Product Information

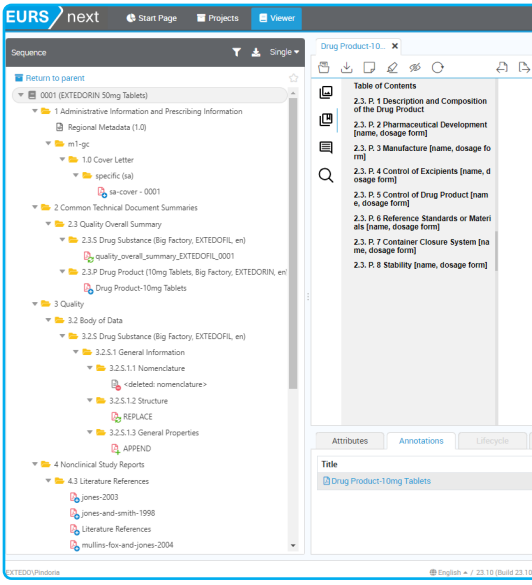
EURSnext™

The eCTD viewing and reviewing solution regulatory agencies choose

The successful validation and timely assessment of electronic submissions is an essential part of the regulatory process.

Benefits

- Modern, web-based solution
- Powerful navigational tools and an intuitive user interface requires minimal training
- Scalable and high performance solution
- Easy access to submissions with a lifecycle overview
- Supports parallel work between numerous users
- Advanced features for display and printing
- Based on best practices gained from global regulatory authorities
- Supports global standards such as eCTD 3.2, eCTD 4.0, NeeS and VNeeS
- Powerful search functionalities



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

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

EXTEDO's EURSnext is a modern web-based solution designed to simplify the viewing and review of regulated electronic submissions within authorities. It's user-friendly functionality enhances reviewing of eCTD and NeeS-based submissions, including eCTD 4.0. EURSnext supports numerous regional standards including EU (with most local European NCAs), CH and other regions worldwide.

With periodic modifications to the ICH and Module 1 eCTD specifications and other formats being common, EURSnext is continually updated to ensure that it remains at the leading edge.

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 easily in-house or deployed as a cloud solution. For organization that are already using EURS, EURSnext works seamlessly with other EURS-based deployments.

Its user-friendly and intuitive interface ensures ease of adoption amongst your users, and minimizes the need for expensive training sessions. For distributed workforces, EURSnext provides an extremely performant and scalable solution that ensures increased operational efficiency which further streamlines the reviewing process in your organization.

Functional Overview

- 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 PDF files without changing the original documents
- Annotations can be exported easily to speed-up the creation of your assessment report
- Quick access to submissions throughout the entire lifecycle of a medicinal product
- Scalable for many users and ideal solution for collaborative working between agency staff and external assessors where IT resources may be limited

Comprehensive collaborative reviews

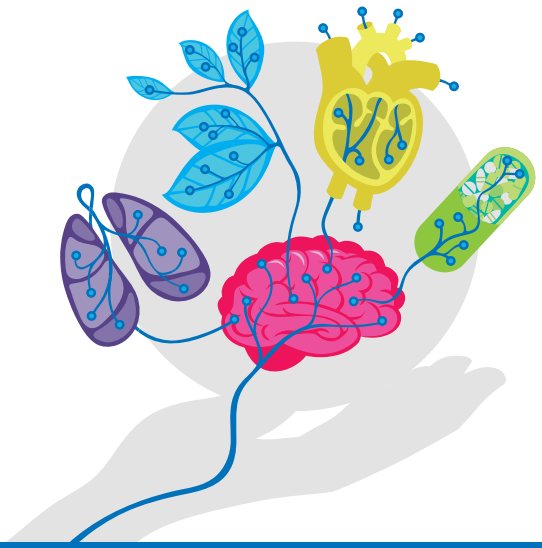
EURSnext allows users to quickly read and mark-up any documents within a submission directly without the need to have specific PDF viewing or annotation software installed.

To optimize performance EURSnext includes integrated state of the art viewing technology that presents only relevant pages of a document to a user's web browser.

Simple to use and always current

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. EURSnext ensures compliance with future standards updates and is able to utilize these 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 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

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