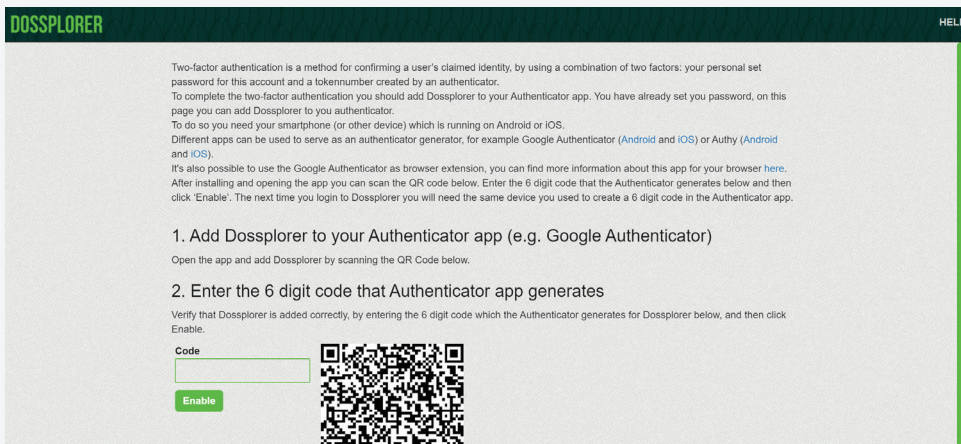# Dossplorer

Viewing Matters!

More than just an eCTD Viewer

Create transparency, consistency, and instant analysis, with our leading cloud-based technology.

Dossplorer™ is an advanced, cloud-based dossier management solution which eliminates manual steps in the exchange of regulatory dossiers and allows you to share, view, review and analyze eCTD, NeeS and other dossier formats from any region and access them in any location.

Unlock and explore the true value of your regulatory dossiers in a safe and secure, web-based eCTD management tool.
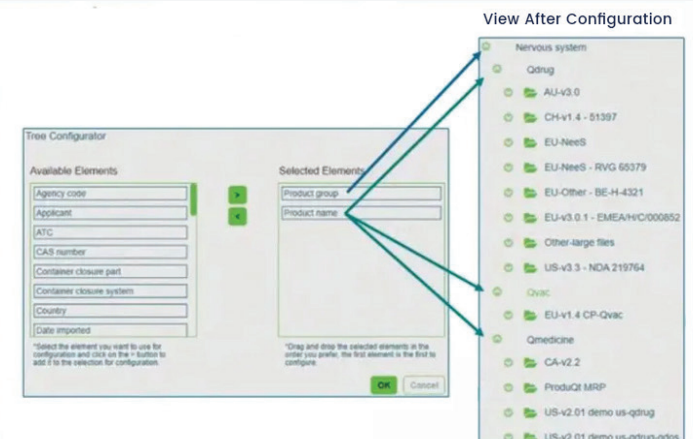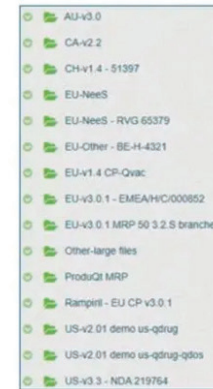
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Extra Layer of Security & Protection with Two-Factor Authentication

To ensure the security of user accounts, Dossplorer uses a two-factor authentication method for access control. To help monitor and safeguard sensitive information, a user needs to enter a personal password for the account and a token number is created by an authenticator to confirm claimed identity.

Import Dossiers in Dossplorer eCTD Viewer

Unlock the true value of your information assets automatically with enriched metadata - extracted directly from your submission. Dossplorer functions as your own safe repository to import full applications and individual submissions. Additional metadata can be added manually as part of the import process, capturing regulatory information belonging to the application, regulatory activity and/or sequence.

Unique Views on eCTDs

Easily compare documents across different strengths, dosage forms and manufacturers with current and cumulative views on individual regulatory activities and merge branches (e.g. 3.2.P branches for drug products or 3.2.S branches for drug substances) into a single branch.

Explore Across Dossiers & Products

Uncover a holistic view across products and applications worldwide. Dossplorer provides a consolidated view across dossiers in a single CTD structure, allowing for easy comparison of content and data across multiple eCTDs and enabling the metadata to indicate to you the different purpose of the documents.

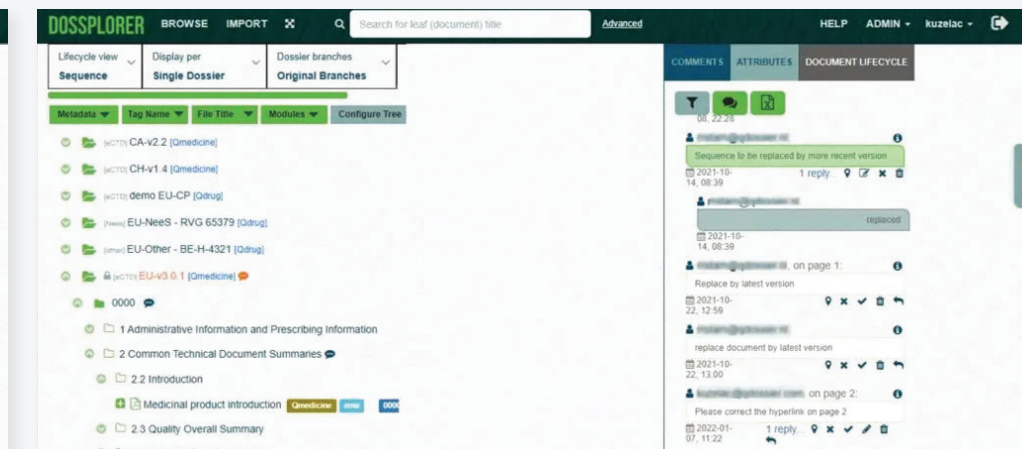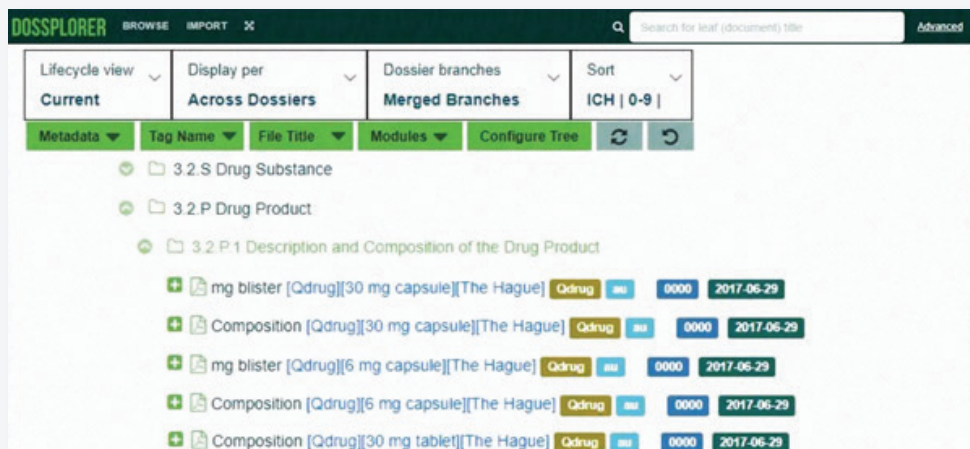## Collaborate with your Peers, Review & Add Comments to Dossiers

Review and support eCTD life cycle management, submission publishing and internal review workflows in Dossplorer, adding comments to various dossiers, including eCTD and NeeS. For example the status can be displayed as 'open', 'resolved' and 'closed'. Data can also be exported to Excel.

Personalized Navigation Tree

Personalize the navigation tree utilizing metadata already present in your dossiers, making the process much more efficient. For example, the tree configurator allows you to change the hierarchical organization of dossiers and setting views, to make the view fit for your purpose. Expanded nodes and selected metadata are also stored and available after re-login.

Dossplorer Xchange Bot & Automated Import Agent

Save time with our instant and automated import agent. Dossplorer Xchange Bot scans for new dossiers and sequences published on the connected network locations and the automatic import agent detects the submissions and imports them automatically. Dossplorer only stores references to the files rather than duplicating the physical content.

Intuitive Full Text Search Functionality

Unlock the full potential of regulatory dossiers and bring greater efficiencies to eCTD compliance with intuitive full text search functionality and enhanced AI. The advanced search module enables users to find documents and registrations in seconds and filter searches as required. The functionality also makes it easier to identify and assess where a certain substance or manufacturer has been referenced previously, enabling users to create transparency, consistency, and reusability across regulatory dossiers.

Regulatory Data Tracking

Enrich your dossiers with relevant metadata for improved oversight. Index.xml and submission envelope data are extracted automatically for submissions. Additional metadata can be added on both an application and sequence level, and inherited by all documents.

Multiple Dossier Formats Supported

Streamline the process by viewing any file and folder structure in one place. Dossplorer is more than just a eCTD and NeeS viewer; you can import virtually any regulatory dossier, including medical device dossiers, CTA dossiers, Paediatric Investigation Plans (PIP) and Investigational Medicinal Product Dossiers (IMPD). Local eCTD specification updates resulting in an updated DTD are typically supported by configuration only. As a result, software application updates and corresponding deployment and validation efforts are limited to a minimum.

Advanced Restrictions

Our advanced security permissions enable you to apply node restrictions to sequences or sections within a dossier to limit access - allowing you to restrict specific content such as non-blinded clinical study data or confidential details about quality and manufacturing to a limited group of users.

Regulatory Data Enrichment

Keep your regulatory data well-organized and up to date using 'Metadata import-export' functionality. This feature allows you to export all your dossiers to your applications and sequences metadata in your legacy dossiers to Excel, giving you the ability to bulk import the changes in the single iteration, to avoid manual updates.

Hybrid-cloud, Full Cloud or On-Site Architecture

Take advantage of our latest benefits in real time with our hybrid cloud / on-site solution, which offers you cloud-based software as a service - while keeping your data securely stored on-site or in a virtual private cloud. Alternatively, Dossplorer can be installed as a full on-site solution. All you need is a web browser, such as Chrome or Edge to connect, without any local installation required.

eCTD Viewer with Single Sign-on Solutions

Safe and secure access to Dossplorer can be facilitated with single sign-on applications, such as Okta, PingFederate and Microsoft 365.

Why Choose **Dossplorer?**

Intuitive Full Text Search Functionality

- Find documents and filter searches in seconds, using the advanced search module. The advanced search module scans the full content, and the metadata enables users to find documents and registrations instantly.

20+ Unique Views of your Dossiers
(Including Across-Dossiers view)

- Holistic view across products and applications worldwide allows for easy comparison of content and data across multiple eCTDs.

Dossplorer Xchange Bot & Automated Import Agent

- Avoid manual steps with the automatic transfer and import of applications and submissions to the Dossplorer private cloud.

Personalized Navigation Tree

- Group applications in any logical order using the navigation tree configurator.

Metadata at Leaf Level

- See documents in context by selecting relevant metadata displayed behind each leaf.

Import any File & Folder Structure

- Import any regulatory application, such as volumised PDFs, CTAs, IMPDs, PIP and Medical Devices.

Document Translator

- The built-in translation functionality enables instant translation of your documents to and from more than 100 languages.

Ready to demo Dossplorer with your team?

CONTACT US!

info@celegence.com

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