

Product Information

EURSvalidator™

The trusted technology for eCTD and NeeS compliance

Trusted by regulatory authorities across the world, including the European Medicines Agency (EMA), EURSvalidator is designed to ensure eCTD and NeeS compliance.

Benefits

- **Trusted technology:** 80 % of regulatory authorities in Europe use EXTEDO validation technology (EURS) for ensuring eCTD and NeeS compliance.
- **Flexible:** Multiple subscription options for individual validation requirements
- **Up-to-date:** Latest validation sets provided in timely manner
- **One tool:** Integrated validation sets on a global scale
- **Expertise:** EXTEDO is the consulting partner of choice for more than 35 regulatory authorities worldwide – Profit on the back of our success!

EXTEDO's EURSvalidator provides multiple subscription options for individual validation requirements and enables users to configure their EURSvalidator subscription according to the country or region they want to file the submission. The validator enables users to combine different validation set packages within one subscription.

EXTEDO cooperates closely with regulatory authorities in order to guarantee that the relevant validation sets are included in the respective subscription packages and validation sets are up-to-date. EURSvalidator is also prepared for future standards such as eCTD 4.0.

As the consulting partner of choice for more than 35 regulatory authorities worldwide, we ensure the greatest possible accuracy in managing your medicinal or veterinary eSubmissions.

Result:	✗ Invalid
Submission:	Product ABC
Sequence:	0008
MD5:	530659857d0773a496e18b7c846f388b
Validation Start:	19.08.2015 21:09
Validation Time:	0 s
File Level Tests	
Total:	14 files
Valid:	7 files
Valid with Minor Issues:	5 files
Invalid:	2 files
Skipped:	0 files
Submission Level Tests	
Failed:	1 tests
Severities	
Error	3 tests
Warning	6 tests
Success	2 tests

Validation result of a submission sequence

ProductXYZ	0001	✗	EU-eCTD v5.0 (DTD 2.0)	▼	Validation finished.
Product zyx	0000	✗	EU-eCTD v4.1 (DTD 1.4)	▼	Validation finished.
Product zyx	0001	✓	EU-eCTD v4.1 (DTD 1.4)	▼	Validation finished.
Product ABC	0000	✓	EU-eCTD v2.1 (DTD 1.3)	▼	Validation finished.
Product ABC	0001	✓	EU-eCTD v2.1 (DTD 1.3)	▼	Validation finished.
Product ABC	0002	✓	EU-eCTD v2.1 (DTD 1.3)	▼	Validation finished.
Product ABC	0003	✓	EU-eCTD v2.1 (DTD 1.3)	▼	Validation finished.
Product ABC	0004	▶	EU-eCTD v2.1 (DTD 1.3)	▼	
Product ABC	0005	▶	EU-eCTD v2.1 (DTD 1.3)	▼	
Product ABC	0006	▶	EU-eCTD v2.1 (DTD 1.3)	▼	
Product ABC	0007	▶	EU-eCTD v4.1 (DTD 1.4)	▼	
Product ABC	0008	✗	EU-eCTD v4.1 (DTD 1.4)	▼	Validation finished.
Product ABC	0009	▶	EU-eCTD v4.1 (DTD 1.4)	▼	
Product ABC	0010	▶	EU-eCTD v4.1 (DTD 1.4)	▼	
Product ABC	0011	▶	EU-eCTD v4.1 (DTD 1.4)	▼	

Overview of the validated sequences



Functional Overview

- › **Turn on/off validation sets** – Validation sets can be selected or deselected to be enabled or disabled.
- › **Validation set/DTD Autoselector** – Applicable validation sets are automatically detected and selected (not applicable for NeeS submissions). If needed, users can also manually select validation sets.
- › **Validate multiple submissions or dossiers** – The user can start the validation for all pending submissions in the Submission Explorer simultaneously.
- › **Display envelope information** on the envelope tab page
- › **PDF reporting** – Short Report: This standard report type contains detected errors only. Long Report: The long report contains detected errors and additionally, warnings, and detailed information.
- › **Report auto-save** – A detailed summary or validation report is automatically saved.
- › **Report mail service** – Detailed summary or validation report can be sent out via mail.

Available Modules

EURSvalidator uses a regional subscription model with packages of validation sets available depending on the country or region you want to file your submission within. Different validation set packages can be combined within one subscription. Modules for the following regions are available:

EU North

(Sweden, Norway, Denmark, Finland, Iceland)

EU West

(France, Belgium, Netherlands, Luxembourg)

EU Central

(Germany, Austria, Liechtenstein)

EU South

(Spain, Portugal, Italy, Malta, Greece, Croatia, Slovenia, Cyprus)

EU East

(Poland, Czech Republic, Slovakia, Hungary, Estonia, Latvia, Lithuania, Bulgaria, Romania)

EU UK & Ireland

(United Kingdom, Ireland)

Switzerland

(Switzerland (without eDok))

North America

(USA, Canada)

Asia Pacific

(all member countries of the Gulf Cooperation Council (GCC), Australia, Jordan, Japan, Thailand, Taiwan)

South Africa

(South Africa)

Global

(all available validation sets)

EU Unlimited

(all EEA countries and EMA, all procedure types)

For further information contact your local EXTEDO representative:



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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

Microsoft Partner
Gold Application Development