

Product Information

eSUBmanager™

Reducing the complexity of viewing and reviewing electronic submissions

All regulatory submissions start their life as a series of discreet documents and metadata. These are formed into a structured submission before being validated, published, and transmitted to the authorities. This is a long and complex process involving many different individuals, working with many forms of content, using a variety of systems, over an extended period of time. Needless to say, working together on these can be incredibly complex and time consuming.

Benefits

- Access all submission content from multiple sources within a single, intuitive user interface
- Insights during submission preparation (with a connector to a publishing system)
- Multi-region and legacy versions of eCTD
- Prepared for new standards such as eCTD 4.0
- Server based deployment, high performance and minimum training

EXTEDO eSUBmanager delivers effortless management of regulatory submissions. Its modular approach provides a modern, end-to-end solution that improves the collaborative review process surrounding submission content and metadata in readiness for transmission to the publishing system.

Viewing from multiple sources

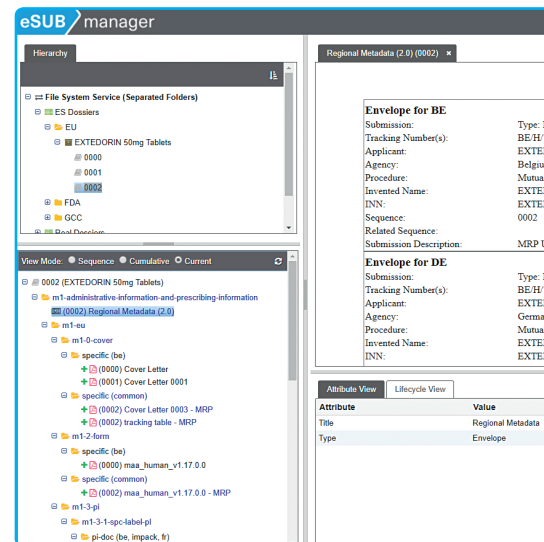
The structure of an electronic submission like eCTD is highly complex and tightly governed. eSUBmanager delivers a unified view of all folders, documents, and metadata that form submissions and applications, enabling users to quickly visualize their content. An application located on a connected common file system together with its content can be browsed instantly.

With no need to import applications or documents from their original source the cost and effort involved in transporting content is eliminated, and regulatory managers can see updates happening in near real-time.

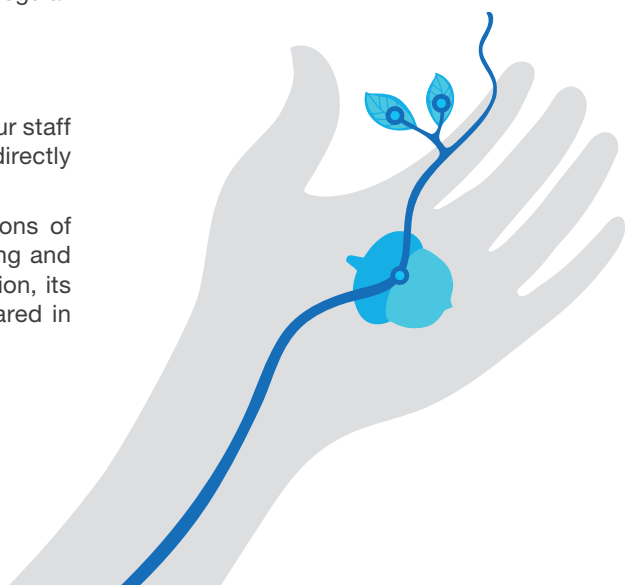
Comprehensive collaborative reviews

Using its web-based content viewer module, eSUBmanager allows your staff to quickly read and mark-up any documents within a submission directly without the need to have specific editing software installed.

Its integrated viewing technology streams only the requested sections of content directly to a viewer's web browser, enabling optimized viewing and mark-up without the need to download the entire document. In addition, its collaborative mark-up tools enable suggestions to be made and shared in real-time, without requiring direct edits on the original content.



Display a whole MRP Envelope as a single page



Functional Overview

eSUBmanager is modular software, its component parts provide the following key capabilities to support production of your electronic submissions, including:

- › Browsing within file shares to locate the application to be viewed
- › Easily navigate around the structure of a submission in different view modes (single sequence, cumulative and current view of the application)
- › Browse, read and review the contents of documents within submissions

Improved dossier management

During production, documents are added into the submission structure from numerous master sources. Typically, these systems are separate from the main submission management platform and host their own preparatory structures. If not properly controlled this can mean that structures differ, and updates between the systems is a manual user process. This can result in a delay and can be highly error prone, especially when update rates are high.

Using eSUBmanager, your regulatory management staff, as well as other interested groups within your company, can review the entire structure of submissions using just their web browser.

Planning the path ahead

In addition to content in production it is highly likely that there are numerous documents that you know will have to be written, but at this time are not in a position to create. Using future eSUBmanager document placeholders, it will be possible to insert planned content into the submission structure before it is authored. Placeholders contain meta-information about the forthcoming document, or section within the submission, to enable regulatory affairs, operations and managers to instantly identify content that needs to be completed before a submission can be finalized.

User experience is king

Built with simplicity at its heart eSUBmanager is a completely web-based solution designed for the modern IT environment. It is simple to deploy across your company and requires minimal end-user training. Being prepared for eCTD 4.0, it also ensures that your company is able to transition and utilize forthcoming standards as soon as they are approved.

eSUBmanager is the online review solution for modern life sciences companies, ensuring effortless collaboration around regulatory submissions.

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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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