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

Intuitive user interface and self-explanatory icons

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.

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.
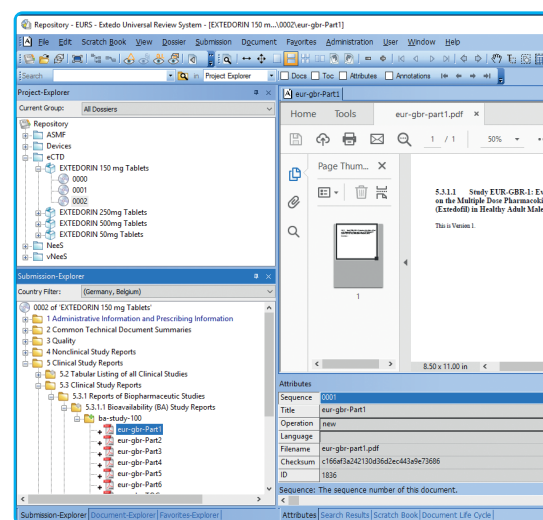
Easy to deploy solution that integrates with third party systems

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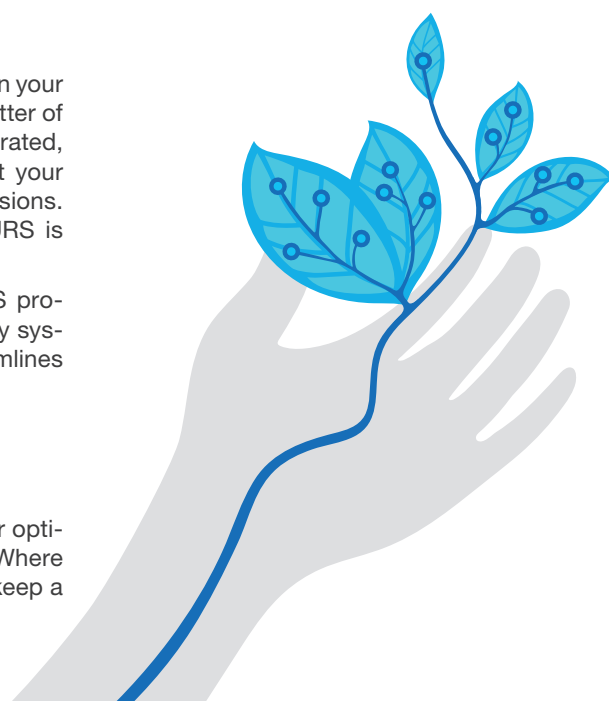
To ensure a seamless connection into your existing processes EURS provides an API that enables you to readily integrate with many third-party systems. This ensures increased operational efficiency and further streamlines the validation processes within your organization.

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

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

Distributed Working: Allows the installation of EURS as a background windows service. This can be helpful for long-running tasks like import & validation under times of heavy workload

Web Broker: A web interface to list, pause and resume EURS background validation or import tasks. It also enables load balancing between multiple services, allowing more work to be done in the same amount of time

Automation Engine: A console-based application that can be used to automate EURS functions such as submission import, validation and indexing from the command line

CESP connect: Provides an automatic import of submissions received through CESP (FTP) to the EURS repository to speed up processing and minimize manual interaction

DMSconnect: Enables the storage and access of submission files from a DMS e.g. OpenText Documentum and IBM FileNet. This provides extra document security via existing DMS infrastructure

Active Directory Connect: Enables the use of a corporate Active Directory to configure and maintain access control of users and groups to EURS. The users can use their regular windows password to log into EURS

EURS API: A REST-based programming interface used to create and run tasks within a EURS service. It enables easy integration of EURS tasks within existing automated processes

CR Connect: Provides a direct connection to EMA Central Repository. It automatically transfers dossiers to the local EURS repository to save manual time and effort

Server Monitoring: Allows monitoring multiple servers in a single job file. Automatically unzip and import received submissions triggered by an external PowerShell Script to the EURS repository.

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.

24/03

For further information contact your local EXTEDO representative: