eCTD manager

EXTEDO
eRegulatory Affairs

Product Information

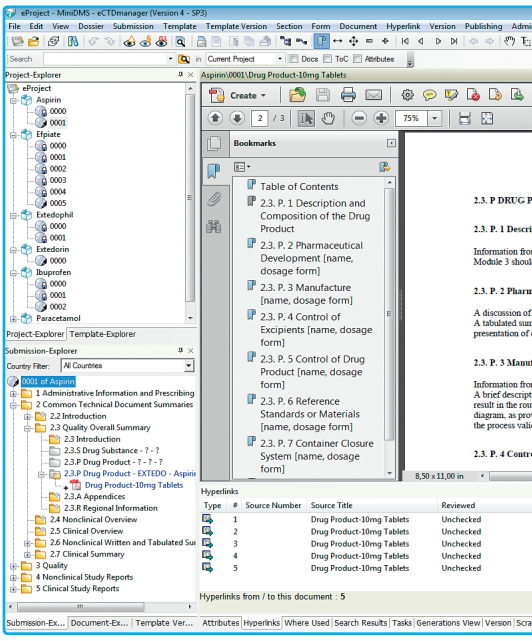
eCTDmanager™

Reducing the expense of managing compliant electronic submissions

The effective management of validated and compliant submissions is a complex process. The need to build, view, validate and publish submissions based on standardized submission formats comes with its own set of challenges. In addition, managing submissions in multiple regions also requires that all submissions must be compliant with the ICH and regional specifications, which further complicates the overall process.

Benefits

- Rapid compliance with latest regulatory changes worldwide
- Ability to validate and publish submissions from a single application
- Improves submission quality and consistency
- Supports publication of submissions in structures and formats for all regions of the world
- Prepared for future standards like eCTD 4.0
- Supports parallel work locally and worldwide
- Sophisticated management of hyperlinks and bookmarks
- Conforms to ICH and regional filenames and 21 CFR Part 11
- Minimal hardware requirements, rapid deployment and system validation, high performance and minimum training



Intuitive user interface: handling of pharmaceutical submissions without the knowledge of XML-technology

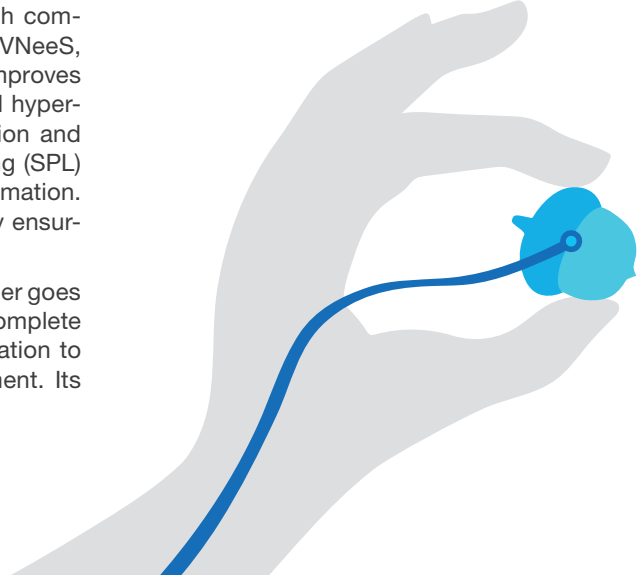
To ensure compliance, you need a solution that enables you to maintain a comprehensive overview of your submission statuses across a number of products within multiple different geographic markets. EXTEDO eCTDmanager is designed to meet exactly these needs and ensure effortless compliance with regulatory requirements.

The comprehensive electronic submission management solution

eCTDmanager provides you with a complete regulatory dossier assembly and management solution. Its scalable, all-in-one submission management capabilities meet the requirements for both electronic and paper submissions.

With eCTDmanager, you are able to build, view, validate and publish compliant submissions based on eCTD, NeeS, eCopy, IMPD, CTA, PIP, VNeeS, DMF, ASMF and other regional formats. eCTDmanager significantly improves the quality and consistency of your submissions, proving a powerful hyperlinking and bookmarking engine that allows the detection, notification and correction of broken links. Sophisticated Structured Product Labeling (SPL) capabilities also enable data entry and maintenance of product information. eCTDmanager enables you to streamline your global submissions by ensuring full compliance with ICH and regional specifications

As the trusted validator used by more than 35 authorities, eCTDmanager goes beyond a basic eCTD submissions tool. It also provides you with a complete regulatory dossier assembly environment that enables your organization to operate in a compliant manner within a heavily regulated environment. Its



Functional Overview

eCTDmanager is equipped with various functions for critical submission support, including:

- Support of parallel submissions (MAA, NDA, BLA, NDS and IND)
- Time-sensitive tracking functions for dossiers, which prevent the delays in filling
- Sophisticated management of hyperlinks and bookmarks, including automated text to hyperlink functionality supporting most technical writing standards
- SPL data entry and management
- Incremental publishing and export capabilities
- Support for Critical Submissions
- Supported regional eCTD standards include EU, US FDA, AU, CA, CH, GCC/KSA, JO, JP, TH, ZA, as well as other submission standards like IMPD, CTA, NeeS
- Integrated validator for US FDA, EU (EMA approved) and many more
- DMS integrations available for BIOVIA, Generis, MasterCotrol, Microsoft SharePoint, OpenText/Documentum, Veeva, and additional document management systems

intuitive interface enables you to easily handle electronic submissions without prior knowledge of XML-technology, and its unique visual aids provide context, ensuring simplified completion and unprecedented accuracy.

eCTDmanager includes an integrated validator for medicinal or veterinary eSubmissions within global validation scenarios, supporting regions like North America (FDA, CA), EU (EMA approved), CH (Swissmedic approved), GCC, Asia-Pacific and South Africa. The majority of global authorities use validation technology developed by EXTEDO. Additionally, it provides DMS integrations with BIOVIA, Generis, MasterControl, Microsoft SharePoint, OpenText/Documentum, Veeva and several other document management systems.

Available both as an in-house or hosted solution, eCTDmanager enables your organization to be prepared for upcoming regulatory and technical changes, like the introduction of future standards such as eCTD 4.0.

Trusted by over 35 regulatory authorities worldwide, EXTEDO's submission management suite reduces the time and effort involved in generating, publishing, managing and (re)-viewing validated electronic submissions.

eCTDmanager is your complete regulatory dossier assembly and management solution.

Available Modules

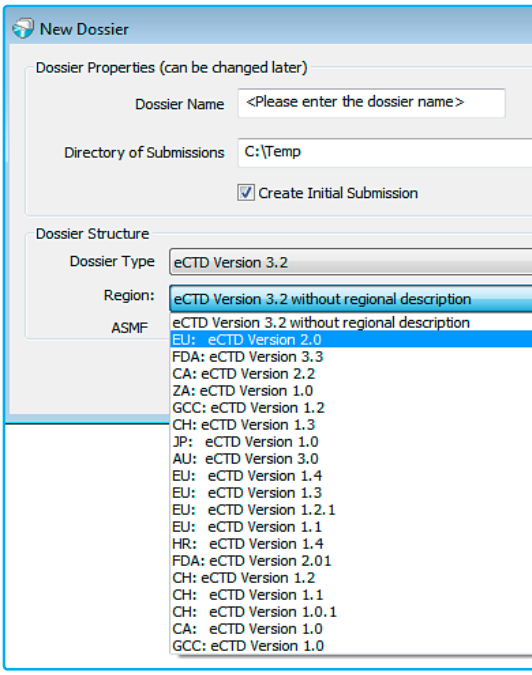
miniDMS
Document version control

DMSconnect
Integration with leading document management systems

DOCmanager
Allows creation and maintenance of many child dossiers based on one parent dossier

RLPmanager
Report Level Publishing including lifecycle management

Publish Service
Global solution offering local eCTD, e-paper and paper publications



New dossier dialog

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

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