supports corrective profiles, which can modify PDF files as well as XML backbone files.</p> <p>Corrective profiles will not be delivered as part of the standard packages. They require customer specific configuration – for example, which PDF modifications should be done, such as "change the color for all hyperlinks to blue". Therefore, corrective profiles should be installed and configured as part of a dedicated project on site.</p>	<p>eValidator5-FSP-6023</p>



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-342 EVA-1778	<p>The eValidator can check for markup annotations in PDF documents. By default, form fields and links will not be reported as annotations (even though they are annotations from a technical point of view). This can be configured through the rule parameter "ignore_annotation_types".</p> <p>Optionally, annotations details can be exported to an XML file for further processing.</p>	eValidator5-FSP-6024
EVA-387	<p>When the user specifies an initial sequence number greater than the current sequence, the eValidator will silently set the initial sequence number to the current sequence number. The validation reports will show a corresponding note in the application identification section.</p>	eValidator5-FSP-6025
EVA-429	<p>For eCTD submissions (all regions): The MD5 Proofreading profile can correct invalid checksums, add missing checksums, and remove checksums from elements where no checksum is expected.</p>	eValidator5-FSP-6026
EVA-466	<p>For eCTD submissions, any included dataset definition files (define.xml) will be examined to report non-existing files referenced therein.</p>	eValidator5-FSP-6027
EVA-569	<p>In PDF analysis, the eValidator can identify and report documents, which contain JavaScript at document level as part of the opening actions.</p>	eValidator5-FSP-6028
EVA-464 EVA-1136	<p>In PDF analysis, the eValidator can identify PDF XFA documents and retrieve all contained form data in XML format.</p> <p>Corrupted XFA documents can also be detected (e.g., the ones showing "Please wait" in Adobe Acrobat).</p>	eValidator5-FSP-6029
EVA-730 EVA-731 EVA-1624 EVA-1625	<p>In PDF analysis, the eValidator can retrieve the action types of hyperlinks and bookmarks and search for hyperlinks or bookmarks by action type.</p> <p>Supported action types: JavaScript, Sound, GoTo3DView, GoTo, GoToR, URI, Movie, Launch.</p> <p>A wildcard (*) can be used to get bookmarks / hyperlinks for all action types.</p> <p>Furthermore, it is possible to search for and identify</p>	eValidator5-FSP-6030



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>hyperlinks and bookmarks that execute JavaScript as part of their assigned actions.</p>	
<p>EVA-1328 EVA-1334 EVA-1340 EVA-1347 EVA-1421 EVA-1505 EVA-1905 EVA-1910 EVA-2140 EVA-4384 (removed 2 profiles)</p>	<p>For the validation of US eCTD submissions, special additional profiles exist (named “controller” profiles), which can be used with the eValidator jobs in LORENZ Job Management to:</p> <ul style="list-style-type: none"> • Validate all contained application sequences in a grouped submission (also handling scenarios where the same application number is used more than once, in the same grouped submission) <p>Removed in release 23.1:</p> <ul style="list-style-type: none"> • Profile_US_eCTD_High_Error_Report.xml • Profile_US_eCTD_ApplicationReport.xml <p>Furthermore, a profile exists to generate summary reports for application sequences, based on previous validation results stored in the jobs database (result and reports tables). This also includes information about and links to cross references applications. These application reports will only list the rules that have findings but not the rules that passed without findings.</p> <p>When using the eValidator Batch Processing application, separate validation tasks for each application sequence in a grouped submission will be created.</p>	<p>eValidator5-FSP-6031</p>
<p>EVA-1425 EVA-2728</p>	<p>For SAS XPT files, a workflow extension exists to process and examine the content of such files. This extension can convert XPT files to CSV or XML and retrieve specific data from an XPT file.</p> <p>Creating XPT files from XML sources is also supported.</p> <p>XPT files with multiple tables are supported.</p> <p>Processing SAS XPT files is currently limited to format version 5 (described in ts140.pdf).</p>	<p>eValidator5-FSP-6032</p>
<p>EVA-1590</p>	<p>For extraction of text from PDF documents, the eValidator uses the IFilter interface. A separate workflow Action method has been implemented for this.</p> <p>On Windows operating systems other than Windows 8.1, Windows 10, or Windows Server 2016, make sure an IFilter has been installed (the systems mentioned</p>	<p>eValidator5-FSP-6033</p>



Ref. Numbers	Specification Text and Comments	FSP Codes
	above already have an IFilter built-in). This can be achieved by installing Adobe Acrobat Reader (or full version), or by installing the Adobe IFilter directly.	
EVA-1583	For PDF analysis, the eValidator supports retrieving annotation details in raw format (the original annotation definition string as contained in the PDF file).	eValidator5-FSP-6034
EVA-1595 EVA-1661 EVA-2486	<p>For Microsoft Office documents, the eValidator supports:</p> <ul style="list-style-type: none"> • Retrieving text content and formatting from Word documents • Retrieving cell text and cell formatting from Excel documents • Updating and creating Excel documents and worksheets. • Getting cell background color • Getting cell border style • Merging cells • Setting horizontal alignment for text in cell • Changing size of cells • Changing number format • Changing the wrapping of cell content • Adding/Removing Figures • Converting Excel worksheets to XML 	eValidator5-FSP-6035
EVA-1604	In PDF analysis, the eValidator optionally supports writing the findings to variables or to an external file instead of reporting them directly.	eValidator5-FSP-6036
EVA-1605	In PDF analysis, the metadata can be retrieved from a document based on the metadata item names.	eValidator5-FSP-6037
EVA-1614	In PDF analysis, the layout setting details can be retrieved from a document.	eValidator5-FSP-6038
EVA-1616	In PDF analysis, the page dimensions (width/height) and rotation can be retrieved from a document.	eValidator5-FSP-6039
EVA-1623	In PDF analysis, the eValidator will report the annotation type for annotations without text, (if applicable to the profile context).	eValidator5-FSP-6040



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-1626	In PDF analysis, the page count can be retrieved from a document and written to the report or assigned to a variable for further processing.	eValidator5-FSP-6041
EVA-1641	For STF validation, the eValidator desktop client will show additional progress information (name of the STF currently being processed, number of items processed vs. total number of items). This applies to submissions with a large number of STFs and/or STFs with a large number of elements (more than 100).	eValidator5-FSP-6042
EVA-1766 EVA-1779 EVA-2028	<p>The eValidator can retrieve all form fields and values from a PDF document (AcroForm) and save it as XML.</p> <p>If can also check for specific form fields and their values (e.g., in US eCTD profiles: application number, submission date).</p> <p>When determining whether a document is an AcroForm, the eValidator can be configured to ignore AcroForm documents that do not have any form fields.</p>	eValidator5-FSP-6043
EVA-1787	A validation rule can be configured to change its severity level at runtime. Please note that the Workflow Profile Editor is needed to configure this.	eValidator5-FSP-6044
EVA-1840	<p>To determine the PDF document version, the eValidator does the following:</p> <p>Let vH be the version information from the first line of the document (header version)</p> <p>Let vC be the version information from the document root catalog (catalog version)</p> <p>A valid version has the format x.y, where x and y are numbers.</p> <p>If both vH and vC are present and valid, the higher value will be used.</p> <p>If vC is missing or invalid, vH will be used.</p> <p>If vC and vH are invalid, vH will be used.</p> <p>If vC is valid and vH is invalid, vC will be used.</p>	eValidator5-FSP-6045
EVA-1900	<p>The eValidator method to retrieve a form field value from a PDF document can handle both XFA and regular AcroForm document.</p> <p>For US eCTD 3.3, an Action method exists that can</p>	eValidator5-FSP-6046



Ref. Numbers	Specification Text and Comments	FSP Codes
	locate a form document in a submission by its number (e.g., 1571) and its reference in the regional backbone. The method can retrieve any form field value from the located form, regardless of its format (XFA, or regular AcroForm).	
EVA-1929	In PDF analysis, the eValidator can check the page sizes of a document (for all pages) against configured dimensions. The standard dimensions are letter and DIN A4.	eValidator5-FSP-6047
EVA-1943	In PDF analysis, the eValidator can validate Microsoft Word documents to check if a document cannot be opened (because it is corrupted, or password protected). Furthermore, it can be checked if a document is using an external DOTX.	eValidator5-FSP-6048
EVA-1966	In PDF analysis, the eValidator can check the status of bookmarks (collapsed or expanded).	eValidator5-FSP-6049
EVA-1969	In PDF analysis, when examining bookmarks or hyperlinks, the eValidator can optionally check all actions assigned to the corresponding bookmark or hyperlink, not just the first one.	eValidator5-FSP-6050
EVA-2083	For PDF Analysis, PDFIUM or YAPP extension methods can be used.	eValidator5-FSP-6051
EVA-2243	PDF documents with additional text following the PDF version in the header line will be reported as invalid. Example: %PDF-1.6 SOME TEXT Here "SOME TEXT" is an invalid comment. Some PDF viewers might tolerate this; however, the PDF specification clearly states that the header line must only contain the version information.	eValidator5-FSP-6052
EVA-2204	With the PDFIUM extension methods, text can be extracted from PDF document pages for content analysis.	eValidator5-FSP-6053
EVA-96	The eValidator can be configured to use two libraries when analyzing PDF documents: <ul style="list-style-type: none">- LORENZ YAPP will always be used first trying to examine a document.- If LORENZ YAPP fails analyzing a document,	eValidator5-FSP-6054



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>optionally PDFIUM can be used for examination instead, either for the specific check to be performed or for all subsequent checks on that document (e.g., when processing all PDFs in a folder structure, using a loop construct in the profile).</p>	
EVA-96	<p>When using the PDFIUM library, the eValidator supports processing documents that have been saved with AES-256 encryption.</p>	eValidator5-FSP-6055
EVA-4214	<p>Optionally, all execution results from a validation can be written into the central database. This includes both the number of findings and the finding details per activity item. Instructions for how to enable database writing are provided in the eValidator Administrator Guide.</p>	eValidator5-FSP-6056
EVA-2014 EVA-2020 EVA-2024 EVA-2937 EVA-4087	<p>When validating US eCTD submissions, different tracking modes can be configured:</p> <ul style="list-style-type: none"> • “folder”: All information is retrieved from the folder structure • “docubridge”: The tracking repository to be used is docuBridge 22.2. • “external”: The tracking repository to be used is a custom third-party system. <p>For the last two tracking modes, the profile will load an external file with the business logic for how to access the tracking repository.</p>	eValidator5-FSP-7014 eValidator5-FSP-6057



4.7 PowerShell Scripting in eValidator

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-84	The eValidator uses a workflow engine that is fully scriptable using PowerShell. This goes beyond the scope of using the command line switches for the eValidator desktop client program or the eValidatorConsole program. A custom PowerShell host application with pre-loaded components is included for the user to simplify controlling the validation engine.	eValidator5-FSP-7001
EVA-72 EVA-84	Controlling the validation through the workflow engine by using scripts allows requesting profile content reports.	eValidator5-FSP-7002
EVA-73 EVA-84	Controlling the validation through the workflow engine by using scripts allows requesting eValidator extensions reports (reference reports for the profile methods).	eValidator5-FSP-7003
EVA-84	Controlling the validation through the workflow engine by using scripts allows validating single application sequences.	eValidator5-FSP-7004
EVA-84	Controlling the validation through the workflow engine by using scripts allows validating multiple application sequences.	eValidator5-FSP-7005
EVA-84	Controlling the validation through the workflow engine by using scripts allows validating multiple applications with multiple sequences.	eValidator5-FSP-7006
EVA-84	Controlling the validation through the workflow engine by using scripts allows running multiple eValidator engine instances in parallel.	eValidator5-FSP-7007
EVA-5 EVA-8 EVA-84	The eValidator supports custom validations through scripting (see also eValidator5-FSP-1012).	eValidator5-FSP-7008
EVA-137	When executing a scripted rule, the PowerShell console window will be hidden by default.	eValidator5-FSP-7009
EVA-202 EVA-1254	The eValidator PowerShell host supports executing scripts in non-interactive mode (hidden host program). There are two PowerShell hosts applications available: <ul style="list-style-type: none"> AutomatorPSConsole.exe: A full featured PowerShell custom console to test and run scripts and commands interactively. 	eValidator5-FSP-7010



Ref. Numbers	Specification Text and Comments	FSP Codes
	<ul style="list-style-type: none">AutomatorPS.exe: A PowerShell custom console to run scripts or commands in hidden mode. Error log output is supported by this program.	
EVA-190	Aborting validations that have been started in PowerShell is supported for both synchronous and asynchronous validations. This is possible through the Abort() method in the eValidatorContainerListener interface.	eValidator5-FSP-7011
EVA-1570	The eValidator desktop client exposes the ID of the Workflow Engine Listener host through a runtime variable "r_engine_listener_id". This allows profiles with hosted PowerShell scripts to be used in the eValidator desktop client.	eValidator5-FSP-7012
EVA-1780	The eValidatorConsole program can be used to run profiles without validation context (e.g., profile format is "None"). In such cases, the "application" command line switch can have a text value other than an application path.	eValidator5-FSP-7013



4.8 REMOVED: eValidator webPanel

EVA-4264:

With release 23.1, the eValidator webPanel has been replaced by the LORENZ Job Management component. The functions and features listed in this section are no longer available. Please refer to section 4.9 instead.

Features listed in this section apply to the eValidator FIVE version only.

Application	Progress	Results	Created	Started	Completed	User	Priority
local: 111333/0000	Completed	Best Practice	1	25/03/2022 07:47:05	25/03/2022 07:47:05	abassemann	
local: LORENZ Automator Workflow Profile Editor.pdf	Completed	Medium Information	34	25/03/2022 07:46:50	25/03/2022 07:46:58	abassemann	
local: 090907/0002	Completed	High	5	25/03/2022 07:46:13	25/03/2022 07:46:32	abassemann	
local: 111333/0002	Completed	Best Practice	1	25/03/2022 07:47:17	25/03/2022 07:47:17	abassemann	
local: 007007/0001	Completed	High Medium	5	25/03/2022 07:46:00	25/03/2022 07:46:00	abassemann	
local: 111333/0005	Completed	Best Practice	1	25/03/2022 07:47:42	25/03/2022 07:47:42	abassemann	
local: ch1238/0000	Completed	Final Fail	6	25/03/2022 07:46:22	25/03/2022 07:46:26	abassemann	
local: 111333/0001	Completed	Best Practice	1	25/03/2022 07:47:11	25/03/2022 07:47:11	abassemann	
local: 111333/0003	Completed	Best Practice	1	25/03/2022 07:47:24	25/03/2022 07:47:24	abassemann	
local: 007007/0000	Completed	High Medium	5	25/03/2022 07:45:55	25/03/2022 07:46:06	abassemann	
local: 111333/0004	Completed	Best Practice	1	25/03/2022 07:47:37	25/03/2022 07:47:37	abassemann	
local: grouped_submissions\EVA-2278\ind111111	Completed	Error	1	25/03/2022 07:46:32	25/03/2022 07:46:37	abassemann	

Figure 10: LORENZ eValidator webPanel

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-133 EVA-244 EVA-1462 EVA-2746 EVA-3150	The LORENZ eValidator webPanel is a web based user interface for validation job management and submission validation. The eValidator webPanel is based on the Automator webPanel, i.e., both use the same code base, but with a different “branding”. The eValidator webPanel will be installed/updated with the eValidator server setup package (it is a standard feature).	eValidator5-FSP-8001
EVA-3669 EVA-3678 EVA-3710	The LORENZ eValidator webPanel authenticates and authorizes users through LORENZ Foundation. Powershell scripts are provided to support the configuration of eValidator servers other than the Foundation server. For the migration of users from the legacy webPanel authentication to LORENZ Foundation based authentication, a migration profile is available, which can be executed in the eValidator webPanel.	eValidator5-FSP-8002



Ref. Numbers	Specification Text and Comments	FSP Codes
n/a	This feature has been removed with release 22.1.	eValidator5-FSP-8003
EVA-133 EVA-193 EVA-224 EVA-580 EVA-1917	<p>Through the LORENZ eValidator webPanel the user can process validation jobs (tasks). The following features are available:</p> <ul style="list-style-type: none"> • Add new jobs • Start jobs • Abort jobs • Remove jobs (move them to the recycle bin) • Delete jobs • Filter jobs • Archive jobs <p>The triggering user will be stored with the following status changes: Start, Abort, Archive, Remove, Delete.</p> <p>Completed jobs will be displayed with a color code corresponding to the highest severity of the findings in the report. The colors can be customized in the workflow profiles, including the color for success (which defaults to green, but can be configured through the Workflow Editor).</p> <p>Deleting a job will remove the report folder, and delete any job records from the database, including the Results and Reports tables if applicable.</p>	eValidator5-FSP-8004



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-133 EVA-219 EVA-228 EVA-299 EVA-304 EVA-3568	<p>The user can add new jobs for a single sequence or for multiple sequences of a given application (by selecting the application and specifying the list of sequences—this will automatically create the corresponding number of jobs).</p> <p>The webPanel supports the same parameters and settings for a validation job as the eValidator desktop client for a validation task.</p> <p>The application browser dialog in the webPanel can be configured to search for applications in the top-level folders of the selected application data pool or in the whole folder structure of the selected pool. Furthermore, it can be configured to automatically list the top-level folders without specifying a search text.</p> <p>A maximum number of files/folders shown in the application browser dialog can be configured to avoid timeout issues when retrieving the information. This is called “chunk view”. The user can easily navigate to the previous/next chunks in the tree view.</p> <p>Application data pools and their file/folder content can either be retrieved directly through the webPanel application or through the Workflow Service API.</p> <p>When using the eValidator Workflow Service for providing the application data pools, it can be configured to use mapped drives instead of UNC paths. The mapping will happen inside the Windows Service according to the configured data.</p> <p>When selecting an application sequence from an application pool, the sort order of sequence folders is using natural sort order.</p>	eValidator5-FSP-8005
EVA-133 EVA-2506	<p>The LORENZ eValidator webPanel allows running multiple jobs in parallel. The maximum number can be defined through the configuration file(s). Changing this number does not require restarting the eValidator Workflow Service, because it will be read on the fly (based on a file watcher).</p> <p>Version 20.1 or later: When checking for pending jobs, the Automator Workflow Service will always start as many pending jobs as free slots are available for parallel execution.</p>	eValidator5-FSP-8006
EVA-144	The LORENZ eValidator webPanel uses the LORENZ eValidator Workflow Service to execute the configured jobs.	eValidator5-FSP-8007
EVA-1355	Users can be managed in the LORENZ adminPanel.	eValidator5-FSP-8008
EVA-145 EVA-3017	LORENZ eValidator webPanel can be used with any eValidator FIVE license.	eValidator5-FSP-8009



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-161 EVA-256 EVA-276	<p>When running validations in bulk mode (using the Workflow Service), suspending, and resuming jobs is supported.</p> <p>When configured accordingly, suspended jobs can also be resumed manually from the webPanel. Otherwise suspend and resume work automatically based on (external) conditions or events.</p> <p>To support handling for large amounts of suspended jobs, two types of suspension modes [trigger] and [manually] are available.</p> <p>The dialogs for resuming a job ("user dialogs") can be customized using external HTML files.</p> <p>See the webPanel user guide and the "Inside Profiles – Reference Guide" for further information</p>	eValidator5-FSP-8010
EVA-172	<p>The webPanel allows adding and changing annotations (user comments) for jobs. These annotations can also be used in the filtered searches.</p>	eValidator5-FSP-8011
EVA-187	<p>The webPanel has a license option that limits the number of users (both for the number concurrent users and the number of configurable users)</p>	eValidator5-FSP-8012
EVA-194 EVA-476 EVA-948	<p>When accessing a validation report through the webPanel in a browser, the links to the PDF documents are not functional if they point to a location on a server. Even if this location is a shared drive, most browsers would prevent the user from opening them due to security constraints.</p> <p>Therefore, the webPanel can be configured to use URLs instead of file path expressions to make these link destinations accessible.</p> <p>When showing/activating a report link, the webPanel will automatically update the address by applying the corresponding application setting from the web.config (reportPools and reportPoolAddresses). This way it is possible to change the base URL (virtual directory) for the reports without losing access to the reports.</p> <p>For Workflow Editor users: The report URL for the current job is available as a runtime variable "r_report_url".</p>	eValidator5-FSP-8013



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-195 EVA-224 EVA-409	<p>The following filter options are available:</p> <ul style="list-style-type: none"> • Filter by creation time • Filter by application name and description • Filter by user name (owner name) • The webPanel allows searching for jobs based on more than one result name (e.g. all jobs that had a Warning or a Medium level finding: • Warning Medium). A regular expression can be used to specify the combined results filters. • Show executing jobs • Show pending jobs • Show suspended jobs • Show completed jobs • Show aborted jobs • Show archived jobs • Show removed jobs <p>Filter settings (except the creating time filter) will be saved with the user data and automatically be re-applied in future web sessions</p>	eValidator5-FSP-8014
EVA-197 EVA-264 EVA-329 EVA-2035 EVA-2309 EVA-2803	<p>The eValidator Workflow Service uses a database to store job data (the job storage database):</p> <ul style="list-style-type: none"> • Microsoft SQL Server 2005 or higher • Microsoft SQL Server Compact Edition 3.5 (SSCE) • ORACLE 11 or higher • PostgreSQL 12, 13, 14 • SQLite <p>The default location for the SSCE database and the job folders is inside the eValidator configuration folder (subfolder Repositories\Jobs). This can be customized through system configuration.</p> <p>When using SQL Server, PostgreSQL, or ORACLE: The database can be integrated with the database used by LORENZ Foundation. Optionally, the database can be installed with the LORENZ dbaPanel utility.</p> <p>A database migration tool exists to copy job records from one database type to another.</p>	eValidator5-FSP-8015
EVA-226	<p>The webPanel allows adding a site label and color as an identification string (e.g., when working with multiple webPanel installations).</p>	eValidator5-FSP-8016



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-225	<p>The webPanel allows configuring whether disabled buttons should be visible or not.</p> <p>This applies to the legacy webPanel only.</p>	eValidator5-FSP-8017
EVA-236 EVA-1913 EVA-1914 EVA-3213	<p>The following configuration settings and options are supported by the eValidator webPanel and the underlying eValidator Workflow Service:</p> <ul style="list-style-type: none"> • webPanel authentication/authorization mode • Application data pools • Report pools • Log files • webPanel: Job list refresh timer (also used as the timer for updating job progress information) • Maximum number of jobs in web page list • Maximum number of folders in application browser • Annotation length in web page job list • Workflow service connectivity • Number of parallel executed jobs • Timer for checking for new/pending jobs (jobs added through the eValidator webPanel will be started immediately provided that a free job slot is available). • Timer for checking suspended jobs • Workflow service debug mode • PowerShell mode in post processing • Job progress messages ratio • Job storage provider settings (incl. database) • Job filter: case sensitivity • Job filter: apply for executing jobs yes/no <p>Refer to the webPanel user guide for additional information</p>	eValidator5-FSP-8018
EVA-250	<p>The webPanel allows configuring and running jobs that have no electronic submission context (and if required not even a file or folder context). See the webPanel user guide for information about jobs for profiles with format set to "None".</p>	eValidator5-FSP-8019
EVA-252	<p>The webPanel allows assigning different priorities for the jobs to be executed.</p>	eValidator5-FSP-8020
EVA-261	<p>The webPanel remembers the most recently used profile per user.</p>	eValidator5-FSP-8021



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-291	For aborted jobs, the incomplete validation reports can be accessed through the webPanel user interface.	eValidator5-FSP-8022
EVA-321	The Workflow Service supports job dependencies: A job can be configured to wait for the completion of one or more other jobs before it starts execution.	eValidator5-FSP-8023
EVA-237 EVA-581 EVA-2656	<p>The Workflow Service creates audit trail records when jobs are being added, aborted, archived, removed, suspended, resumed, or deleted. Records will also be generated when job settings have been modified.</p> <p>Audit trail reporting is available through the GetAuditTrailRecords() API in the eValidator PowerShell host, and also through the configPanel (for job records only).</p> <p>LORENZ Foundation audit trail records will be generated for failed login attempts (both for invalid credentials and missing authorization data).</p>	eValidator5-FSP-8024



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-288 EVA-359 EVA-360 EVA-1854 EVA-1873 EVA-1903	<p>The eValidator webPanel supports multiple Workflow Service instances. This includes the capability to execute a job by a Workflow Service instance that runs on a different physical server. By default, a new job will be assigned to Workflow Services using a load balancing algorithm (the Workflow Service with the lowest number of already running and/or pending jobs will get the new job assigned).</p> <p>The list of available profiles shown in the dropdown list when adding a new job is the distinct superset of all profiles configured for the active Workflow Service instances.</p> <p>The load balancing algorithm will consider if the selected profile is available on the Workflow Service instance that has the lowest load.</p> <p>Important: If the auto detect profile (autodetect.xml) is available for a Workflow Service instance it is assumed that all other profiles are also available at that instance.</p> <p>Profiles can be hidden from that list through a specific attribute value in their root elements.</p> <p>Load balancing also works for auto detect scenarios and for bulk validation scenarios (when selecting multiple sequences at once, in a single job, which will then fork a sub-job for each sequence).</p> <p>Load Balancing works for jobs added in the webPanel manually.</p> <p>Load Balancing works for jobs added through the AddJob() API method of the Workflow Service.</p> <p>Load Balancing works for jobs added through XML tickets in the Incoming folder of the Workflow Service.</p> <p>When adding a new job through XML ticket or API, the profile can be specified with or without path information. Each Workflow Service in a load balancing infrastructure will check if the requested profile exists at the given path. In this scenario, the profile does not necessarily have to exist in the standard Profiles folder.</p>	eValidator5-FSP-8025
EVA-297	<p>The webPanel allows modifying the following profile settings before starting a new job:</p> <ul style="list-style-type: none"> • Report Title • Report Description Text • Report Branding Text • Exclude User name from report or not <p>The Create Date/Time folder for reports option cannot be changed and is true by default.</p>	eValidator5-FSP-8026



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-317	The webPanel can be configured to show summary validation results (finding totals) while the validation is still running. The totals will be updated whenever a validation category (group) has completed execution.	eValidator5-FSP-8027
EVA-393	In a multi instance installation, each Workflow Service can be configured to execute jobs for a subset of the profiles only (e.g., for specific regions only).	eValidator5-FSP-8028
EVA-468 EVA-523	<p>Stopping the Workflow Service through the eValidator configPanel or the Windows Services dialog will automatically stop (kill) any JobWorkerConsole process that has been invoked by the Workflow Service. This way, any running job will be aborted.</p> <p>Note that stopping the Workflow Service in Windows Task Manager will not stop any attached JobWorkerConsole processes.</p>	eValidator5-FSP-8029
EVA-492 EVA-1148	<p>Jobs interrupted by a system failure (computer shutdown, computer crash etc.) will be set to ABORTED status once the Workflow Service has been restarted. Those jobs will not automatically be started again but can be re-submitted manually if required.</p> <p>Job in ABORTED status (either manually aborted jobs or interrupted jobs) can have resume points. If a resume point exists when an aborted job shall be resumed (restarted), the system will not execute the profile from the beginning but at the last resume point found.</p> <p>Resume points can be defined for Rules, Groups, and Loops in a profile using the Workflow Editor. Whenever a resume point has been reached while executing a profile, the system will take a snapshot of the system status (before the item is being executed) and save it together with the report files. The next resume point reached will overwrite any previous resume point snapshots.</p> <p>The webPanel will show a Resume hyperlink for aborted jobs if resume point snapshots exist. Otherwise, the job can only be re-executed ab initio.</p>	eValidator5-FSP-8030
EVA-497	This feature has been removed with release 22.1	eValidator5-FSP-8031
EVA-220	This feature has been removed with release 22.1	eValidator5-FSP-8032



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-523 EVA-2325	<p>For each job, a new JobWorkerConsole process will be started to execute it. When the job has completed, the JobWorkerConsole process will be terminated.</p> <p>The option to use JobWorkerBee processes instead of JobWorkerConsole processes has been removed from the LORENZ eValidator.</p>	eValidator5-FSP-8033
EVA-535	The Workflow Service can be configured to use a server certificate for message level encryption and to request a client certificate for access authentication.	eValidator5-FSP-8034
EVA-542	The job list displayed in the webPanel can be exported in XML format (both generic XML and Excel friendly XML).	eValidator5-FSP-8035
EVA-571	<p>By default, the log file is shared by all eValidator processes using the workflow engine. This can lead to very large log files and the content of the files will be a mixture of all those processes (making it difficult to read the content).</p> <p>To avoid such problems, the system can be configured to write separate log files per eValidator process instance.</p>	eValidator5-FSP-8036
EVA-511 EVA-3552	The webPanel allows using the "old" report stylesheets for validation reports. Release 22.1: By default, the new styles will be applied.	eValidator5-FSP-8037
[EVA-615] EVA-623	<p>The webPanel allows the user to define and save named custom filters in addition to the two standard filters "Today" and "Since Yesterday".</p> <p>For these filters, the date/time range can be specified as "dynamic", i.e., always referring to the n last days. A value of "0" means that the filter will list the jobs from today only. A value of "1" means that the filter will list the jobs from today and yesterday.</p>	eValidator5-FSP-8038
[EVA-615] EVA-255	The webPanel allows grouping the job list by application, progress results, owner, and date/time.	eValidator5-FSP-8039
EVA-1103	To support lower screen resolutions, the search/filters pane can be closed and opened by the user.	eValidator5-FSP-8040
EVA-1104	The webPanel user guide can be accessed through a hyperlink on the web page.	eValidator5-FSP-8041



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-1160 EVA-1835	<p>The Details pane (job properties) can be accessed directly through web links such as:</p> <p><u>https://HOSTNAME/validation-jobs/jobs/JOBID</u></p> <p>(Where HOSTNAME and JOBID are placeholders for the actual server name and the actual Job Id)</p> <p>Provided that a user has access permission for the job, the details will be displayed regardless of the current filter settings.</p>	eValidator5-FSP-8042
EVA-1352	<p>The application path, as selected through the webPanel application browser dialog, can be made available to the Workflow Service and Workflow Engine with the original upper/lower case name(s).</p> <p>Two specific runtime variables can be used to access the original path name: <code>r_app_path_original</code> and <code>r_sequence_path_original</code>.</p> <p>The default behavior is turning all paths into lower case. So, when the original case is needed, make sure using those variables.</p>	eValidator5-FSP-8043
EVA-1976	<p>For the webPanel user interface, different localizations are being provided: English, German, and French.</p>	eValidator5-FSP-8044
EVA-2436	<p>With an external load balancer, multiple independent WF Service instances can be accessed and combined. To avoid using multiple separate webPanel installations, a configuration option exists to allow a single WF service instance reading jobs from all other instances even if they are not connected through Automator Load Balancing.</p> <p>This applies to SQL Server, PostgreSQL, and ORACLE databases. This does not apply for SSCE databases, which should never be shared between instances.</p> <p>Examples (system.config appSetting):</p> <pre>jobhandler_svc_instances_combined="*" jobhandler_svc_instances_combined="abc"</pre> <p>An enumeration of service instances is not supported. Therefore, when setting up the system, the instance names should be defined carefully so that a subset of the instances can be easily combined. Normally, it will be all instances or none (* or not defined).</p>	eValidator5-FSP-8045



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-3333 EVA-3335 EVA-3392 EVA-3290	<p>Starting with eValidator Release 21.2:</p> <p>The eValidator Workflow Service is exposing its API via REST endpoints. SOAP via TCP is no longer used.</p> <p>The communication between eValidator webPanel and eValidator Workflow Service is now using REST endpoints instead of the SOAP based protocols.</p> <p>Whenever the eValidator Workflow Service starts, it adds a URL Rewrite Rule to the Default Web Site in IIS with the Prefix "LZRPEV_". If the Rewrite Rule already exists, it will be deleted and re-created. If it doesn't have the required file permissions, it will write a corresponding error message to the log.</p> <p>Release 22.1: All SOAP configuration settings have been removed from the configuration files.</p>	eValidator5-FSP-8046
EVA-3308	Records for jobs and audit trail information in the job storage database will be saved with the Foundation user id. Previously (before eV 21.2), the username was stored in the database.	eValidator5-FSP-8047
EVA-3548 EVA-3662	<p>To access the webPanel, links in the LORENZ Menu (in LORENZ Foundation) can be used. No shortcuts will be created on the desktop.</p> <p>The product URL to access the webPanel directly is "validation-jobs", for example, https://myserver/validation-jobs</p>	eValidator5-FSP-8048
EVA-3661	The eValidator webPanel uses the common web page header, with the LORENZ menu integrated.	eValidator5-FSP-8049
EVA-3417	<p>LORENZ Dashboard gadgets are available for eValidator:</p> <ul style="list-style-type: none"> • Validation for Job Results • Validation Job Runtime Performance • Validation Jobs by State • Validation Completed Jobs • Validation Executing Jobs • and Validation Job Statistics. 	eValidator5-FSP-8050
EVA-4131	Using a configuration setting, the eValidator webPanel can be hidden from the LORENZ menu.	eValidator5-FSP-8051



4.9 eValidator in LORENZ Job Management

LORENZ eValidator can be used from the LORENZ Job Management web interface to execute and monitor validation jobs.

The screenshot displays the LORENZ Job Management web interface. The main area shows a table of jobs with columns for Description, Results, Started, Completed, Status, Job Type, Started By, Assigned To, and Runner. The jobs listed include various automation tests and validation tasks with their respective statuses (Fault, Passed, Information, Warning, Error) and counts. A details panel on the right provides further information for a selected job, including Results, General information (Description, Comment), Report Settings (Culture, Report Branding, Report Description, Show User Name in Results, Use old Report Style, Compress Reports (zip), Create XML Reports, Create PDF Report), and Other details (ID, Job Priority, Template Name, Profile, Runner, Is Archived).

Description	Results	Started	Completed	Status	Job Type	Started By	Assigned To	Runner
Automation Test Missing profile	Fault (1)	Mar 21, 2023, 11:35:14 AM	Mar 21, 2023, 11:35:17 AM	faulted	Automation	ADMIN	ADMIN	Amanda
Automation Test	Passed	Mar 21, 2023, 11:35:04 AM	Mar 21, 2023, 11:35:13 AM	completed	Automation	ADMIN	ADMIN	Amanda
S1/US/123012/0001 US eCTD - Val. Crit. 4.4 (CDER)	Information (1) Low (1) Medium (1)	Mar 20, 2023, 5:52:46 PM	Mar 20, 2023, 5:52:59 PM	completed	Validation	ADMIN	ADMIN	Amanda
S1/eCTD4/mda911885/2 US eCTD 4.0 - Validation Criteria 1.2	Warning (3)	Mar 20, 2023, 5:50:43 PM	Mar 20, 2023, 5:50:53 PM	completed	Validation	ADMIN	ADMIN	Amanda
S1/ZA/za21/0003 ZA eSubmission - Validation Criteria 1.0	Information (1) Best Practice (117) Pass/Fail (16)	Mar 20, 2023, 5:45:15 PM	Mar 20, 2023, 5:45:22 PM	completed	Validation	ADMIN	ADMIN	Amanda
S1/CA/e999668/0000 CA eCTD - Val. Crit. 5.1	Information (6) Warning (4) Error (174)	Mar 20, 2023, 5:44:04 PM	Mar 20, 2023, 5:44:14 PM	completed	Validation	ADMIN	ADMIN	Amanda
S1/au/3.1/e000222/0000 AU eCTD - Val. Crit. 3.1	Information (26) Error (7)	Mar 20, 2023, 5:43:26 PM	Mar 20, 2023, 5:43:39 PM	completed	Validation	ADMIN	ADMIN	Amanda
Automation Test	Passed	Mar 19, 2023, 6:26:03 PM	Mar 19, 2023, 6:26:08 PM	completed	Automation	ADMIN	ADMIN	Amanda
Automation Test	Passed	Mar 19, 2023, 6:26:01 PM	Mar 19, 2023, 6:26:06 PM	completed	Automation	ADMIN	ADMIN	Amanda
Automation Test	Passed	Mar 19, 2023, 6:25:58 PM	Mar 19, 2023, 6:26:03 PM	completed	Automation	ADMIN	ADMIN	Amanda

Figure 11: LORENZ eValidator webPanel



Ref. Numbers	Specification Text and Comments	FSP Codes
AM-8459 AM-8316 AM-8415 AM-8414 AM-8413 AM-8412 AM-8411 AM-8408	<p>Through LORENZ Job Management the user can process validation jobs. The following features are available:</p> <ul style="list-style-type: none"> • Add new jobs • Start jobs • Abort jobs • Delete jobs • Archive jobs • Filter jobs • Duplicate jobs • Assign jobs (not applicable to validation) • Resume jobs (not applicable to validation) <p>The triggering user will be stored with the following status changes: Start, Abort, Archive, Delete, Resume.</p> <p>Completed jobs will be displayed with a color code corresponding to the highest severity of the findings in the report. The colors can be customized in the workflow profiles.</p> <p>Deleting a job will remove the report folder, and delete any job records from the database, including the Results and Reports tables if applicable.</p>	eV-FSP-20001
AM-8316 AM-8199	<p>Access to validation jobs is controlled through Job Template ACLs in LORENZ adminPanel. These ACLs can be created and modified by users with the _CFG function assigned.</p>	eV-FSP-20002
AM-8316 AM-8199	<p>Users with the _JOB function assigned through LORENZ adminPanel will have administrative permissions (i.e., access to all profiles and job-related functions and settings).</p>	eV-FSP-20003
AM-8316	<p>When selecting a job from the list view, the Details pane will open and show additional information about the selected job.</p>	eV-FSP-20004
AM-8316	<p>Audit Trail:</p> <p>Through the context menu, job history information can be retrieved for a selected job.</p>	eV-FSP-20005
AM-8316	<p>While a job is being executed, progress information will be shown in the job list. The job results (number</p>	eV-FSP-20009



Ref. Numbers	Specification Text and Comments	FSP Codes
	of findings per severity level) will also be updated in the job before the job has completed execution.	
AM-8316	When a validation job has been completed or aborted, the validation reports can be opened through a hyperlink from the job list or from the details pane. This applies to both HTML and PDF reports.	eV-FSP-20010
AM-8316	<p>The following job settings can be configured for a new job:</p> <ul style="list-style-type: none"> • Report title • Report description text • Report branding text • Add name of the user to report • Use legacy style report • Generate PDF report • Create XML reports • Create ZIP from report • Description • Report pool <p>The generated report will always be stored in a date/time-stamped sub-folder.</p> <p>By default, the job description will be the selected application/sequence folder.</p> <p>By default, the job annotation (comment) in the job list will be the name of the validation profile.</p>	eV-FSP-20011
AM-8316	<p>The job list view can show jobs in grouped mode, based on the parent job relationships.</p> <p>For example, this applies to US eCTD grouped submissions, where the primary application validation job and any secondary application validation jobs will be displayed in a grouped hierarchy.</p>	eV-FSP-20012
AM-8316 AM-8735	Through the archive function, validation jobs can be exempted from the job retention policy configuration. Archived jobs will never be deleted automatically by the system.	eV-FSP-20013
AM-8316 EVA-4379	When adding a new job, the user can select the job template (profile) from a categorized list. The list	eV-FSP-20014



Ref. Numbers	Specification Text and Comments	FSP Codes
	provides additional information for each validation profile. Expired profiles are available through a separate category.	
AM-8316	In addition to executing validation jobs directly, jobs can be scheduled through the Job Management user interface. Both one-time jobs and recurrent jobs can be scheduled.	eV-FSP-20015
EVA-4410	When eValidator profiles have been updated, added, or removed, the LORENZ Job Management Services will not automatically detect the changes. To avoid a restart of this service it is possible to use the profile "Validation Templates Reload" to trigger a reload.	eV-FSP-20016
EVA-4399	With the 23.1 release, the eValidator-specific functions and group settings have been removed from LORENZ adminPanel. eValidator is now fully integrated and controlled through LORENZ Job Management. The group settings have been replaced by the Job Template ACLs.	eV-FSP-20017
EVA-4258	For validations that have been configured to store results in the database it is now possible to request the corresponding XML reports through a REST API endpoint.	eV-FSP-20018
EVA-4559	A profile to clean up old and duplicated validation job results from the database is available.	eV-FSP-20019



4.10 eValidator webAccess

Features listed in this section apply to the eValidator FIVE version only.

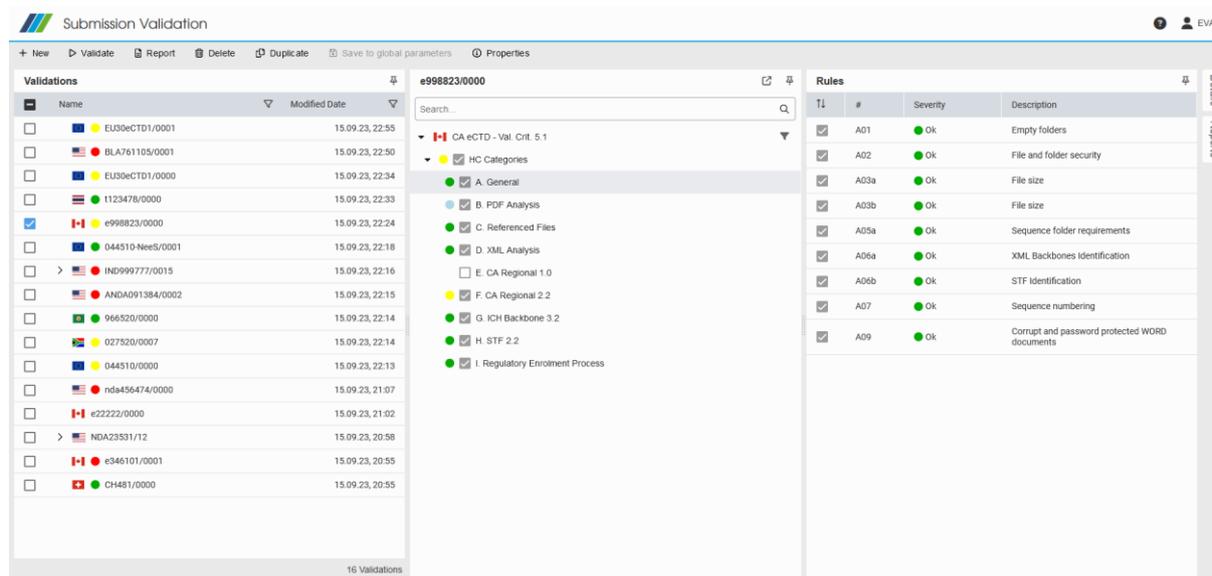


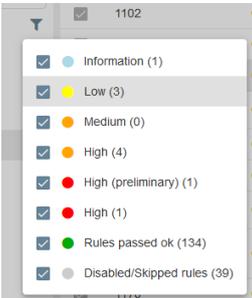
Figure 12: LORENZ eValidator webAccess

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-2760 EVA-3017 EVA-2746 EVA-2886 EVA-3150 EVA-4412 EVA-4424	<p>The LORENZ eValidator webAccess is a web-based user interface for submission validation.</p> <p>The eValidator webAccess is an optional feature to be installed/updated when the eValidator server setup package is used. The eValidator webAccess feature is controlled by the Submission Validation Services. When executing the setup, you can select the user account that shall be used to run this service.</p> <p>It can be used with any eValidator FIVE license.</p> <p>Using eValidator webAccess requires LORENZ Foundation 23.1 or higher. The configuration files (modules and resources) will be automatically copied to the Foundation configuration folder by the eValidator server setup.</p>	eValidator5-FSP-12001
EVA-2760 EVA-4222	The eValidator webAccess authenticates and authorizes users via LORENZ Foundation. The user claims are the same as configured for the LORENZ Job Management.	eValidator5-FSP-12002
EVA-2760	The eValidator webAccess allows running multiple validations in parallel.	eValidator5-FSP-12003



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-2760	Submissions, or other files and folders to be validated, can be selected from the locations that have been defined (and assigned to the users) in the LORENZ adminPanel / Storage Management.	eValidator5-FSP-12004
EVA-2760 EVA-2950	<p>The eValidator webAccess uses the eValidator REST Service. To execute a validation, the eValidator REST Service will trigger a job through LORENZ Job Management.</p> <p>When installing eValidator webAccess, the eValidator REST Service will also be installed automatically.</p>	eValidator5-FSP-12005
EVA-1677 EVA-2760	<p>A validation session (also referred to as “validation”) is defined by its name, the selected file/folder, and the assigned validation profile.</p> <p>Multiple validation sessions can be created and maintained by an individual user.</p> <p>For a given validation session, multiple validation results can exist (if the validation was executed multiple times). For each result, the corresponding reports can be downloaded in all available formats (e.g., HTML, ZIP, or PDF).</p> <p>The results of the most recent validation execution will be shown in the webAccess user interface directly, using a profile tree structure.</p> <p>When a validation is started, any current result for this session will be reset in the user interface (reports will still be available).</p>	eValidator5-FSP-12006
EVA-2760 EVA-3870 EVA-3872	<p>When creating a new validation session, the application browser dialog will open automatically. The profile will be assigned automatically using the autodetect feature of the LORENZ eValidator (in this case, the AutoDetect profile will be applied by the REST Service).</p> <p>The automatically assigned profile can be changed by the user.</p> <p>Once a validation session has been created, the application (file/folder path) and the profile cannot be changed.</p> <p>The location selected will automatically be used as the initial location the next time the users opens the browser dialog again (when the user logs out, this information will be discarded).</p>	eValidator5-FSP-12007



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-2760	<p>LORENZ eValidator webAccess can be accessed from the web-based LORENZ menu.</p> <p>The product URL to access it directly is “validation”, for example, https://myserver/validation</p>	eValidator5-FSP-12008
EVA-2760	LORENZ eValidator webAccess uses the LORENZ common UI framework.	eValidator5-FSP-12009
EVA-2760 EVA-3330	<p>Through the toolbar menu, validations can be added (“New”), started (“Validate”), aborted (“Stop validation”), and deleted (“Delete”).</p> <p>Validation sessions can be requested to be displayed in a new browser tab.</p>	eValidator5-FSP-12010
EVA-2760 EVA-3060	For each validation session, a Search function exist to filter the profile tree content.	eValidator5-FSP-12011
EVA-2760	<p>When a validation has completed, the results summary can be displayed in a pop-up window that allows filtering the results view.</p>  <p>Figure 13: Results Summary</p>	eValidator5-FSP-12012
EVA-2760 EVA-4239	<p>For standard profiles, no changes can be made by the user before running a validation.</p> <p>For extended profiles, rules and categories can be enabled or disabled before running a validation. It is also possible to lock extended profiles so no changes can be made by the users.</p>	eValidator5-FSP-12013
EVA-2760	<p>For the eValidator Workflow Service, the features and functions described in the chapter for eValidator webPanel also apply to the eValidator webAccess.</p> <p>webPanel and Workflow Service have been removed with release 23.1.</p>	eValidator5-FSP-12014



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-3062 EVA-4764	eValidator webAccess supports validation of US Grouped Submissions, which includes both primary and secondary applications in the group.	eValidator5-FSP-12015
EVA-3181	Validation related information (e.g., profile settings, session information) will be saved in the job storage.	eValidator5-FSP-12016
EVA-3262	When user creates a validation where the format of the submission doesn't match the respective validation profile, a warning message is displayed.	eValidator5-FSP-12017
EVA-3288	When user creates a validation, based on the path of the selected application, the name of a validation will be proposed by using the last two levels of the user selection.	eValidator5-FSP-12018
EVA-3289	The eValidator webAccess allows users to rename the validation after the creation.	eValidator5-FSP-12019
EVA-3304	The eValidator webAccess displays country and profile usage flag after a new validation was created.	eValidator5-FSP-12020
EVA-3315	The eValidator webAccess allows to open single validation and US grouped submission validation in a new browser tab.	eValidator5-FSP-12021
EVA-3231	The eValidator webAccess allows to create a copy of an existing validation, including all profile settings and save it as new validation with user's choice for sequence and name.	eValidator5-FSP-12022
EVA-3065 EVA-4516	The eValidator webAccess allows custom users settings on validation rule details, where users can define individual parameter to configure single validation checks	eValidator5-FSP-12023
EVA-3428 EVA-3594	PDF report renditions can be created on demand for a completed validation. PDF reports will not be available for aborted validations.	eValidator5-FSP-12024
EVA-3346 EVA-4751	The properties and settings for a validation session are accessible in a popup dialog. The following options can still be modified after a validation has been created: <ul style="list-style-type: none"> • Alternate location of previous sequences, • Run validation offline • Apply Baseline Optimization 	eValidator5-FSP-12025



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-3345 EVA-3861	<p>When selecting a validation from pane with the list of validations, the corresponding profile content tree will be displayed in the middle pane (second from the left).</p> <p>Starting with release 22.1, panes will not be opened or closed automatically anymore, except for the Rules pane, which will be opened when the user selects a node in the Profile Navigation Tree. For all other panes, the user decides which panes should be displayed or closed. The initial view after login will show the panes Validations, Profile Navigation Tree, and Rules.</p>	eValidator5-FSP-12026
EVA-3317	<p>For the list of validations, a filter function exists:</p> <ul style="list-style-type: none"> • Filter by name • Filter by modified date 	eValidator5-FSP-12027
EVA-3553	<p>For validation reports, the eValidator webAccess allows using the “old” style layout instead of the new style layout.</p> <p>Release 22.1: The new style (formerly used for US eCTD validation reports) is the default.</p>	eValidator5-FSP-12028
EVA-3579 EVA-3880	<p>For validations that already show results:</p> <p>If the underlying profile has been updated since the last time the validation was executed, the results will no longer match the profile. Therefore, the profile will automatically be updated in the affected validations. The previously used update notification dialog has been removed.</p>	eValidator5-FSP-12029
EVA-3747 EVA-3583 EVA-4740	<p>Users can now select multiple validations in eValidator webAccess and delete all selected ones with one delete request. Users will see a confirmation message that shows either the name of the validation (if only one has been selected) or the number of selected validations to be deleted.</p>	eValidator5-FSP-12030
EVA-3580	<p>When a validation has been created, it will be marked as selected in the list of existing validations.</p>	eValidator5-FSP-12031



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-3525 EVA-3720	<p>Software module "web sockets" in Internet Information Services (IIS) is now mandatory for using webAccess. Please refer to LORENZ eValidator administration guide for installation prerequisites.</p> <p>In case of a failure with web socket communication, the web page will display an error after 10 retries.</p>	eValidator5-FSP-12032
EVA-3551	The profile selection will only list extended profiles for licensed regions and formats.	eValidator5-FSP-12033
EVA-669 EVA-3869	The eValidator webAccess user interface can be controlled through the keyboard to support section 508 requirements.	eValidator5-FSP-12034
EVA-3871	The validations in the left pane are sorted by modified date, in descending order.	eValidator5-FSP-12035
EVA-3881 EVA-4740	It is possible to select and start multiple validations.	eValidator5-FSP-12036
EVA-4057 EVA-4239	<p>For validations using extended profiles, the user can change the severities of one or more rules before starting the validation. The administrator can make severity changes to a profile that will be applied to all users.</p> <p>It is also possible to lock extended profiles so no changes can be made by users (except administrators).</p>	eValidator5-FSP-12037
AM-8316	All validations triggered through eValidator webAccess will be executed as jobs that can be monitored in LORENZ Job Management. By default, these jobs are hidden from the job list. Users can add these jobs to the list by selecting the "webAccess Validation" in the "Job Types" filter dropdown list.	eValidator5-FSP-12038



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-4351	<p>The number of validations executed in parallel is limited (configuration setting for validation jobs). A validation that has been triggered but is in pending state will indicate this state through a spinning wheel without progress percentage. The spinning wheel will show the text "Waiting for free slot" when the user hovers the mouse over it. Once the validation started execution, a progress value will be shown, and the</p>	eValidator5-FSP-12039
EVA-4354	<p>The LORENZ Menu will show the item "Submission Validation (eValidator webAccess)" under the following conditions:</p> <ul style="list-style-type: none"> • The webAccess.txt feature flag file is available (please see LORENZ eValidator Administrator Guide for further information). • The User has been granted access to at least one validation profile. 	eValidator5-FSP-12040
EVA-4585	<p>Validations triggered from webAccess will always create a date/time folder for reports.</p> <p>The configPanel setting Create Date/Time folder for reports is ignored for validations triggered from eValidator webAccess.</p>	eValidator5-FSP-12041



4.11 REMOVED: eValidator configPanel

EVA-4264:

With release 23.1, the eValidator configPanel has been removed. The functions and features listed in this section are no longer available. Please refer to section 4.12 instead.

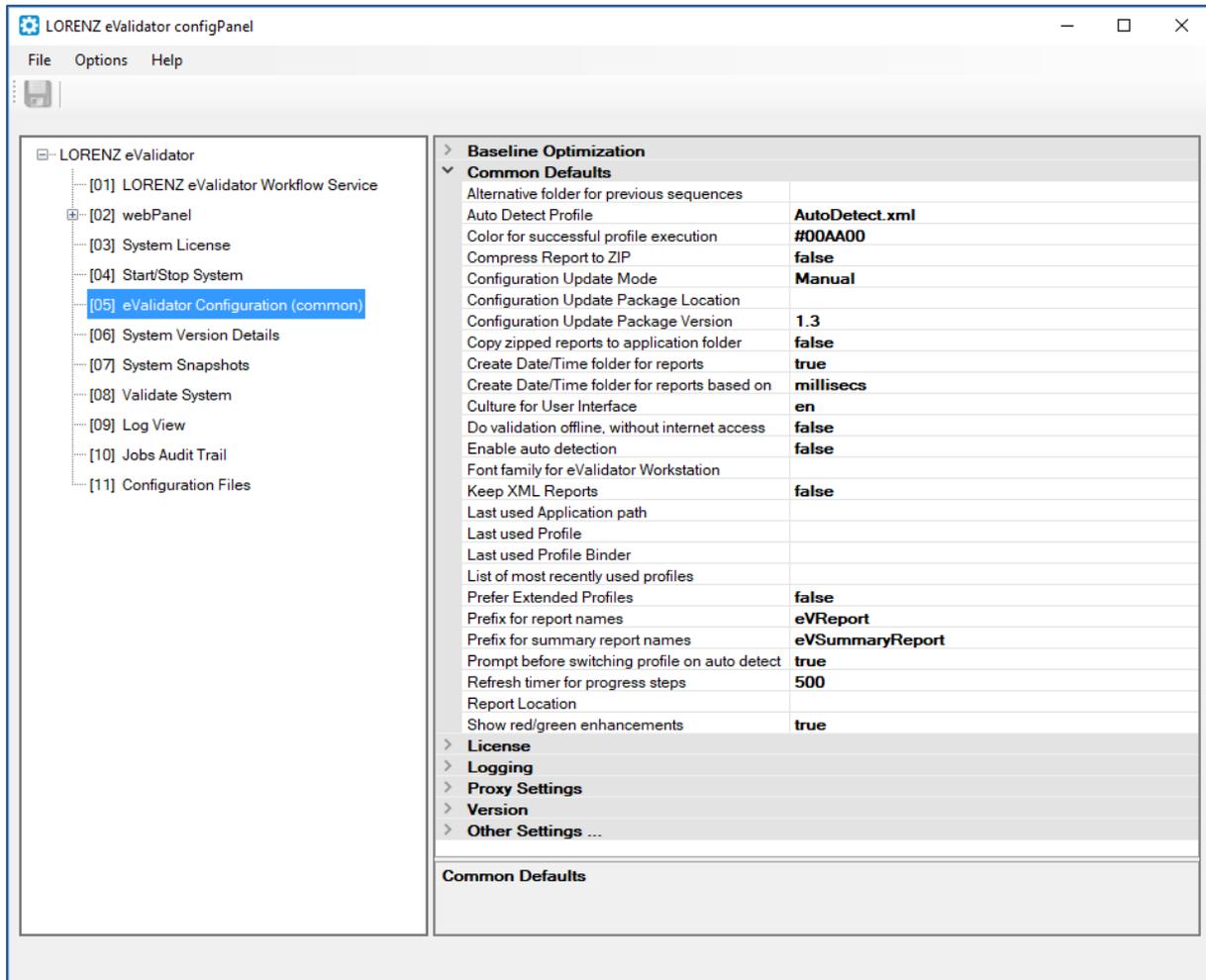


Figure 14: LORENZ eValidator configPanel

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-300	The eValidator configPanel is a utility to centralize and simplify configuration tasks for the system administrator when deploying or maintaining the LORENZ eValidator system (webPanel, Workflow Service). It will be installed when the Workflow Service feature has been selected in the setup.	eValidator5-FSP-9001
EVA-300	Through the eValidator configPanel, the administrator can	eValidator5-FSP-9002



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>configure all relevant Workflow Service settings through a categorized property grid view.</p> <p>For every setting, a description text will be displayed in a separate pane when the setting has been selected.</p> <p>Whenever the administrator changes the value for a setting, a field level validation will be performed.</p> <p>For settings with fixed value lists (e.g., Boolean), dropdown lists are being used to simplify modification.</p> <p>For settings with structured values, special editor dialogs are being used.</p>	
EVA-300	Through the eValidator configPanel, the administrator can configure all relevant webPanel settings through a categorized property grid view.	eValidator5-FSP-9003
EVA-300	Through the eValidator configPanel, the administrator can configure all relevant Automation script settings through a categorized property grid view.	eValidator5-FSP-9004
EVA-300	Through the eValidator configPanel, the administrator can manage the webPanel users and the webPanel password policy (when using the built-in webPanel authentication mode).	eValidator5-FSP-9005
EVA-300	Through the eValidator configPanel, the administrator can view and manage the system license.	eValidator5-FSP-9006
EVA-300	Through the Automator configPanel, the administrator can view and manage the system license.	eValidator5-FSP-9007
EVA-300	<p>Through the eValidator configPanel, the administrator can view the log files created by the eValidator components Workflow Service and webPanel.</p> <p>Advanced filter options can be used here to support the log data examination.</p>	eValidator5-FSP-9008
EVA-300	Through the eValidator configPanel, the administrator can configure all relevant eValidator desktop client settings through a categorized property grid view. This applies to the common configuration settings (in the ProgramData folder) but not to the user specific settings.	eValidator5-FSP-9009
EVA-300	Through the eValidator configPanel, the administrator can take snapshots of the current system configuration	eValidator5-FSP-9010



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-571	<p>(snapshot export).</p> <p>The snapshots are ZIP compressed files, which can contain the following information:</p> <ul style="list-style-type: none"> • Configuration files • Operating system information • User comments for the snapshot • The eValidator system version • Log files (also job specific log files in case of log separation) • System validation reports <p>Snapshots can also be re-imported into the system through the configPanel.</p>	
EVA-300	<p>Through the eValidator configPanel, the administrator can start and stop the Workflow Service, modify the startup type and the account credentials used to run the Workflow Service.</p>	eValidator5-FSP-9011
EVA-300 EVA-3241 EVA-3151 EVA-3680 EVA-3752 EVA-3751	<p>Through the eValidator configPanel, the administrator can validate the current system configuration. This validation is called system validation. Its results can be viewed directly in the Automator configPanel and will also be saved in HTML reports for archiving purposes. The report folder location can be modified by the administrator.</p> <p>The system validation uses a profile (and PowerShell scripts) to perform the checks. The profile includes rules for the following subjects:</p> <ul style="list-style-type: none"> • PowerShell execution policy • File/folder existence for the configured paths in webPanel and Workflow Service • Virtual directory existence in IIS for the mapped URLs in webPanel • Workflow Service account vs. usage of network paths • Plausibility of timer threshold settings for webPanel and Workflow Service • Network connectivity (TCP) for webPanel and Workflow Service • Database access (job storage) • eValidator webAccess access and configuration • Mandatory IIS components 	eValidator5-FSP-9013



Ref. Numbers	Specification Text and Comments	FSP Codes
	<ul style="list-style-type: none"> Access to Foundation configuration folder <p>When performing system validation in the configPanel, the system validation profile is executed in the REST API endpoint of the eValidator REST Service (which is hosted in the eValidator Workflow Service). This way, the same privilege for the system validation is used as configured for the eValidator Workflow Service.</p>	
EVA-300	<p>By default, the eValidator configPanel will locate the required configuration files in the standard folders as created or used by the setup. If the files need to be loaded from other locations, the administrator can specify those other locations in the eValidator configPanel. The modifications will be stored in the Windows Registry and loaded automatically when the configPanel is being started the next time.</p>	eValidator5-FSP-9014
EVA-300	<p>The eValidator configPanel allows changing the user interface language.</p>	eValidator5-FSP-9015
EVA-300	<p>The eValidator configPanel allows changing the font used in the user interface.</p>	eValidator5-FSP-9016
EVA-300	<p>The eValidator configPanel can be extended to load additional configuration files.</p>	eValidator5-FSP-9017
EVA-426	<p>The font for the user interface components can be specified through the Options menu. It is also possible to specify the font family and font size in the localization resource files (requires restarting the configPanel to apply the font change after language switching).</p>	eValidator5-FSP-9018
EVA-571	<p>The log file viewer allows selecting and viewing any log file that has the standard log file format used by the eValidator system.</p>	eValidator5-FSP-9019
EVA-582	<p>To prevent corrupting configuration files when saving them, the configPanel will check the version of the web.config file upon loading and saving. If the version does not match the expected version of the release, the save operation will be rejected.</p> <p>A possible scenario where this might happen is when the user installs an update to the eValidator Workflow Service but forgets to install the latest webPanel package before</p>	eValidator5-FSP-9020



Ref. Numbers	Specification Text and Comments	FSP Codes
	he/she starts using the configPanel.	
EVA-585 EVA-2319	The password (if any) in the connection string for the job storage database can be encrypted. Please refer to the eValidator Administrator Guide for how to configure the encryption. When using Microsoft SQL Server Compact Edition 3.5 (SSCE), the database password can be changed and encrypted directly in the configPanel. Furthermore, the configPanel allows optimizing the SSCE database file by compacting it.	eValidator5-FSP-9021



4.12 eValidator in LORENZ configPanel

With the 23.1 release, LORENZ eValidator uses the LORENZ configPanel for configuration. This applies to eValidator server installations.

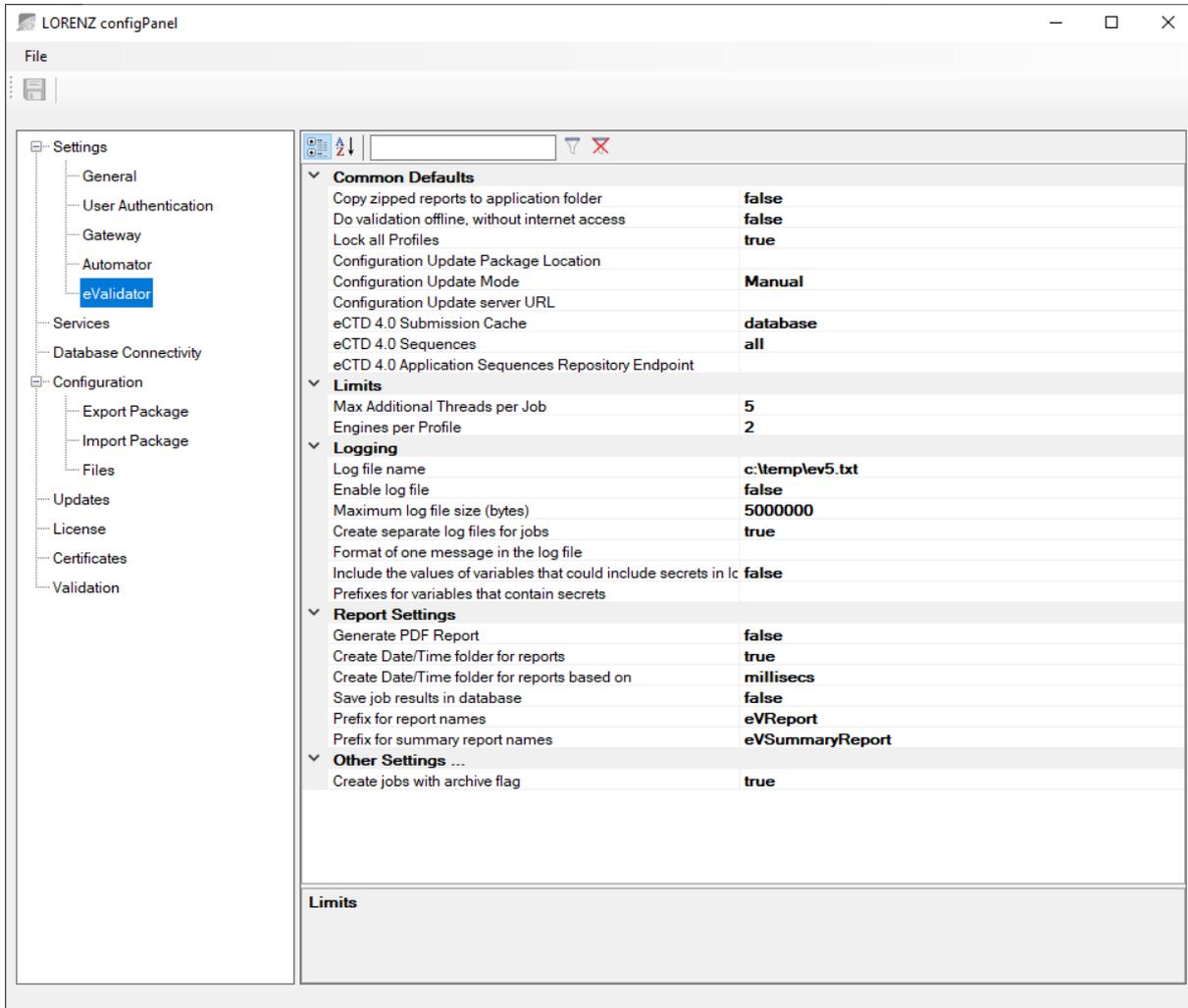


Figure 15: LORENZ configPanel

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-4308	The eValidator settings can be configured through the LORENZ configPanel: The settings are available under Settings/eValidator. For details about the available settings, please refer to the LORENZ eValidator Administrator guide.	eV-FSP-30001
EVA-4194 EVA-4405	On server installations, the LORENZ eValidator retrieves license information through LORENZ Foundation. The LORENZ RIM license contains all necessary details. A separate license file for the	eV-FSP-30002



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>LORENZ eValidator is no longer required for server installations. This also applies to the built-in validation triggered from docuBridge publishing.</p> <p>On server installations, where the RIM license does not have eValidator FIVE settings enabled, the LORENZ eValidator will allow validations triggered from docuBridge publishing only. In this case, users cannot start any validation from LORENZ Job Management or eValidator webAccess.</p>	
EVA-4375	<p>Installing and configuring the LORENZ eValidator in a multi-server environment is only required on the primary server. Deploying the necessary files to the secondary (extension) servers will happen automatically through the LORENZ Job Management Services.</p> <p>As a prerequisite, the additional servers must have been configured as extension servers in LORENZ Foundation.</p>	eV-FSP-30003
AM-8795	<p>Multiple report pools can be configured in LORENZ configPanel.</p> <p>In LORENZ Job Management, the user can select the report pool to use.</p> <p>In eValidator webAccess, always the first report pool will be used.</p>	eV-FSP-30004
EVA-4403	<p>LORENZ configPanel will check access permission to the configured storage locations for the Submission Validation Services when running a system validation.</p>	eV-FSP-30005



4.13 eValidator Batch Processing Application

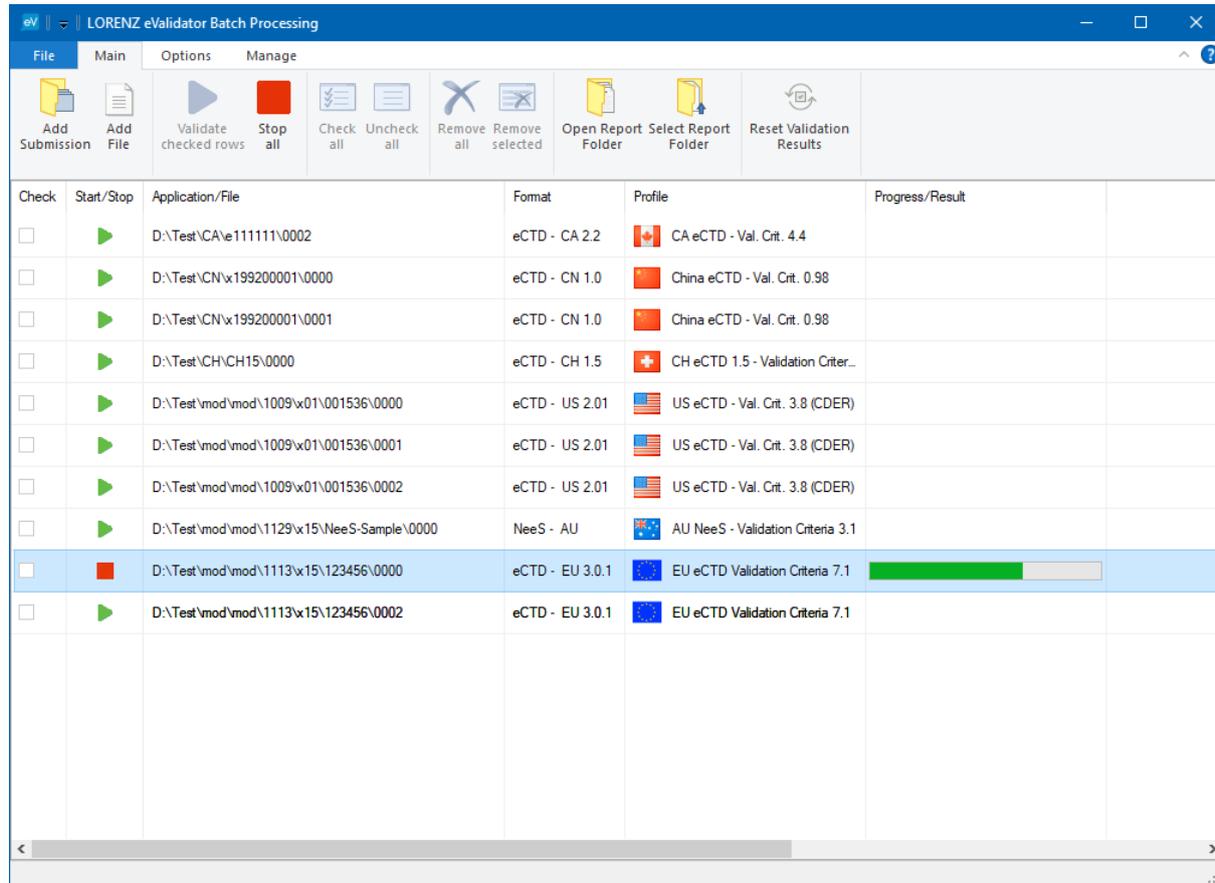


Figure 16: LORENZ eValidator Batch Processing

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-1487	The eValidator Batch Processing application is a Windows client program that allows planning and running the validation for more than one submission or sequence. Using the eValidator Batch Processing requires an eValidator FIVE license.	eValidator5-FSP-10001
EVA-1487 EVA-1687 EVA-2442	The eValidator Batch Processing application can be installed through the standard eValidator setup by selecting the Batch processing feature. The .Net 4.7.2 framework version must be installed on the computer to use the application.	eValidator5-FSP-10002
EVA-1487 EVA-1798	The eValidator Batch Processing application works with a list of files and folders (e.g., submission sequences), which can be populated through drag & drop from Windows Explorer or through the buttons in the ribbon menu.	eValidator5-FSP-10003



Ref. Numbers	Specification Text and Comments	FSP Codes
	<p>Items can be removed from the list through the buttons in the ribbon menu.</p> <p>The lists can be saved. When starting the Batch Processing application, the next time, the lists can be reloaded.</p>	
EVA-1487	<p>It is possible to individually validate a selected item from the list or to validate all marked items.</p> <p>Validation can be aborted for individual items or for all items.</p> <p>For the actual validation execution, the Batch Processing application uses the eValidatorConsole programs.</p>	eValidator5-FSP-10004
EVA-1487 EVA-2029	<p>When adding items to the list, the program will automatically detect the format and assign the corresponding profile. The profile can be changed by clicking in the profile cell.</p> <p>To refresh the automatic profile assignment, press CTRL+R or F5.</p>	eValidator5-FSP-10005
EVA-1487	<p>For completed validations, the report can be opened by clicking in the Progress/Result cell. Summary information about the number of findings per severity level is shown directly in the list.</p>	eValidator5-FSP-10006
EVA-1487	<p>In the Options menu, the following functions are available:</p> <ul style="list-style-type: none"> • Select the validation report output folder • Enable/disable report compressing • Enable/disable compressed report copying to the submission folder • Set the maximum number of parallel validations • Enable/disable baseline optimization mode • Set the root folder for previous sequences • Enable/disable timestamp subfolder for reports • Enable/disable validation in offline mode • Enable/disable XML reports • Use "old" style reports • Web proxy configuration 	eValidator5-FSP-10007
EVA-1487	<p>In the Manage menu, the following functions are available:</p> <ul style="list-style-type: none"> • License management • Open user guide • Check for program updates • Change user interface language 	eValidator5-FSP-10008



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-1559 EVA-1725 EVA-1998	<p>For error analysis, the eValidator Batch Processing can be configured to write log files (using the Log4Net logging framework). When the application has been started already, logging can be turned on through CTRL+F7 and turned off through CTRL+F8. Both keyboard shortcuts will change the logging status temporarily only, the changes will not be written to the configuration file.</p> <p>If necessary, a log level "Trace" exists that can be used to write all details, including every single Action step into the log files.</p>	eValidator5-FSP-10009
EVA-2667	<p>Through the Main menu, the user can specify the report folder location.</p> <p>The user can open the currently configured report folder in Windows Explorer (this will either be the report root folder or the individual report folder for a submission if a submission has been selected in the list).</p>	eValidator5-FSP-10010



4.14 eValidatorConsole OEM features

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-2147	<p>In the eValidatorConsole application, additional command line switches are now available for multi-client scenarios:</p> <pre data-bbox="523 488 1038 555" style="border: 1px solid black; padding: 5px;">/clients_file</pre> <p>Through this command line parameter, the name and location of a client definition file can be specified. An example is available in the folder Repositories\OEM. Please refer to the user guide for further information.</p> <pre data-bbox="523 748 1038 815" style="border: 1px solid black; padding: 5px;">/client_id</pre> <p>The ID of a client from the clients definition file. The name of the client will then be shown in the validation report (instead of the name of the license holder). Furthermore, the validation report will be placed in the folder that has been specified for this client in the client definition file.</p>	eValidator5-FSP-11001
EVA-2200	<p>In the eValidatorConsole application, additional command line switches are now supported:</p> <pre data-bbox="523 1149 1038 1216" style="border: 1px solid black; padding: 5px;">/extended_results</pre> <p>When this is specified in the command line, the eValidatorConsole will provide additional result summary information in the standard output (the console window) when the validation has finished. This information contains a list of all findings and severities, by rule number. Third-party applications can use this information to evaluate the validation results without opening the report files.</p> <pre data-bbox="523 1507 1038 1574" style="border: 1px solid black; padding: 5px;">/p_copy_profile_to_report</pre> <p>By setting this to false (default is true), no profile copy will be created in the report folder when the validation has finished</p>	eValidator5-FSP-11002



4.15 eValidator REST Service

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-2950 EVA-3258	<p>The eValidator REST Service is a generic RESTful service that can be configured with custom endpoints and APIs. It uses MultiWorkerConsole processes to execute eValidator profiles, which have been assigned to the endpoints.</p> <p>A profile that will be used by the eValidator REST Service is called a "REST Endpoint Profile". For such profiles certain default input and output runtime variables exist for the communication with the REST Service.</p> <p>The eValidator REST Service is hosted in the Job Management Services.</p> <p>User authentication for accessing the REST service uses LORENZ Foundation.</p> <p>User authorization can be configured through Role and Group membership in LORENZ Foundation.</p> <p>The endpoint definition in the meta.xml allows setting values for runtime or profile variables that will be passed to the Workflow Engine before the configured profile will be started.</p> <p>REST API documentation can be obtained using swagger.</p>	eValidator5-FSP-13001
EVA-2975	<p>An attribute <code>UseReportFolder</code> can be added to the <code>Folder</code> element of the REST Service meta.xml. When set "true" for a given endpoint, this endpoint will use the report folder of the REST Service configuration. A runtime variable <code>r_rest_report_folder</code> exists that contains this value as specified in the configuration.</p>	eValidator5-FSP-13002
EVA-2859	<p>The eValidator REST Service implements an endpoint for downloading files.</p>	eValidator5-FSP-13003
EVA-2921	<p>The eValidator REST Service implements an endpoint that allows retrieving documentation (from the LORENZ Help Center web page).</p>	eValidator5-FSP-13004
EVA-3157 EVA-3158 EVA-3159 EVA-3160 EVA-3162 EVA-3163	<p>The eValidator REST Service implement endpoints that allow management of configuration settings.</p>	eValidator5-FSP-13005



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-3164 EVA-3307 EVA-3161		
EVA-2844	The eValidator REST Service implements an endpoint that can install Regulatory Update Packages.	eValidator5-FSP-13006
EVA-3238	The eValidator REST Service implements an endpoint that supports preloading profiles to optimize performance. This endpoint is not available in the public REST API.	eValidator5-FSP-13007
EVA-3204	The eValidator REST Service implements an endpoint that can be used to compile application sequence data (locations) for US eCTD grouped submissions from one or more root folders.	eValidator5-FSP-13008



4.16 eCTD 4.0 Validation

Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-4108 EVA-3875 EVA-4091	<p>US FDA eCTD 4.0 submissions can be validated.</p> <p>The Forward Compatibility requirements are supported.</p> <p>TMM is not supported because it has been withdrawn by ICH and US FDA.</p>	eValidator5-FSP-14001
EVA-3577	JP PMDA eCTD 4.0 submissions can be validated.	eValidator5-FSP-14002
EVA-4014 EVA-4050	<p>Validations can be executed in “local” mode or “database” mode. The “local” mode does not support cross-application scenarios for document or application references.</p> <p>The “database” mode uses a submission cache database to store information about previously validated submissions. This mode requires LORENZ Foundation, and an eValidator FIVE license.</p> <p>Configuration options exist to control how to retrieve information about the previous sequences for the current submission unit (e.g., from the folder structure, from a sequence listing file, from a custom REST endpoint, or from docuBridge).</p> <p>The cache database can be reset per application (configuration option) or entirely (dbaPanel).</p>	eValidator5-FSP-14003
EVA-4024	The scope for checking the uniqueness of the submission unit ID can be either “application” or “global”. This is a configurable option in the profile.	eValidator5-FSP-14004
EVA-4072	<p>With applications from more than one eCTD 4.0 region in the repository database, the scope of the global uniqueness checks (document IDs, submissionUnit IDs) will be limited to the receiving agency of the current submission.</p> <p>Examples: A document with ID X can be used in both a US eCTD 4.0 application and in a JP eCTD 4.0 application. This must not trigger an error about duplicates!</p> <p>Affected:</p> <ul style="list-style-type: none"> • Document Id root • submissionUnit Id root • submission Id root 	eValidator5-FSP-14005



Ref. Numbers	Specification Text and Comments	FSP Codes
EVA-3867	The submission cache database stores the sha256 value with each submission unit. When validating sequence n, the stored sha256 values of the submission units will be compared with the sha256.txt files from the folder structure (for all previous sequences 1 to n-1). Before starting the validation of sequence n, the cached database content will be rebuilt for all previous application sequences where the sha256 values do not match (new sequences will be added, deleted sequences will be removed from the database)	eValidator5-FSP-14006

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