

Product Information

# eCTDmanager™ Starter Package

Managing compliant eSubmissions based on different standards, comes with its own set of challenges including the need to understand and fulfill regional requirements. Some companies have to comply with these regulations globally while other life sciences companies only sell their products nationally. Compliance is essential for any size of life sciences company but with a lot of license models only offering global solutions, small organizations only submitting to one region often struggle with the associated costs for implementing such a solution. Therefore, EXTEDO has designed an eCTDmanager Starter Package that is designed to cure this pain.

## Benefits

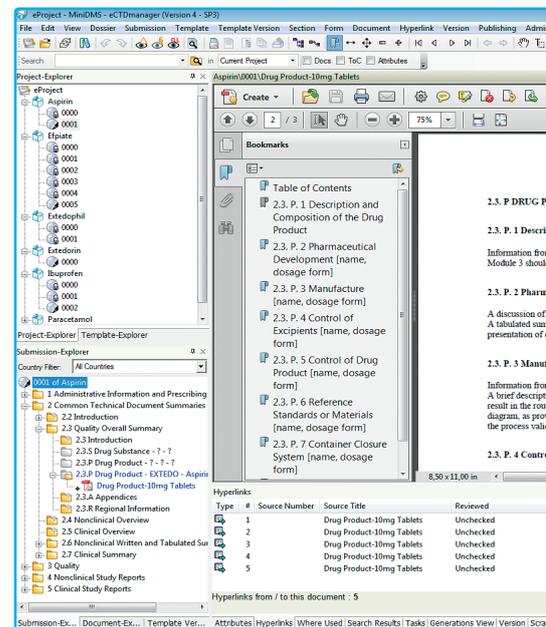
- Rapid compliance with latest regulatory changes in your region
- Significantly reduced costs compared to global licenses
- Ability to validate and publish submissions from a single application
- Improve submission quality and consistency
- Minimal hardware requirements
- Rapid deployment and system validation
- Minimum training

eCTDmanager is an off-the-shelf scalable all-in-one electronic submission management solution for eCTD and non-eCTD electronic and paper submissions. The tool enables users to easily build, view, validate and publish (electronic and paper) compliant submissions based on eCTD, NeeS, eCopy, IMPD, CTA, PIP, VNeS, DMF, ASMF and other regional formats.

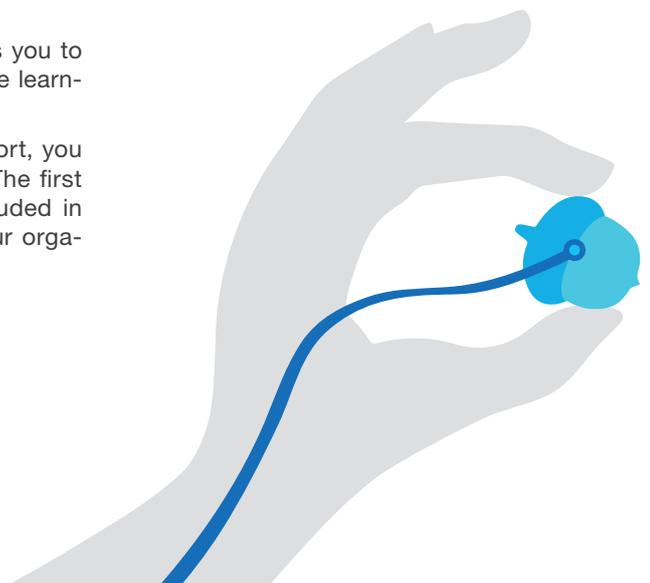
The eCTDmanager Starter Package is specifically designed to meet the needs of small, national life sciences organizations. It is a yearly on-premise subscription to eCTDmanager that enables one user to manage an unlimited number of sequences for a single region in all available submission formats. This allows companies submitting to national regions a cost saving, associated with the purchase of an electronic submission software solution. You can choose one of the following supported regions: Europe, South Africa, GCC, Canada, Japan, Australia, Thailand and Jordan. During the subscription period, you have access to all eCTDmanager updates including regulatory updates within your region.

The user guide and access to EXTEDO's eLearning platform allows you to complete a basic product training based on EU best practice. These learnings are easily transferable to your purchased region.

In case you require any kind of regulatory or software usage support, you can benefit from the EXTEDO customer support team expertise. The first 10 software usage and regulatory support cases are already included in the package. This approach ensures effortless compliance for your organization.



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

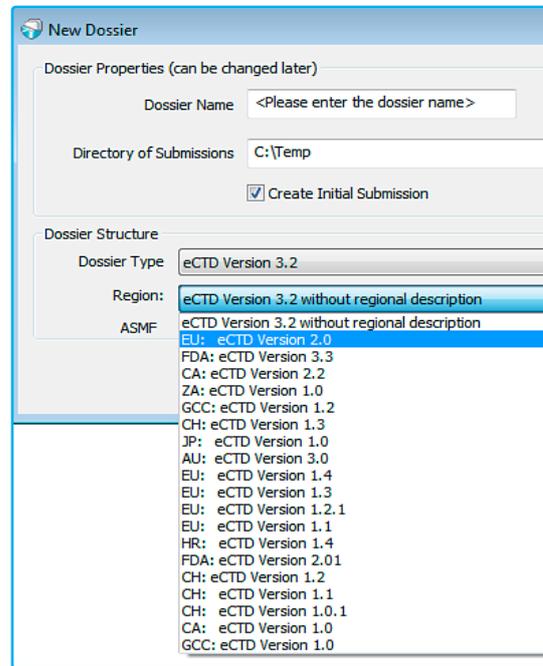


## Functional Overview

- › Design the user interface that works for you (Flexible Graphical User Interface)
- › Create initial and follow-up submissions with relevant documents including life cycle and metadata
- › Advanced Hyperlinking and Bookmarking Features
- › Pre-validation check
- › Export, import (single and batch) and validate eCTD submissions
- › Paper formats including Volume Definition, Format Templates, Tab Sheets and Cover Pages are supported
- › Search Functionality
- › Re-use of submissions and documents
- › Reviewing Features like Annotations or Highlights
- › Automated adaption of file names according the technical requirements, where applicable
- › Easy multi-Envelope handling (e.g. MRP/DCP in EU)
- › ASMFs & DMFs submissions are included. Applicant's Part / Restricted Part Concept for EU ASMF and CA Master Files
- › Dynamic Table of Contents for NeeS and Paper Submissions
- › Automated adaption of PDFs according technical specification, e.g. PDF version, activation of Fast Web View, setting default page layout.
- › Interim Documents as Placeholder
- › User Management to add/edit users, assign or create roles, assign permissions
- › Audit Trail accessible for the Administrator
- › Report Generation (Standard Reports included, Customized Reports possible)

## Technical validation

As the trusted validator used by more than 35 authorities around the globe, eCTDmanager goes beyond a basic eCTD submissions tool. The integrated validation function ensures compliance of the generated submission to ICH and regional specifications.



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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