eSUB manager

EXTEDO
eRegulatory Affairs

Product Information

eSUBmanager™

Reducing the complexity of viewing and reviewing electronic submissions

All regulatory submissions start their life as a number of discreet documents and fragmented 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 stakeholders, working with multiple types 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

› Save time identifying multiple dossiers of interest, by easily searching on metadata
› Centralized overview of regional submissions compiled by local affiliates
› Optimized simultaneous collaboration between publishers and reviewers via in-progress submission access
› Effortlessly view submissions with full lifecycle support
› Do you see what I see? – 35 regulatory agencies worldwide use EXTEDO technology
› Supports global regulatory standards such as eCTD 3.2 and eCTD 4.0, as well as legacy versions of eCTD
› Available as inhouse or hosted solution

EXTEDO eSUBmanager improves the collaborative viewing and reviewing process surrounding submission content and metadata in readiness for transmission to the publishing system.
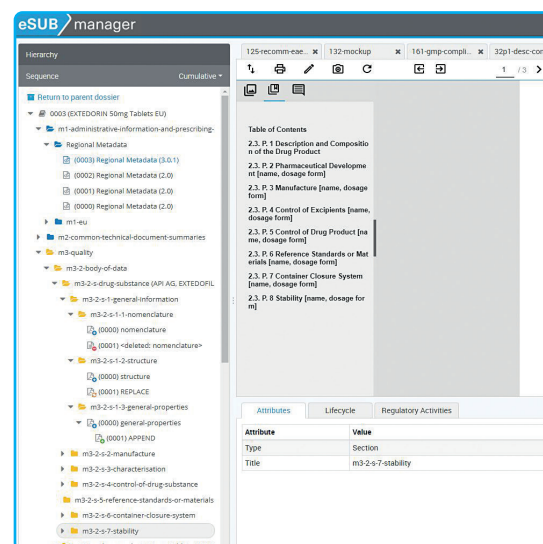
One consolidated view from multiple sources

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.

Comprehensive collaborative reviews

Using its web-browser based viewer, 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.

Functional Overview

⟩ Plan your eCTDmanager submission content
⟩ 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
⟩ View and review in-progress submissions compiled in eCTDmanager
⟩ Compare document lifecycles
⟩ Easily create, edit, filter and consolidate annotations within documents
⟩ Quickly identify documents with full-text search
⟩ Ensured system access security with two-factor authentication
⟩ No VPN required
⟩ Effortlessly filter your dossiers using metadata and our powerful search
⟩ Easily navigate to recently viewed 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 key

Built with simplicity at its heart eSUBmanager takes away the burden and let's you concentrate on what's most important – high quality dossiers.

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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 1000 maintained customers across 65 countries to deliver Effortless Compliance™.

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