



Benefits

- Fast access of submissions
- Manages the entire life cycle of a drug product
- Support of parallel work
- Advanced features for validation, import, display, search and printing
- Extensive audit trail
- Powerful navigating tools
- Intuitive and configurable user interface
- Configurable validation requirements to verify eCTD compliance
- Extremely fast and easy-to-use search functions
- Simulate your submissions from NCAs perspective



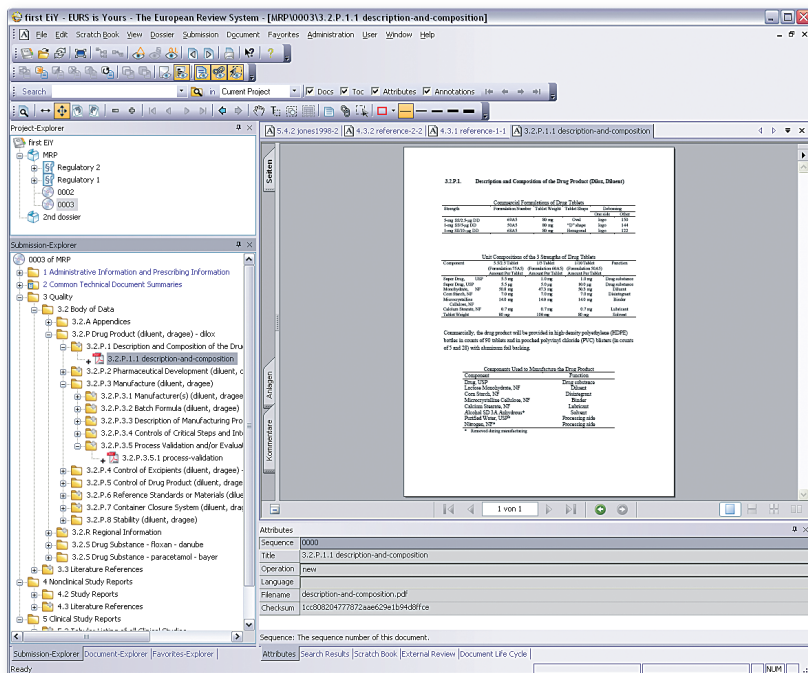
Product Information EURS is Yours™

Efficient reviewing of electronic submissions

EURS is Yours is a multifunctional software solution that serves as an overall eCTD validation and reviewing software tool. It reports whether a submitted eCTD- or NeeS-based application conforms to the official eCTD format.

It is especially designed for the validation, acceptance, import, review and maintenance requirements of the EMA (European Medicines Agency), the associated national competent authorities (NCAs), and also of authorities outside of the European Union, e.g. the FDA or the Swissmedic. It operates on basic hardware and software.

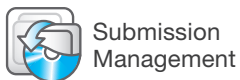
EURS is Yours is independently controlled by EMA and NCAs. It is updated regularly to reflect changes in the ICH eCTD Specification and/or Module 1 Specifications, ICH-developments and developments by authorities in the context of the EMA driven eCTD Implementation Group. EXTEDO designed and implemented EURS is Yours as a standardised software solution covering the EURS specifications and the extensions to these specifications.



Intuitive user interface and self-explanatory icons



Registration Management



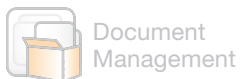
Submission Management



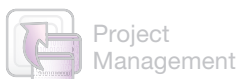
Labeling Management



Pharmacovigilance Management



Document Management



Project Management

Supporting complex reviewing processes

Once an eCTD submission has been imported within EURS is Yours by the agency, its drug approval maintenance life cycle starts.

With EURS is Yours you can access the submissions to search, view, and/or annotate them or you can print certain regulatory documents. Self-explanatory icons mark added, deleted, replaced, and appended doc-

uments (i.e. every version-related change of the dossier). It supports you in organizing and filtering submissions by certain regulatory activities that represent the overall regulatory status of a drug product.

EURS is Yours allows different users to access a dossier simultaneously. A sophisticated caching mechanism (Central Repos-

itory) can be implemented especially for using EURS is Yours in internationally distributed workgroup communities to reduce network traffic and waiting periods. EURS

is Yours can also be integrated into state-of-the-art document management systems by using standard interfaces.

Functional overview

EURS is Yours runs on various types of IT infrastructures (standalone, groupware) and provides the following:

- Intuitive and configurable user interface
- Configurable validation support to verify eCTD compliance according to the published validation criteria of the regulatory agencies throughout the world.
- Fast and accurate import procedure into a standard eCTD or NeeS repository supporting out-of-sequence imports
- Efficient handling of huge numbers of dossiers and their submissions
- The use of PDF annotations, highlights, and hyperlinks without changing the originally submitted PDF documents.
- Easy-to-use search functions based on full text for documents, eCTD-envelopes, table of content elements, and review annotations.
- Intuitive user-interface with an integrated, context-sensitive online help to improve the electronic reviewing processes
- Configuration of individual variables that can also include envelope information. These variables can be used for full-text search as well as for grouping of dossiers in the project explorer of EURS is Yours.

From an authority's point of view, the most important features of EURS is Yours are the ability to access submissions quickly and to cover the entire life-cycle of a drug product.

Available Modules

➤ DMSconnect:



Integration with leading document management systems

About us

EXTEDO is the key software and service solutions provider in the field of Regulatory Information Management. The complete EXTEDOsuite is unique in all that it covers within eRegulatory Affairs:

- Product Registration Planning & Tracking
- Submission Management (eCTD, CTD; NeeS, CADDY, ePRISM, eIndex, eNTA, vNeeS)
- Pharmacovigilance Management (SUSAR, ICSR, PSUR, E2B)
- Labeling Management and
- Document Management

We provide configurable off-the-shelf products, as well as customized and integrated solutions. EXTEDO also provides EURS is Yours, the validation, review and approval software solution for the EMA and more than 25 Regulatory Authorities worldwide.

Today we serve more than 700 customers in 57 countries ranging from small companies with less than 25 employees to large multinational organizations. EXTEDO operates in the following areas of life sciences: pharmaceutical, biotech and biopharma, generics, homeopathics, medical devices, healthcare, and public sector.

EXTEDO is recognized as one of the worldwide leaders in each of our areas of operation.

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