EURS

EXTEDO
eRegulatory Affairs

Product Information

EURS™

The eCTD validation and reviewing solution the regulatory agencies choose

The reviewing of electronic submissions upon receipt is a critical process for regulatory authorities. Validating large numbers of submissions can quickly become a bottleneck, requiring a significant investment in both time and resources.

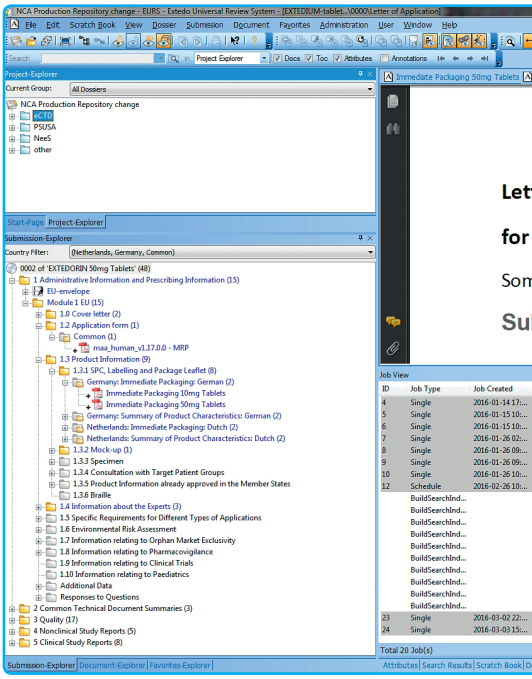
Benefits

- Quick access to submissions
- Scalable solution supporting parallel work between numerous users
- Advanced features for validation, import, display, search and printing
- Extensive audit trail of user activities related to submissions
- Powerful navigational tools and an intuitive user interface means minimal training
- Proven technology used by more than 35 authorities worldwide
- Configurable validation requirements to verify eCTD compliance
- eCTD 4.0 / RPS ready

EXTEDO EURS is designed to simplify the validation and review of regulated electronic submissions within authorities. It provides you with tools for the validation, acceptance, import, review and maintenance of eCTD and NeeS-based submissions, giving you complete confidence that they conform to your official standard. EURS supports numerous regional agencies including EMA (with most local European NCAs), Swissmedic and other regions worldwide.

EURS is also eCTD 4.0/RPS ready.

As one of the NCA´s leading validation and reviewing solutions, numerous regulatory authorities use EURS to support their internal review processes. With periodic modifications to the ICH eCTD and Module 1 specifications, as well as ICH-developments and other changes introduced, EURS is continually updated to ensure that it remains at the leading edge.

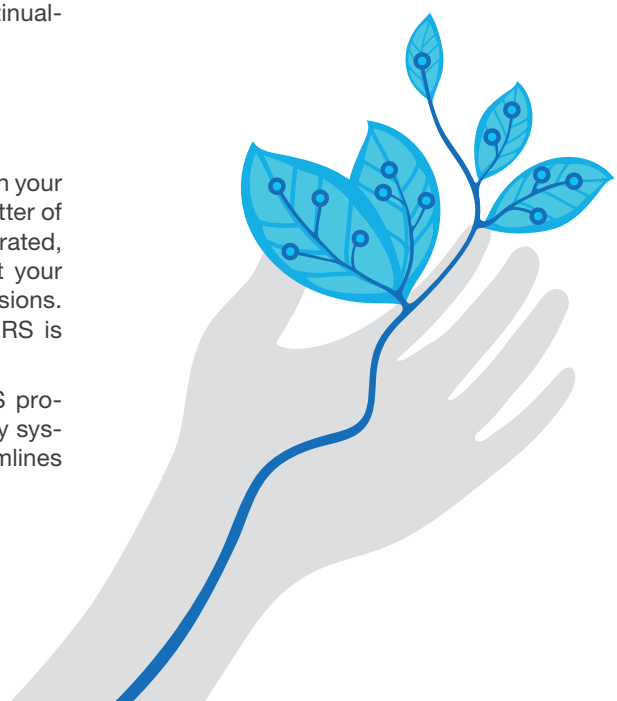


Intuitive user interface and self-explanatory icons

Easy to deploy solution that integrates with third party systems

EURS is powerful, yet simple to deploy within your agency. Depending on your system specifications, EURS can be installed and validated within a matter of days. Its user-friendly and intuitive interface is equipped with an integrated, context-sensitive online help that ensures ease of adoption amongst your users, and minimizes the need for expensive structured training sessions. Supporting distributed workforces with many hundreds of users, EURS is also an extremely scalable solution.

To ensure a seamless connection into your existing processes EURS provides an API that enables you to readily integrate with many third-party systems. This ensures increased operational efficiency and further streamlines the validation processes within your organization.



Functional Overview

EURS provides the following functionality:

- Validation support for regional compliance around the globe
- Fast and accurate import of any standard submission format
- Efficient handling of large numbers of dossiers and their submissions
- Annotate, highlight and hyperlink PDFs without changing the original documents
- Export of annotations can support the creation of your assessment report
- Full text search within documents, eCTD-envelopes, table of content elements and review annotations
- Quick access to submissions throughout the entire lifecycle of a drug product
- Scalable up to and beyond 400 users
- Supports automated processing
- API support
- Portal / Gateway Integration
- DMS Support

Available Modules

DMSconnect

Integration with leading document management systems

Automate validation processes and connect to EMA Common Repository

Communication with the EMA Common Repository (CR) is essential for optimized processes, and EURS is equipped with an integrated connector. Where required, its sophisticated CRconnector enables you to automatically keep a local EURS repository, or partial repository, that is synchronized with the EMA Common Repository.

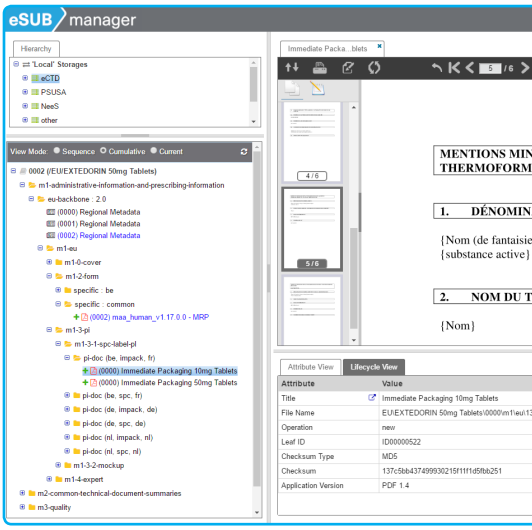
Quick access to your relevant information by full text-search and filtering

Through the EURS interface you can access imported submissions and search, view, and annotate them. EURS powerful features allow you to organize and filter submissions based on certain criteria such as regulatory activities corresponding to the overall regulatory status of a drug product.

As recognized by regulatory authorities around the globe, EURS is the requisite solution for effortless review and validation of regulatory submissions.

EURSnext – the web interface to EURS

If you need online access to previously submitted electronic dossiers, then EURSnext is the answer. EURSnext is the lightweight companion to EURS. It provides a fully functional reviewing system for agencies, enabling them to view and review submission data directly within a web browser. With no need for client software, EURSnext is the ideal solution for collaborative working between agency staff and external assessors where IT resources may be limited. EURSnext is a package based on eSUBmanager and is only available to regulatory authorities.



EURSnext/eSUBmanager: view and review submission data directly within a web browser

18/02

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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 700 maintained customers across 60 countries to deliver Effortless Compliance™.

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