







 Registration Management

 Submission Management

 Labeling Management

 Pharmacovigilance Management

 Document Management

 Project Management

User Guide



EURSvalidator™

Version 2.0

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1 Welcome to 'EURSvalidator'

EXTEDO's 'EURSvalidator' supports you in validating medicinal and veterinary eSubmissions, according to a variety of official eCTD regulations including EU Validation Criteria.

'EURSvalidator' is free of charge and can be downloaded from the **EXTEDO** homepage. Please refer to www.extedo.com, section **Support & Downloads**.

'EURSvalidator' is integrated into the **EURS is Yours** solution, which is used by the majority of European National Authorities including EMA to ensure eCTD and NeeS compliance. It utilizes the same validation component as **EURS is Yours**.

Using 'EURSvalidator' in advance of submitting electronic submissions minimizes the risk of failing technical validation at the regulatory authorities.

With just a few clicks you can start the validation. 'EURSvalidator' detects the applicable validation sets automatically. It supports the following standards: Europe (eCTD and NeeS), US / FDA (eCTD and NeeS), Croatia (eCTD and NeeS), Switzerland (eCTD) and Veterinary (i-eNTA and p-eNTA).

Related Information:



[The EURS \(European Review System for eCTDs\)](#) (link to external resources)

1.1 About this User Guide

This user guide contains a description of the graphical user interface (GUI) of 'EURSvalidator', with best practices and examples for an assessor's work and an agency's workflow. For a more detailed GUI reference refer to the online help of 'EURSvalidator'.

1.1.1 Notational conventions

The following notational conventions are used:




Commands	References to commands and dialog boxes are marked bold in addition.
Bold text	All user interface items (field names, options, etc.) appear in bold text.
Dialog box	A dialog box enables the user to add, edit or delete parameters.
Window	A window displays functional elements of the 'EURSvalidator' application.
Tab	A tab is mostly sub-section of a window or a dialog box.
	Additional information
	Precedes text to which particular attention should be paid.

1.1.2 Standards of the Graphical User Interface of 'EURSvalidator'

Title Bar and Standard Elements

The title bar contains the name and version of 'EURSvalidator'. It can be dragged to move the window. Dialog boxes can also be moved by dragging their title bar.

As well the title bar contains the following standard elements:

	Minimizes a current window or dialog box to an icon
	Maximizes a current window to full screen
	Closes the current window or dialog box. In case of a program's window it terminates the program.

1.1 About this User Guide

Software Language

'EURSvalidator' specific user interface elements and messages are written in English. Information provided by the underlying Windows operating system may appear in the language configured for your local system.

Third Party Features

Integrated third party features may be displayed in the country specific language of the Windows operating system.

Dialog Boxes

Dialog boxes may be affected by multiple operating system languages, showing individual button labels in a non-English language.

Menu Bar / Tool Bars / Context Menus

Executing a 'EURSvalidator' command is mostly possible in multiple ways: By using the **menu bar command**, the **tool bar icon**, a shortcut key, or (if available) the right click **context menu** of the related item. As a default the user guide describes the menu bar commands. Feel free, optimising assessor's tasks by trying the alternatives!

1.2 About EXTEDO

EXTEDO is a key services and solutions provider in the field of regulatory data and document management (CTD, eCTD and other formats) for Life Sciences industries and authorities (Pharmaceutical, Crop Science, Chemicals). **EXTEDO** provides highly standardized, as well as customized solutions, in the area of electronic *Regulatory Affairs*.

EXTEDO is recognized as a leader in each of its engaged business activities. **EXTEDO's** unique market position provides a tremendous amount of influence on new developments in the *e-Regulatory Affairs* sector. The company has designed and implemented the EURS system at EMA and other *National Competent Authorities* (NCA). **EXTEDO** also maintains the open standard CADDY.xml for the electronic submission of Crop Sciences applications to support the mission of the ECPA. **EXTEDO**, being globally represented, serves more than 700 Life Sciences organizations in 57 countries.

Munich 07/29/2011

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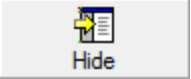
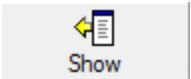
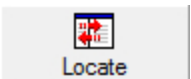

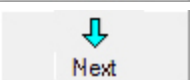
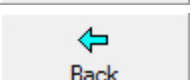
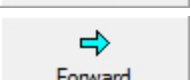

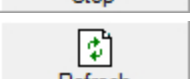

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3 User Interface







3.1 Online Help


3.1.1 Online Help User Interface

The online help uses a standard HTML Help user interface style. It provides the following information panels and commands.

	Title	Description
1	Contents	ToC of the online help, different levels available: <ul style="list-style-type: none"> • Index: Topic selection from pre-defined list in alphabetical order • Search: Any user defined search item • Favorites: User defined important topics
2	Search item	Search item to be entered, result displayed in index list
2	Index list	Index entries in alphabetical order
2 / 3	Search result list	Related topics of search pattern
2 / 3	Keyword	Search pattern to be entered
5	Display area	Displays current topic content
6	Tool bar	Different shortcuts for: <ul style="list-style-type: none">  Hide: Hides the ToC  Show: Displays the ToC  Locate: Opens the search dialog box  Previous: Moves to the next topic in the ToC  Next: Moves to the previous topic in the ToC  Back: Moves one step back in current actions  Forward: Moves one step forward in current actions  Stop: No action  Refresh: Refreshes the content display  Home: Welcome page of the online help

3.2 Application Window Sections

Title	Description
 Font	Font: no action
 Print	Print: Opens the Print dialog box
 About this Help	About this Help: General user information
 Display	Displays content of search result in display area
 Remove	Removes favorite from list
 Add	Adds a favorite to list

 The button labels' language depends on the currently used operating system language.

3.2 Application Window Sections

3.2.1 The Graphical User Interface

After the program starts the main window of 'EURSvalidator' is displayed. It is divided into different sections:

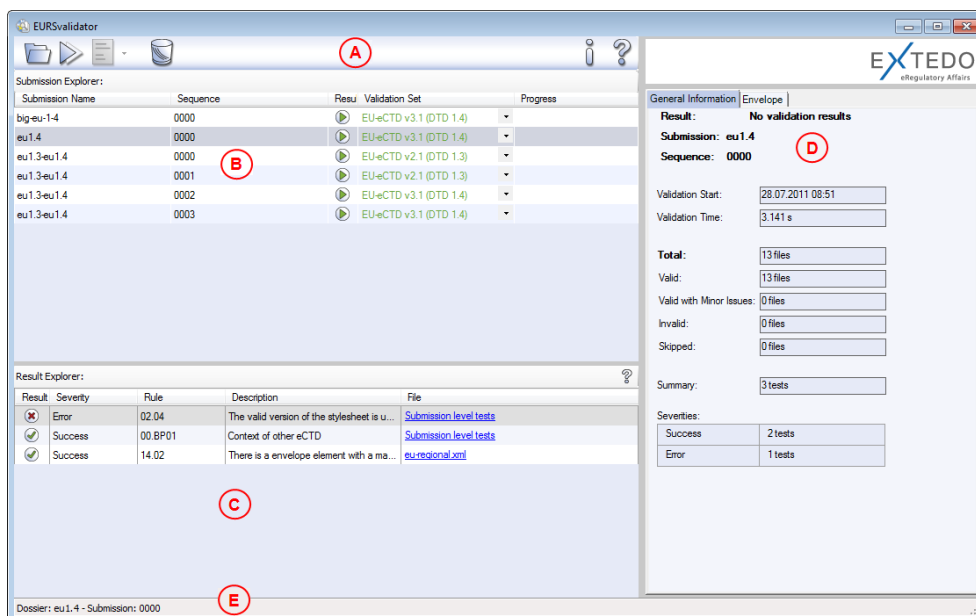


Fig. 1: Graphical User Interface of 'EURSvalidator'

A Tool Bar (see page 11)	Tools for main program commands
B Submission Explorer (see page 12)	Displays the currently loaded submissions, the related validation set, and the validation status
C Result Explorer (see page 14)	Displays the error warning messages that occurred during validation
D Information Explorer (see page 15)	Displays general information, validation details, and additional information
E Status Bar	Displays the selected submission and program status

3.2.2 Tool Bar

The **Tool Bar** is part of the main window and affords to control the submission handling.

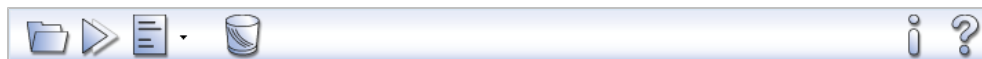















Fig. 2: Tool Bar

The following functions are available:

	Adds one or multiple submissions to the Submission Explorer from the file system. To learn more about additional ways of loading a submission: See 'Adding a Submission' on page 20.
	Starts a mass validation of all unvalidated submissions listed in the Submission Explorer
	<p>Cancels all running validation processes.</p> <p> Only visible while a mass validation is running. See 'Validating Submissions' on page 23.</p>
	<p>Creates a report for the validated submission that is currently selected in the Submission Explorer .</p> <p> The report type that was created last is kept as preset.</p>
	<p>Opens the Create Report toolbar drop-down which offers the following commands:</p> <ul style="list-style-type: none"> •  Report Short (standard) •  Report Long •  Email Reports: Creates both the short and long report and attaches them to an email. • <input checked="" type="checkbox"/> Store Reports in Dossier folder: Toggles whether reports created shall be stored in the dossier's folder or not. If they are not stored in the dossier folder, reports are stored in the 'EURS-validator' subfolder of the users documents folder. Example: (Windows 7, user is 'smith') C:\Users\smith\Documents\EURSvalidator. <p>See 'Generating a Report' on page 29.</p>
	Removes the selected submissions from the Submission Explorer
	Launches the ' EURSvalidator ' online help
	Opens the About Dialog Box

3.2 Application Window Sections

3.2.3 Submission Explorer

The **Submission Explorer** displays the submissions loaded within 'EURSvalidator', their validation status, and their current validation progress.

Submission Explorer:				
Submission Name	Sequence	Result	Validation Set	Progress
eu1.3-eu1.4	0000		EU-eCTD v2.1 (DTD 1.3)	Validation finished.
eu1.3-eu1.4	0001		EU-eCTD v2.1 (DTD 1.3)	Validation finished.
eu1.3-eu1.4	0002		EU-eCTD v3.1 (DTD 1.4)	
eu1.3-eu1.4	0003		EU-eCTD v3.1 (DTD 1.4)	
eu1.4	0000		EU-eCTD v3.1 (DTD 1.4)	Validation finished.
eu1.4	0001		EU-eCTD v3.1 (DTD 1.4)	Validation finished.
big-eu-1-4	0000		EU-eCTD v3.1 (DTD 1.4)	Running (67%)

Fig. 3: Submission Explorer

Submission Name	Name of the loaded submission, taken from the concerning submission folder	
Sequence	Sequence number of the loaded submission, taken from the concerning submission folder	
Result	Result of the validation process	
		Submission has not been validated yet. Click the icon to start validation.
		Validation is running. Click the icon to stop validation.
		Submission has been validated successfully
		Submission has been validated with errors
Validation Set	drop-down list with currently installed validation sets	
	(Validation set found by autodetection)	Currently used validation set
	CH-eCTD 1.0 (DTD 1.0 / 1.0.1)	Swissmedic (CH) eCTD Validation Criteria
	CH-eCTD 1.1 (DTD 1.1)	Swissmedic (CH) eCTD Validation Criteria
	EU-eCTD 2.0 (DTD 1.2.1)	European (EU) eCTD Validation Criteria
	EU-eCTD 2.1 (DTD 1.3)	European (EU) eCTD Validation Criteria
	EU-eCTD 3.1 (DTD 1.4) - Context of other eCTDs	European (EU) eCTD Validation Criteria
	HR-eCTD 2.1 (DTD 1.4)	Croatia (HR) eCTD Validation Criteria
	FDA-eCTD v1.0 (DTD 2.01)	FDA (US) eCTD Validation Criteria
	VMD-eNTA (immunological product) DTD 0.9	Veterinary Medicines Directorate (UK)
	VMD-eNTA (pharmaceutical product) DTD 0.9	Veterinary Medicines Directorate (UK)
	HR-NeeS v1.0	Croatia (HR) NeeS Validation Criteria
	EU-NeeS v1.0	European (EU) NeeS Validation Criteria
Progress	Validation progress of the loaded submission	
	(empty)	Submission has not been validated yet
	Running	Submission validation is proceeding; a progress bar displays the advancement of the process.
	Validation finished	Submission has been validated

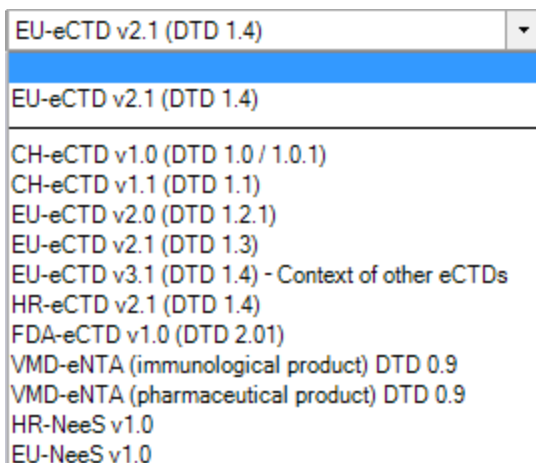


Fig. 4: Validation Sets

Submission Explorer Context Menu

The **Submission Explorer** also provides a **context menu** with the mostly used commands. Right click in the grid to open the context menu.

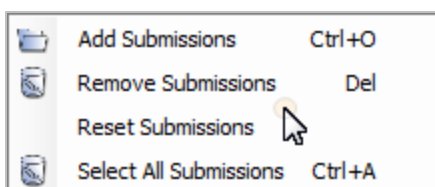


Fig. 5: Submission Explorer Context Menu

Add Submissions	Opens the Browse for Folder dialog box to add a submission.	Ctrl + O
Remove Submissions	Removes the currently selected submission(s) from the Submission Explorer .	Del
Reset Submissions	Resets already validated submission to unvalidated state.	
Select all Submissions	Selects all submissions in the grid.	Ctrl + A

3.2 Application Window Sections

3.2.4 Result Explorer

The **Result Explorer** displays the test results of each rule of the validation process.

Result Explorer: ?				
Result	Severity	Rule	Description	File
	Error	02.04	The valid version of the stylesheet is u...	Submission level tests
	Success	00.BP01	Context of other eCTD	Submission level tests
	Success	14.02	There is a envelope element with a ma...	eu-regional.xml

Fig. 6: Result Explorer

Result		Indicates a successful validation. Displayed for specific validation rules that are required for ' EURS-validator ' internal processes only, e.g. creating PDF reports.
		Indicates a warning or error
		Indicates a validation abort ('skipped')
Severity		'Success'. Displayed for specific validation rules that are required for ' EURSvalidator ' internal processes only, e.g. creating PDF reports.
		'Warning'
		'Error'
Rule		Number of the validation rule
Description		Category name and short description of the validation criterion
File		Links to the problem source (file or submission directory)
?		Opens the online help and displays information about the validation rule currently selected.

3.2.5 Information Explorer

Depending on selecting an item in the **Submission Explorer** or in the **Result Explorer** the **Information Explorer** displays the *submission details* of the currently selected submission or the *result summary* for the selected validation rule.

The screenshot shows two panels of the Information Explorer. The left panel is the 'General Information' tab, and the right panel is the 'Envelope' tab.

General Information tab:

- Result:** No validation results
- Submission:** big-eu-1-4
- Sequence:** 0000
- Validation Start: 28.07.2011 12:40
- Validation Time: 1 min 39.334 s
- Total:** 26 files
- Valid: 23 files
- Valid with Minor Issues: 1 files
- Invalid: 2 files
- Skipped: 0 files
- Summary: 21 tests
- Severities:

Success	2 tests
Error	6 tests
Skipped	11 tests
Warning	2 tests

Envelope tab:

- Country: EMEA

Name	Value
DTD Version	1.4
Application number(s)	EMEA/H/C/3969
Applicant	ETICS 3 EMEA
Agency	EU-EMEA
Submission type	Initial Marketing Authorisation Application
Procedure	Centralised Procedure
Invented name	Efpiate
INN	Eurotriptan Maleate
Sequence number	0000
Description	Initial ETICS 3 test submission for EMEA

Fig. 7: Information Explorer - submission details, displayed on the **General Information** tab page and **Envelope** tab page.

Submission Details of the submission currently selected in the **Submission Explorer**

General Information tab page

Result	Valid	Validation was successful
	Invalid	Validation has raised a warning or an error
Submission		Displays the detected submission name
Sequence		Displays the sequence number
Validation Start		Start date and time of the validation process
Validation Time		Displays the time the validation process needed
Total		Totally validated files. Referenced sequences are also considered.
Valid		Number of files which are valid
Valid with minor issues		Number of files, in which a warning occurs
Invalid		Number of files, in which an error occurs
Skipped		Number of files which have been skipped
Summary		Number of test results collected in the Result Explorer .

3.2 Application Window Sections

Severities	Success	Number of successful tests
	Error	Number of tests, which have detected an error
	Skipped	Number of tests, which have been aborted
	Warning	Number of tests, which have detected a warning

Envelope tab page

On this tab page the information of the submission's envelope is displayed.

Country	If there is information for multiple countries, you can select the desired country from the drop-down list.
Envelope data	These fields list the information of the submission's envelope, depending on the country or region selected.

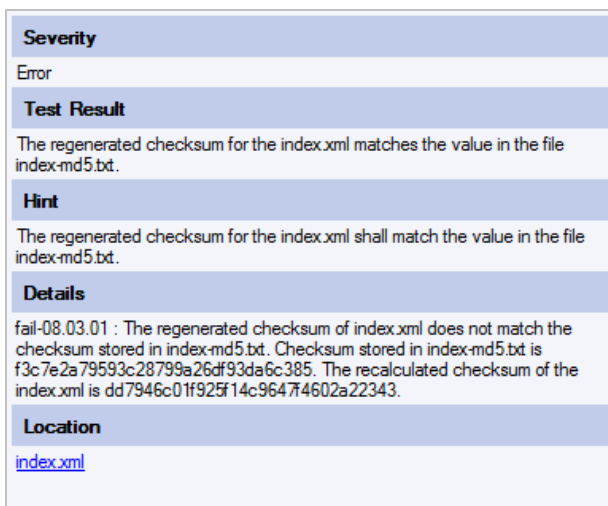


Fig. 8: Information Explorer - Result Summary of the currently selected validation rule.

Result Summary of the validation rule currently selected in the Result Explorer

Severity	Success	Rule has proceeded successfully
	Error	Rule has detected an error
	Warning	Rule has detected a warning
Test result		Description of the problem (Problem Message)
Hint		Locates the problem on file level (Hint Message)
Details		More detailed problem description / method of resolution
Location		Link to the respective problem file

3.3 Dialog Boxes

3.3.1 About Dialog Box

The **About** dialog box represents the program splash with version and release date.



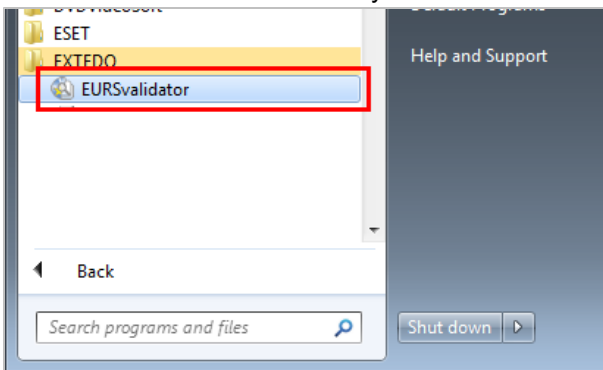
Fig. 9: About Dialog Box

4 Procedures

4.1 Starting 'EURSvalidator'

Proceed as follows:

Select the '**EURSvalidator**' entry in the Windows start menu.



Or: Double click the '**EURSvalidator**' icon on the desktop.

⇒ '**EURSvalidator**' starts.



Fig. 10: '**EURSvalidator**' is starting; the splash screen is displayed.

After a few moments, the main window opens.



If submissions had been added during an earlier '**EURSvalidator**' session , these submissions are reloaded automatically and displayed in the **Submission Explorer**.

4.2 Adding a Submission

4.2 Adding a Submission


Before a submission can be validated, it must be added to the **Submission Explorer**. provides you with the flexibility to add:


- a single submission
- a dossier with all submissions contained
- multiple dossiers with all submissions contained

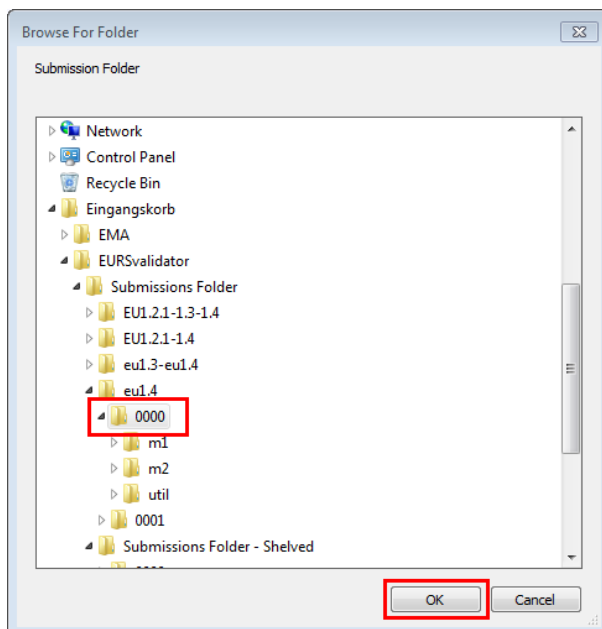
There are multiple ways to add submissions and dossiers.

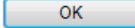
4.2.1 'Add' Command

You can load submissions using the **Add** command of the **Submission Explorer**. Proceed as follows:

1.  Click the **Add** button in the main toolbar.
Or: Right click into the **Submission Explorer** grid. Then select **Add Submissions** from the context menu.
⇒ The **Browse For Folder** dialog box opens.
2. Browse the folders of your file system and select the folder which contains the submission that you want to add.

 Depending on the folder selected, either a **single submission** or the whole **dossier** will be loaded. If the selected folder contains subordinated folders with more than one submission, all of these submissions will be loaded.



3.  Click to close the dialog box.
⇒ The folder is searched for valid dossiers and submission files.

If any submissions are found, they are added to the **Submission Explorer**.


Submission Name	Sequence	Result	Validation Set	Progress
eu1.4	0000		EU-eCTD v3.1 (DTD 1.4)	

Fig. 11: **Submission Explorer**. One submission was added and an applicable validation set detected.

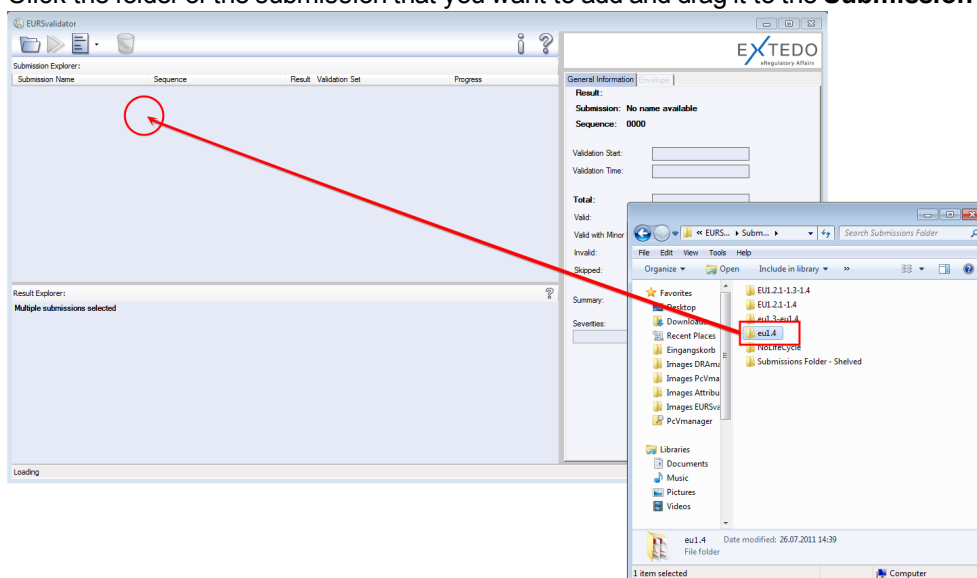
Usually the correct **validation set** for a newly added submission is detected and selected automatically. It is displayed in **green font color**. However, if no validation set could be detected (maybe in case of a NeeS submission) you might have to select it from the validation set drop-down list in the **Submission Explorer** grid manually.

See 'Selecting a Validation Set' on page 22.

4.2.2 Drag and Drop

A very convenient way to add submissions is using drag and drop.

1. Open a Windows explorer window.
2. Browse the folders of your file system and open the folder which contains the submission(s) that you want to add.
3. Click the folder of the submission that you want to add and drag it to the **Submission Explorer**.



⇒ The folder is searched for valid submission files.

If any submissions are found, they are added to the **Submission Explorer**.

4.3 Removing a Submission From 'EURSvalidator'

To remove one or multiple submissions from the **Submission Explorer**, proceed as follows:

1. Select one or multiple submissions in the explorer grid.



2. Click the **Remove** button in the main toolbar.
Or: Right click into the **Submission Explorer** grid. Then select **Remove Submissions** from the context menu.
Or: Just press the **Del** key.

The selected submission(s) are removed from the **Submission Explorer** instantly.



Submissions removed from the **Submission Explorer** are still stored on your local file system and can be added again any time.

4.4 Selecting a Validation Set

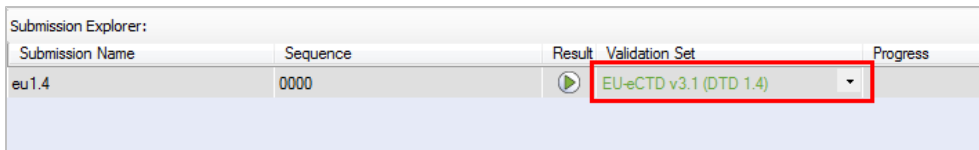
4.4 Selecting a Validation Set

4.4.1 Autodetection of a Validation Set/DTD

Usually the applicable validation set for a newly added submission is detected automatically. It is displayed in the **Validation Set** column of the **Submission Explorer**. This is also the case if multiple validation sets may be applicable for a submission. You have the option to choose between them.

To provide a maximum of transparency the entry in the **Validation Set** column will be colored as follows:

- **Green:** One or more applicable validation sets were found. 'EURSvalidator' chooses the current validation standard automatically. Validation can be started. You still may select one of the detected validation set manually from the Validation Set drop-down list.
- **Red:** No applicable eCTD validation set was found. NeeS validation is assumed. You may select a different validation set manually.



Submission Name	Sequence	Result	Validation Set	Progress
eu1.4	0000		EU-eCTD v3.1 (DTD 1.4)	

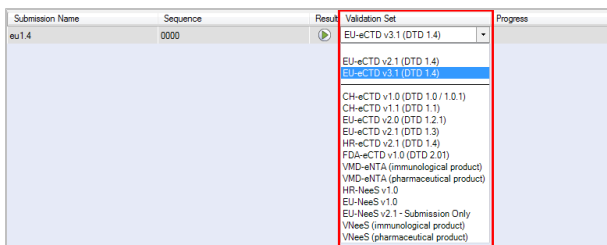
Fig. 12: Submission Explorer. Applicable validation set detected.

4.4.2 Manual Selection of a Validation Set

You can select a validation set from the **Validation Set** drop-down list in the **Submission Explorer** grid manually. This might be necessary if no validation set could be detected and selected automatically.



After a validation set has been selected manually, an autodetection cannot be started any more. Nevertheless if validation sets had been autodetected previously, they remain at top position in the drop-down list.



Submission Name	Sequence	Result	Validation Set	Progress
eu1.4	0000		EU-eCTD v3.1 (DTD 1.4)	

- EU-eCTD v2.1 (DTD 1.4)
- EU-eCTD v3.1 (DTD 1.4)
- CH-eCTD v1.0 (DTD 1.0 / 1.0.1)
- CH-eCTD v1.1 (DTD 1.1)
- EU-eCTD v2.0 (DTD 1.2.1)
- EU-eCTD v2.1 (DTD 1.3)
- HR-eCTD v2.1 (DTD 1.4)
- FDA-eCTD v1.0 (DTD 2.01)
- VMD-eNTA (immunological product)
- VMD-eNTA (pharmaceutical product)
- HR-NeeS v1.0
- EU-NeeS v1.0
- EU-NeeS v2.1-Submission Only
- VNeeS (immunological product)
- VNeeS (pharmaceutical product)

Fig. 13: Selecting a validation set manually

4.4.3 Changing the Validation Set after Validation

After validation was performed, a different validation set may be selected. Proceed as described in section **Manual Selection of a Validation Set (see page 22)**.

↪ The concerning submission's validation result will be reset. You must **restart** the validation.

4.5 Validating Submissions

4.5.1 Preparing a Validation

To validate a submission it must be added to the **Submission Explorer** first. See 'Adding a Submission' on page 20.

4.5.2 Starting Mass Validation

You can start the validation for **all pending submissions** in the **Submission Explorer** simultaneously.




Click the **Start Validation** button in the main **Tool Bar** to start the validation process.

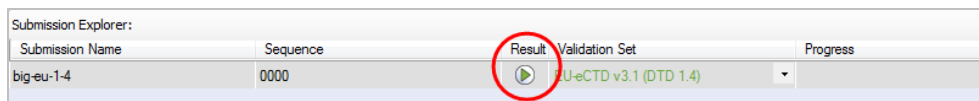
⇒ All pending submissions that have not been validated yet will be validated simultaneously.

4.5.3 Starting Single Validation

You can also start the validation for a **single submission**.

 Click the **Start Single Validation** button in the **Result** column of the concerning submission.

⇒ The selected submission will be validated.




Submission Name	Sequence	Result	Validation Set	Progress
big-eu-1-4	0000		U-eCTD v3.1 (DTD 1.4)	


Fig. 14: Starting validation for a single submission.

4.5.4 Validation in Progress

For each submission in validation, the validation progress is displayed in the **Submission Explorer** grid.

While the validation is running, the **status bar** on the bottom of the window displays an overall progress bar and the message **Validating**.



You can **cancel** the validation process at any time. Just click the **stop validation** button  in the toolbar. Cancelling might take several seconds.

4.5 Validating Submissions

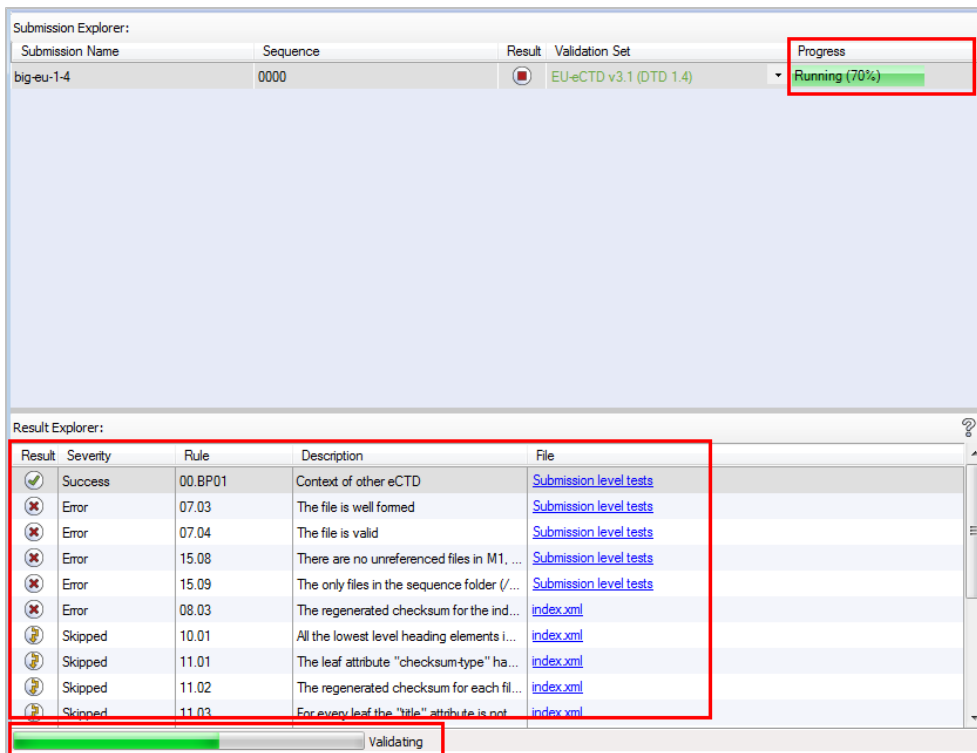


Fig. 15: Submission validation in progress

To see the results of a validation in the **Result Explorer** and the **Information Explorer**, you must select one of the validated submissions in the **Submission Explorer** grid.

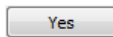
4.5.5 Abort/Cancel Validation

It may be the case that you want to abort a running validation, e.g. because some failures have been detected already that you want to resolve right now.



Click the **Stop All Validations** button in the main toolbar to abort/cancel all running validation processes. The button is only displayed if there are validations in progress.


⇒ You are prompted to confirm this action.



Click to confirm.

⇒ All running validation processes are stopped. Cancelling might take several seconds. The **Submission Explorer** displays a message that the concerning validations have been stopped on user request in the **Progress** column.



To abort/cancel just one single validation process, click the **Stop Validation** button  in the submission's grid entry in the **Submission Explorer**. Cancelling might take several seconds.

4.5.6 Reset Submission for Re-validation

Once a validation has been finished, you cannot restart the validation process for the concerning submission(s) for a second time. To do so, you must reset the concerning submission(s) for re-validation first. By resetting a validated submission, all validation results are cleared.

Proceed as follows:

1. Select the validated submission(s) that you want to reset.
Standard selection features for selecting multiple submission are supported, like **Shift + click**, **Ctrl + click**,

and keyboard operations.

2. Right click into the **Submission Explorer** grid.
 - ⇒ The context menu opens.
3. Select **Reset Submissions** from the context menu.
 - ⇒ The selected submission(s) are reset. All validation results are cleared.

Now you can start a new validation for these submissions.

4.6 Analysing Validation Results

4.6 Analysing Validation Results

To view a submission's validation results, select the concerning submission in the **Submission Explorer**.

⇒ The validation results are displayed in the **Result Explorer** grid, rule by rule.

Validation details are displayed in the **Information Explorer**.

- **No error detected** (✔): Successful validation is not displayed in the **Result Explorer**. However, for some specific rules the successful validation is marked with the icon (✔) for information purpose only. These rules are required for 'EURSvalidator' internal processes only, e.g. creating PDF reports.
 - **Error detected** (✘): If an error for a validation rule was detected, a reason for the failure is displayed in the **Result Explorer** grid. The concerning rule is marked with the icon (✘).
 - **Warning detected** (⚠): If a warning for a validation rule was detected, a reason for the warning is displayed in the **Result Explorer** grid. The concerning rule is marked with the icon (⚠).
 - **Validation skipped** (🛑): A submission may be invalid due to functional reasons; the concerning rule is marked as **skipped** then. A rule may also be marked as skipped due to professional reasons; nevertheless the validation is continued. In both cases the concerning rules are marked with the icon (🛑).
- Example:** A PDF file raises technical problems and cannot be analysed.

Result	Severity	Rule	Description	File
✘	Error	15.06	Only valid characters are used in file n...	index - Copy.xml
✘	Error	15.08	There are no unreferenced files in M1, ...	Submission level tests
✘	Error	15.09	The only files in the sequence folder (/...	Submission level tests
⚠	Warning	15.BP01	Individual files do not exceed 100 MB i...	introduction.pdf
⚠	Warning	15.BP03	The recommended file names from the ...	index - Copy.xml
🛑	Skipped	10.01	All the lowest level heading elements i...	index.xml
🛑	Skipped	11.01	The leaf attribute "checksum-type" ha...	index.xml
🛑	Skipped	11.02	The regenerated checksum for each fil...	index.xml
🛑	Skipped	11.03	For every leaf the "title" attribute is not ...	index.xml
🛑	Skipped	11.04	All leaves with an operation attribute v...	index.xml

Fig. 16: Validation errors listed in the **Result Explorer**

Click a grid entry to see more information about it in the **Information Explorer**.

Click a hyperlink in the **File** column to investigate the concerning document.

4.6.1 Using the Validation Set Documentation


To obtain detailed information about a specific validation rule, 'EURSvalidator' provides an interactive validation set documentation. Proceed as follows:

1. In the **Result Explorer** select the validation rule you want to get detailed information for.
2. ? Click the **Help** button in the **Result Explorer** toolbar.
⇒ The online help opens and displays further information about the selected validation rule.

The information may assist you to evaluate and fix the validation failure quickly.

Result	Severity	Rule	Description	File
✘	Error	15.06	Only valid characters are used in file n...	index - Copy.xml
✘	Error	15.08	There are no unreferenced files in M1, ...	Submission level tests
✘	Error	15.09	The only files in the sequence folder (/...	Submission level tests
⚠	Warning	15.BP01	Individual files do not exceed 100 MB i...	introduction.pdf
⚠	Warning	15.BP03	The recommended file names from the ...	index - Copy.xml
🛑	Skipped	10.01	All the lowest level heading elements i...	index.xml
🛑	Skipped	11.01	The leaf attribute "checksum-type" ha...	index.xml
🛑	Skipped	11.02	The regenerated checksum for each fil...	index.xml
🛑	Skipped	11.03	For every leaf the "title" attribute is not ...	index.xml
🛑	Skipped	11.04	All leaves with an operation attribute v...	index.xml

Fig. 17: Click Help button in Result Explorer toolbar to receive information about the the currently selected validation rule.

 At present the validation set documentation is available for EU eCTD 3.1 and EU Nees V2.1 only



4.6.2 Using the Information Explorer

Depending on your selection in the other explorer windows, the **Information Explorer** provides more detailed information about:

- the **submission** selected in the **Submission Explorer**, divided into **general information** and **envelope information**.
- the validation result of the **rule** selected in the **Result Explorer**.

Submission Validation Results

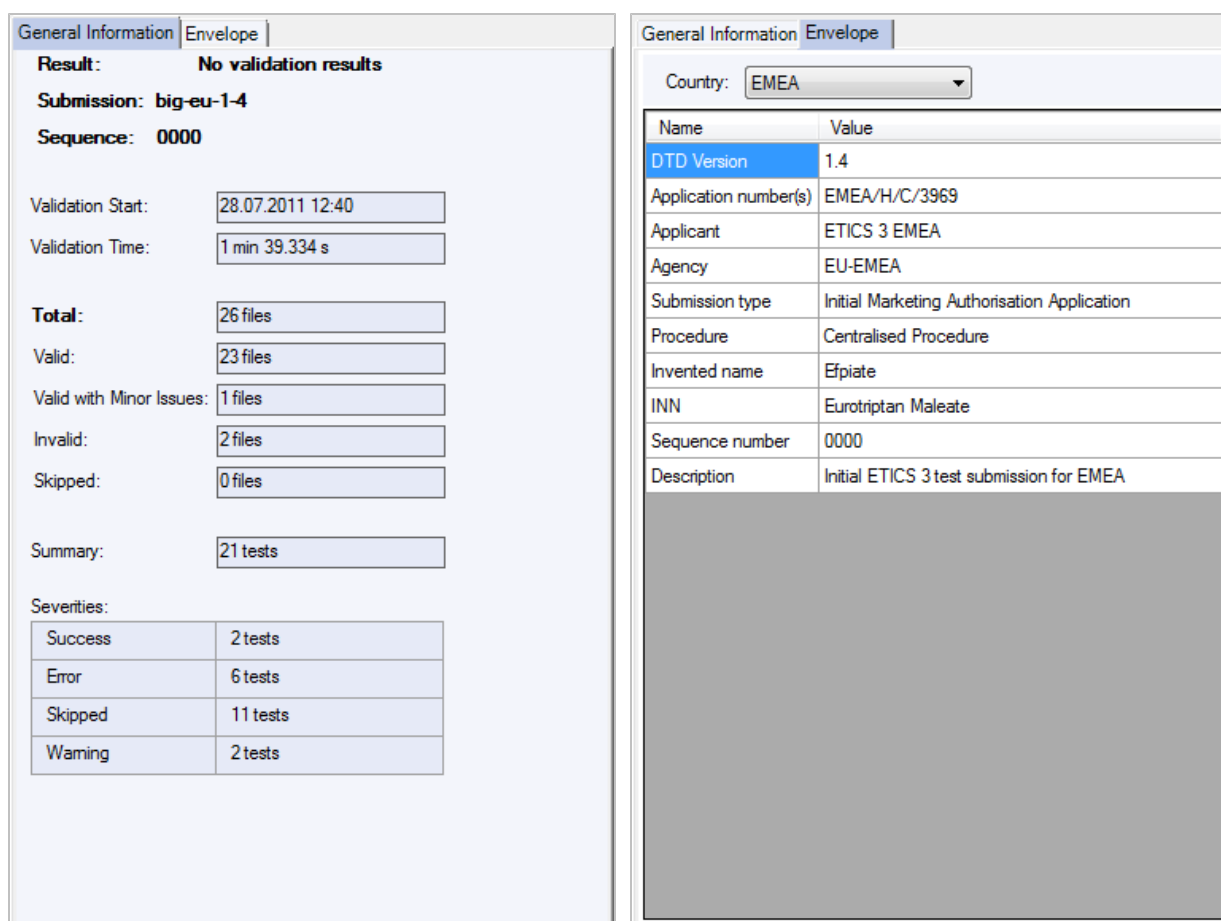
To see an overall information about the submission validation result, select the concerning submission in the **Submission Explorer**.

⇒ The **Information Explorer** will display if the validation was successful  or not .

To see the submission's **envelope information** select the **Envelope** tab page.

⇒ The envelope information is displayed.

If the submission contains envelopes for multiple countries, you can flip through the countries' envelope information by selecting them from the country drop-down list.



The screenshot shows two panels of the Information Explorer. The left panel is the 'General Information' tab, and the right panel is the 'Envelope' tab.

General Information Tab:

- Result:** No validation results
- Submission:** big-eu-1-4
- Sequence:** 0000
- Validation Start: 28.07.2011 12:40
- Validation Time: 1 min 39.334 s
- Total:** 26 files
- Valid: 23 files
- Valid with Minor Issues: 1 files
- Invalid: 2 files
- Skipped: 0 files
- Summary: 21 tests
- Severities:

Success	2 tests
Error	6 tests
Skipped	11 tests
Warning	2 tests

Envelope Tab:

Country: EMEA

Name	Value
DTD Version	1.4
Application number(s)	EMEA/H/C/3969
Applicant	ETICS 3 EMEA
Agency	EU-EMEA
Submission type	Initial Marketing Authorisation Application
Procedure	Centralised Procedure
Invented name	Efpiate
INN	Eurotriptan Maleate
Sequence number	0000
Description	Initial ETICS 3 test submission for EMEA

Fig. 18: Submission details after validation, displayed on the General Information tab page and Envelope tab page.

4.6 Analysing Validation Results

Rule Validation Results

To see a detailed information about a specific rule's validation result, select the concerning rule in the **Result Explorer**.

⇒ The **Information Explorer** will display the validation result for the selected rule.

If the **severity** entry is any other but 'Success', the other entries will provide information for evaluating the cause of the error/warning and resolve the problem:

- **Test result:** Shows which result was expected to obtain a successful validation.
- **Hint:** Displays the result that has been evaluated effectively and locates the problem on file level.
- **Details:** Displays a detailed problem description / method of resolution.
- **Location:** If the error was found in a specific file, a link to this file will be displayed here. Click the link to open the file in the appropriate program.

Severity
Error
Test Result
The regenerated checksum for the index.xml matches the value in the file index-md5.bt.
Hint
The regenerated checksum for the index.xml shall match the value in the file index-md5.bt.
Details
fail-08.03.01 : The regenerated checksum of index.xml does not match the checksum stored in index-md5.bt. Checksum stored in index-md5.bt is f3c7e2a79593c28799a26df93da6c385. The recalculated checksum of the index.xml is dd7946c01f925f14c96474602a22343.
Location
index.xml

Fig. 19: Result Summary of the currently selected validation rule.

4.7 Generating a Report

After performing the validation process, you can generate a report for a selected submission's validation result. There are multiple types of report:

- **Short Report:** This standard report type contains detected errors only.
- **Long Report:** The long report contains detected errors, warnings, and detailed information also.

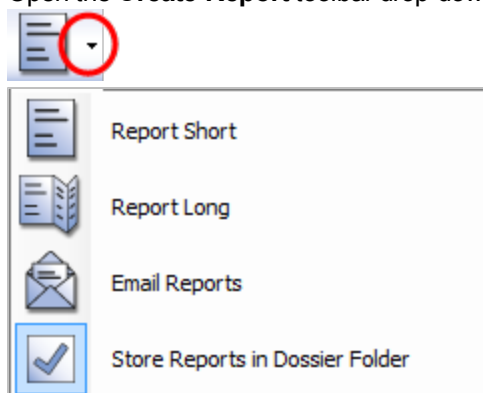
Reports are generated in PDF format and can be opened, viewed, and printed with any PDF reader program.

Hint: Create and use a report when carrying out corrective actions in a submission to keep track of the failures that have been detected.

4.7.1 Creating a Report


To create a report proceed as follows:

1. Select the desired submission in the **Submission Explorer**.
2. Open the **Create Report** toolbar drop-down by clicking the down arrow on the right side of the button.



3. Select **Report Short** to create a short report.
Select **Report Long** if you want to create a long report.
⇒ The selected report is created and opened in your system's default PDF reader program.
4. To print, rename, or save the report file, use the features of your PDF reader program.
Example: In Adobe Acrobat Reader ©, select **File / Print** from the menu bar to print the report.

Close the PDF reader program when finished.

-  A quick way to generate a **short report** is to just select the concerning submission and press **Ctrl + P**.
⇒ The short report is created and opened in your system's default PDF reader program.

4.7.2 Naming of Report Files

As a default all report files are named following a specific convention:

ValidationReport_[dossiername]_[submission sequence].pdf (short report)

ValidationReport_[dossiername]_[submission sequence]_long.pdf (long report)

Example: ValidationReport_SampleSubmission_0000_long.pdf

Reports are either stored in the **dossier's folder**, or in the users documents folder, subfolder **EURSvalidator**.


To store the reports in the dossier folder automatically, tick the option **Store Reports in Dossier Folder** in the **Create Report** toolbar drop-down. See 'Tool Bar' on page 11.

4.7.3 Sending a Report by Mail

You can send a report by mail. Prerequisites: **Microsoft Outlook** must be installed on your system.

Proceed as follows:

4.7 Generating a Report

1. Select the desired submission in the **Submission Explorer**.
2. Select  **Email Reports** from the **Create Report** toolbar drop-down .
⇒ Both a short report and a long report are generated.
A new email is created from your default email program, and the report files are attached to it.
3. Please enter the receiver's **email address** or select it from the address book.
4. Modify the email's **subject and message**.
5. Send the email.

4.8 Handling Invalid Submissions

If the validation results indicate an invalid submission, proceed as follows to resolve the submission's failure(s).

1. Validation failures are marked with a **severity** 'A', 'B', or 'C', or equivalent classifications. Sort the **Result Explorer** grid by severity by clicking the head of the column **Severity**.

Result	Severity	Rule	Description	File
✘	Error	15.06	Only valid characters are used in file n...	index - Copy.xml
✘	Error	15.08	There are no unreferenced files in M1. ...	Submission level tests
✘	Error	15.09	The only files in the sequence folder (/...	Submission level tests
⚠	Warning	15.BP01	Individual files do not exceed 100 MB i...	introduction.pdf
⚠	Warning	15.BP03	The recommended file names from the ...	index - Copy.xml
⚠	Skipped	10.01	All the lowest level heading elements i...	index.xml
⚠	Skipped	11.01	The leaf attribute "checksum-type" ha...	index.xml
⚠	Skipped	11.02	The regenerated checksum for each fil...	index.xml
⚠	Skipped	11.03	For every leaf the "title" attribute is not ...	index.xml
⚠	Skipped	11.04	All leaves with an operation attribute v...	index.xml

2. Run through the validation results to find failed validation rules.
3. Select a failed validation rule to see more details in the **Information Explorer**, especially sections 'Hint' and 'Details'.
4. Additionally you may use the **validation set documentation** for further information about the cause of a failure. See 'Using the Validation Set Documentation' on page 26.
5. Generate a **long report** for a detailed view on the detected failures and concerning messages. See 'Generating a Report' on page 29.
6. Open the submission for editing in the appropriate program.
7. Eliminate **severity 'A' issues first** because these will lead to the rejection of the submission.
8. Continue with severity **'B'** issues after all severity 'A' failures have been resolved.
9. At last care for severity **'C'** issues.

If at least all major failures (severity 'A' and 'B') have been resolved, reload the submission into the **Submission Explorer** and start a new validation.

4.8 Handling Invalid Submissions

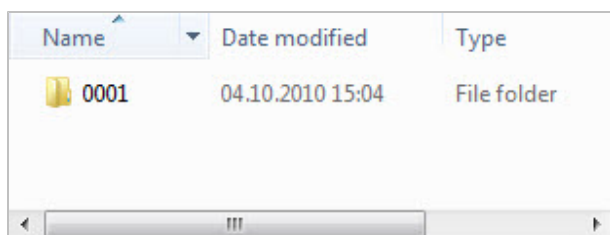
5 Troubleshooting

5.1 Submissions with Modified File Entries

Problem: A follow-up submission validation has been started; the report has identified an error, about *modified file entries*.

Reason: The validated follow-up submission includes references to (a) prior submission(s). The validation process needs to access documents from there. The prior submission(s) and the validated submission are not stored in the same directory.

Scenario: A validated follow-up submission is placed in a directory without any prior version(s), but needs access to them (see above).

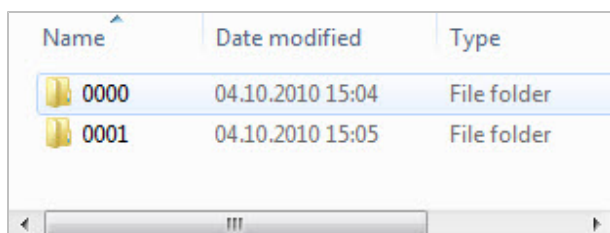


Name	Date modified	Type
0001	04.10.2010 15:04	File folder

The validation report identifies errors.

Result	Severity	Rule	Description	File
✘	Error	02.04	The valid version of the stylesheet is u...	Submission level tests
✘	Error	11.09	The leaf referenced by the modified file...	eu-regional.xml
⚠	Warning	00.BP01	Context of other eCTD	Submission level tests
✔	Success	14.02	There is a envelope element with a ma...	eu-regional.xml

Solution: Ensure that the to be validated submission and all prior versions are stored in the same directory.



Name	Date modified	Type
0000	04.10.2010 15:04	File folder
0001	04.10.2010 15:05	File folder

Now the validation errors concerning the missing prior version(s) will be resolved.

Result	Severity	Rule	Description	File
✘	Error	02.04	The valid version of the stylesheet is u...	Submission level tests
✔	Success	00.BP01	Context of other eCTD	Submission level tests
✔	Success	14.02	There is a envelope element with a ma...	eu-regional.xml

Hint: If a follow-up submission has been delivered on a CD / DVD (without any prior submissions on this data carrier), it is recommended to copy the follow-up submission to the local hard disk, into the same directory where the prior submissions are stored. Start the validation from the local hard disk.

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EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management. The complete EXTEDOsuite is unique in all that it covers within eRegulatory Affairs:

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- Labeling Management and
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