



Benefits

- Improves submission quality and consistency
- Reduces preparation and update time for original applications, variations, amendments, etc.
- Enables fast access to documents and eCTD status for everyone involved in the project
- Reduces paper and lowers logistics overhead
- Supports of parallel work locally and worldwide
- Sophisticated management of hyperlinks and bookmarks
- Improves process efficiency and reduces costs
- Faster time to market
- Easy to use MRP/DCP support
- Integrated EMA approved validator (developed by EXTEDO)
- Compliance with 21 CFR Part 11



Product Information eCTDmanager™ Suite

Comprehensive submission management solution

EXTEDO's eCTDmanager is an off-the-shelf electronic submission management solution that satisfies your requirements for eCTD and non-eCTD submissions, no matter if electronic or paper.

eCTDmanager enables you to build, view, validate and publish compliant submissions based on CTD, eCTD, NeeS, IMPD,

CTA, eNTA, VNeS and other submission structures easily. With its powerful hyperlinking and bookmarking engine, it helps you manage the detection, notification and correction of broken hyperlinks resulting in the creation of high-quality submissions. An integrated validation function ensures compliance of the submissions to ICH and regional specifications.

Simplify life-cycle management of pharmaceutical submissions

EXTEDO's eCTDmanager, including its available modules, simplifies all areas related to the life-cycle management of pharmaceutical submissions. Once an eCTD-based dossier has been approved by the

agency, its post-approval maintenance life-cycle starts. eCTDmanager provides you with unique visual and contextual aids to ensure rapid response and accuracy.



Registration Management



Submission Management



Labeling Management



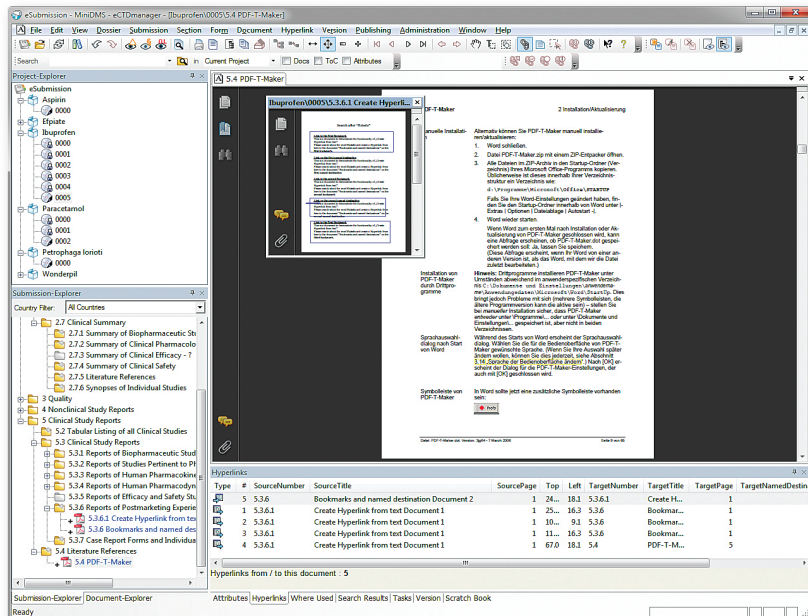
Pharmacovigilance Management



Document Management



Project Management



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

Easy to use

Even without the knowledge of XML technology, you can easily build and review submissions, add, edit and delete elements or even set hyperlinks and comments at any time during the submission compilation. Documents can easily be scanned,

copied, moved or imported from the file system and from most Document Management Systems (DMS).

eCTDmanager includes a sophisticated replication mechanism that provides glob-

ally distributed workgroup users with simultaneous access to a submission. Especially for global acting companies with subsidiaries in other countries, this functionality is a tremendous benefit. In combination with DOCmanager, that allows the creation and maintenance of many child dossiers based on one parent dossier, the solution will be even more effective. eCTDmanager can be easily integrated into document management systems such as:

- EMC Documentum™
- NextDocs™
- CSC FirstDoc™, CSC FirstPoint™
- OpenText™
- IBM SCORE™
- Optimal Systems™
- MasterControl™
- QUMAS DocCompliance™
- Microsoft SharePoint 2007 and 2010™
- Ainea™

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Functional overview

Management, submission component display, paper and e-paper publishing, and report management capabilities include the following:

- Ability to start without using a document management system and grow to integrate with your DMS
- Advanced features for life-cycle management and control through functions like country filter
- Advanced audit trail
- Support of national and comprehensive approach for MRP/DCP procedures
- Powerful hyperlink and bookmark capabilities
 - cross links
 - powerful management of hyperlinks
 - resolution of external hyperlink
 - hyperlinks to bookmarks
 - automated text to hyperlink functionality that supports most technical writing standards
 - handling of named-destinations
 - hyperlink source view enables to view the source and target of a document simultaneously
 - hyperlink review functionality that allows approval of hyperlinks
- Capability to clone submissions
- EU eCTD DTD version upgrades
- Reuse of submissions for other regions
- Sophisticated replication facilitates collaboration in companies with globally distributed workgroups
- Integrated tracking functionalities for dossiers
- Management and generation of Study Tagging Files
- Flexible filename handling that conforms to ICH and regional filenames
- Business Validator for FDA, EU (EMA approved), CH (Swissmedic approved), HR, eNTA, vNeeS
- Supported regional eCTD standards: EU, FDA, CA, CH, JP, HR
- Other supported standards: IMPD, CTA, NeeS
- Interim documents for paper publishing and compilation that allow compilation without having the final document ready
- Publishing Service (optional) publishes paper and electronic submissions locally in a global environment

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.

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.

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