

# LIQUENT INSIGHT<sup>®</sup> VIEWER

eCTD VIEWING, REVIEWING AND COLLABORATION CAPABILITIES.



## WHAT YOU CAN DO

- Easily locate submission materials
- Navigate seamlessly through your dossiers
- View individual eCTD sequences
- Search for submission components
- Share comments and information
- See the eCTD exactly as the agency does
- Share your documents efficiently throughout your organization

## HOW YOU BENEFIT

- Single point of access to all eCTD documents
- Robust search capabilities
- Submission library capabilities
- Secure access from any internet connection

## THE UNIQUE ALL-DEPARTMENTS SUBMISSIONS VIEWER

One of the reasons why your organization may be hesitating to move to the electronic Common Technical Document (eCTD) format is the difficulty of sharing lifecycle-centric submissions materials internally.

However, if you delay your transition to eCTD, you also delay realizing the long-term benefits of its adoption and increase your risk of non-compliance, since more and more regulatory authorities now prefer this format. Some even mandate it.

*Liquent InSight<sup>®</sup> Viewer* is a unique submissions viewer solution that enables regulatory submissions content to be shared throughout your entire organization.

Its intuitive, simple-to-use viewing platform supports Web-based review, collaboration and information sharing of eCTD files, without making any modification or additions to the archived submissions.

## WHEN BUILDING YOUR ECTD

*Liquent InSight Viewer* provides viewing and reviewing capabilities for in-process submissions, streamlining the production and internal approval process. You can distribute parts of your submission as they are finished, aiding collaboration, completeness and quality checking.

## AFTER APPROVAL OR DISPATCH

By enabling you to distribute the same components of the dossier that were approved by or sent to the agency, you can ensure your entire organization has access to up-to-date submission information and help to promote migration from paper-based to eCTD approvals, and your organization's move to eCTD submissions. You can answer agency questions, plan for new indications, and make product decisions based on archived submission data.

## CREATE A SUBMISSIONS LIBRARY

With *Liquent InSight Viewer*, you can create a submissions library containing not just all supported eCTD formats\*, but legacy electronic submissions (such as eNDA, eBLA, eIND, FDA eSubmissions according to the 1999 guidance, European electronic submissions and medical device submissions) and electronic copies of paper volumes.

Simple product navigation enables you to navigate through products, applications, and sequences stored in the submissions library with the minimum of fuss. Its intuitive hierarchical outline means that product submission histories are easy to discern and follow.

\* Supported eCTD types include: eCTD ICH eCTD 3.2, eCTD STF 2.2 DTD/2.6 Specification, eCTD JP Regional M1 1.0, eCTD EU Region M1 1.0, eCTD EU Regional M1 1.1, eCTD EU Regional M1 1.2.1, eCTD US Regional M1 2.01, eCTD CDN Regional M1 1.0.



**COMPREHENSIVE INDEXING, SEARCH, HELP AND SECURITY FACILITIES**

A powerful, integrated indexing and search facility helps you to retrieve information quickly and accurately across all submission types, no matter how demanding your search criteria.

It includes full-text document searching, metadata searching, and comment searching, all from a single, easy-to-use form. Results are ranked in order of relevancy.

Navigation through documents is easy, since *Liquent InSight Viewer* retains all the bookmarks and hyperlinks that appeared in the published output.

With comprehensive help files and an online user manual, each of your users is guided clearly through all aspects of installation, configuration, and day-to-day use.

The security features in *Liquent InSight Viewer* enable you to restrict access to submission material to the intended users only.

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