

Product Information

DOCmanager™

Reducing the effort of managing multi-region product dossiers

The process of marketing pharmaceutical products in multiple countries comes with its own set of complex challenges. Selling a product or ingredient to different customers operating in separate countries and/or regions means that you have to prepare and manage multiple submissions that are compliant with the regulatory requirements of each particular country/region.

Benefits

- Creation and efficient maintenance of many child dossiers based on one parent dossier
- Reduces update times for variations
- Ensures that any changes introduced in the parent dossier are automatically inherited by the child dossiers
- Ease in handling open and restricted information in dossiers (e.g. EU ASMF)
- Reduces error rate through automation
- Reduces costs and streamlines the process of managing submissions

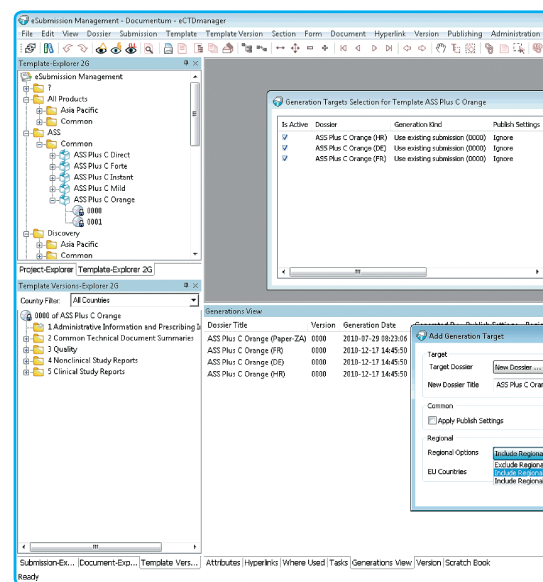
With submission requirements differing from region to region, the process of creating and managing submissions on a global scale can be complex and costly. While much of the information required within each submission is universal, it is common that certain elements apply only to specific regions or countries. In addition, the lifecycle of a submission may vary from region to region, meaning that documents may need to be independently replaced, added or deleted across many different countries.

Active pharmaceutical ingredient manufacturers face a similar challenge when preparing submissions for different authorities in various countries. Selling just one active substance to 5 customers that operate in 5 countries means managing 25 dossiers in parallel. Dossiers can evolve into different versions for internal use and customer use, thus handling multiple dossiers becomes even more complex task.

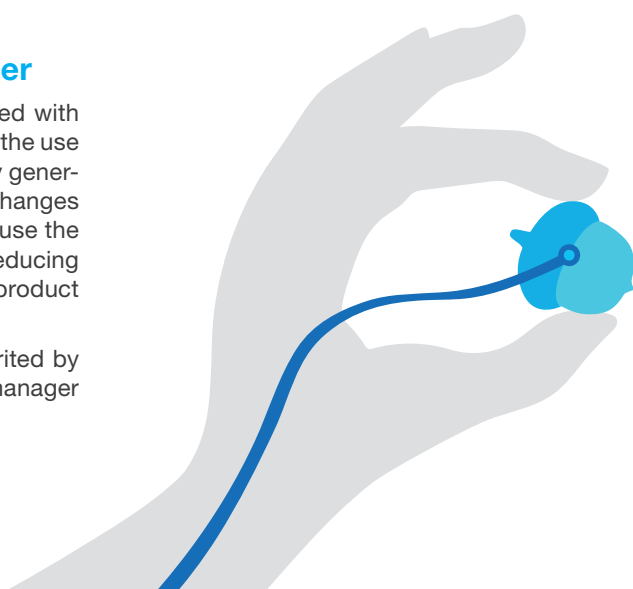
Streamlining global submissions with DOCmanager

EXTEDO's DOCmanager helps you address the challenges associated with creating and managing submissions across multiple regions. Through the use of a parent-child dossier concept DOCmanager enables you to readily generate templates for multiple submissions through simple country level changes whilst keeping common data managed at a product level. You can reuse the content for dossiers based on different submissions scenarios, thus reducing the efforts associated with compiling and maintaining multi-region product dossiers.

Any changes you make to the parent dossier are automatically inherited by the child dossier, thus eliminating the need for revalidation. DOCmanager



Handling a large number of dossiers



Functional Overview

The following provides a high-level overview of DOCmanager's key features:

- › Allows creation of parent dossiers using dossier templates.
- › Sophisticated algorithm that ensures that all changes are rippled-down into child dossier, including eCTD lifecycle, hyperlinks, M1 envelope and STF information
- › Supports creation of a new submission within a dossier and merging changes into existing submissions
- › Easy navigation between parent and children dossiers
- › Conflicts in generation are maintained in a task list. A generation protocol is created and stored for later access.
- › Distinct user rights and permissions ensure maximum security of dossiers
- › Uses the Document Query concept and document placeholders that will be resolved upon submission generation

supports the European MRP and DCP procedures, thus enabling you to update individual submissions or create group updates.

In addition, DOCmanager enables you to create inter- and intra-document hyperlinks as well as print publishing templates that are maintained on the parent dossier and can be passed on to child dossiers. This allows you to manage changes at any level by simply inserting a single change and then passing it on to all child dossiers.

By using Document Queries you can search for documents with specific metadata and place these documents automatically into the eCTD structure within eCTDmanager.

Used by SMBs and multi-national companies around the globe, DOCmanager is the proven solution for efficiently managing regulatory submissions in multiple regions. It saves time, reduces your costs, and eliminates the errors associated with traditional manual dossier management techniques.

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