

Product Information

EURSnext™

The eCTD viewing and reviewing solution regulatory agencies choose

The reviewing of electronic submissions upon receipt is a critical process for regulatory authorities.

Benefits

- Quick access to submissions
- Scalable and high performance solution supporting parallel work between numerous users
- Advanced features for display, search and printing
- Powerful navigational tools and an intuitive user interface means minimal training
- Easy deployment through state-of-the-art web-based technology
- Based on best practices gained from 35 regulatory authorities worldwide
- Prepared for eCTD 4.0 / RPS

As one of the NCA's leading validation and reviewing solutions, numerous regulatory authorities use the parent solution EURS to support their internal review processes.

EXTEDO EURSnext is designed to simplify the view and review of regulated electronic submissions within authorities. It provides you with tools for the inspection and review of eCTD and NeeS-based submissions. EURSnext supports numerous regional standards including EMA (with most local European NCAs), Swissmedic and other regions worldwide.

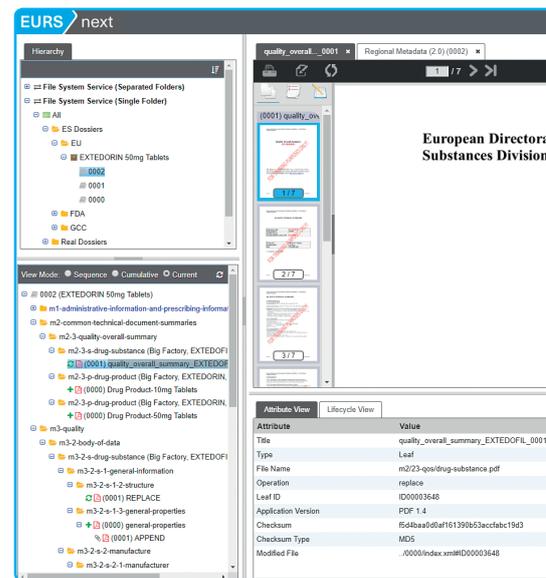
Due to periodic modifications to the ICH eCTD and Module 1 specifications, as well as ICH-developments and other changes introduced, EURSnext is continually updated to ensure that it remains at the leading edge.

EURSnext is also prepared for eCTD 4.0/RPS.

Easy to deploy solution that integrates with third party systems

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

To ensure a seamless integration into your existing IT landscape, EURSnext's installation is purely server-based. This ensures increased operational efficiency and further streamlines the reviewing processes within your organization.



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



Functional Overview

EURSnext provides the following functionality:

- › Efficient handling of large numbers of dossiers and their submissions
- › Easily navigate around the structure of a submission in different view modes (single sequence, cumulative and current view of the application)
- › Annotate, highlight and compare PDFs without changing the original documents
- › Export of annotations to speed-up the creation of your assessment report
- › Quick access to submissions throughout the entire lifecycle of a drug product
- › Scalable for many users

Comprehensive collaborative reviews

EURSnext allows your staff to quickly read and mark-up any documents within a submission directly without the need to have specific editing software installed.

Its integrated viewing technology streams only the requested sections of content directly to a viewer's web browser, enabling optimized viewing and overlay mark-up without the need to download the entire document. In addition, its collaborative mark-up tools enable replies to be made and shared in real-time, without requiring direct edits on the original content.

User experience is king

Built with simplicity at its heart EURSnext is a completely web-based solution designed for the modern IT environment. It is simple to deploy across your agency and requires minimal end-user training. Prepared for Regulated Product Submission (RPS) and eCTD 4.0, it also ensures that your company is able to transition and utilize forthcoming standards as soon as they are approved.

EURSnext is the online review solution for modern regulatory authorities, ensuring effortless collaboration around regulatory submission review.

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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™.