



## HOW YOU BENEFIT

- **Simplification** – Robust functionality without the complexity
- **Modularity** – Select only what is right for your organization
- **Scalability** – The flexibility to grow along with your business
- **Usability** – Intuitive user interface for rapid productivity
- **Speed** – Get to market faster than your competition
- **One** – A single, global platform for regulatory information management

## WHAT YOU CAN DO

- Manage the entire regulatory information lifecycle effectively
- Efficient creation and management of regulatory dossiers
- Improved organizational compliance
- Increase teamwork, reuse planning and collaboration
- Enhanced internal delivery capability for eCTD
- Manage dossier distribution and review
- Reduced compliance risk

A CENTRALIZED, GLOBAL VIEW OF REGULATORY INFORMATION

# LIQUENT *InSight*®

## YOUR SINGLE AUTHORITATIVE SOURCE FOR REGULATORY STRATEGY

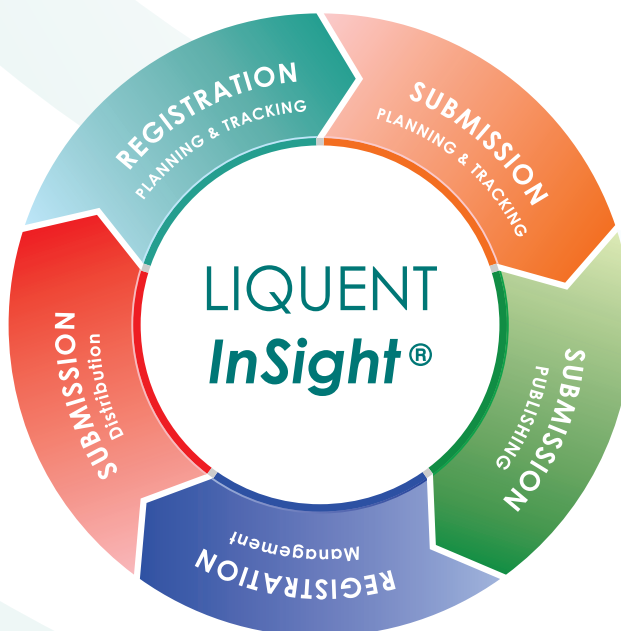
As life sciences organizations are mandated to move to electronic submissions, tracking, viewing and publishing regulatory information has become an increasingly difficult task to complete. No matter the size of your organization, managing regulatory information provides a unique set of challenges. LIQUENT *InSight*® was developed to resolve these challenges.

LIQUENT *InSight*® was created to provide a centralized, global view of product details, dossiers, and submissions, while tracking and planning your information, to support collaboration and compliance requirements for any size life sciences organization. InSight was designed to support the entire electronic regulatory submission process, from authoring documents, publishing PDFs and preparing clinical data, through compiling and validating eCTD, Non-eCTD Electronic Submissions (NeeS) and for the agencies that still require it, paper submissions.

LIQUENT *InSight*® is a collection of individual software modules integrated to provide a complete solution offering comprehensive publishing, compilation, review, printing, submission planning, process management and registration tracking capabilities for companies of all sizes. LIQUENT *InSight*® consists of:

- LIQUENT *InSight*® for Registrations
- LIQUENT *InSight*® for Submissions
- LIQUENT *InSight*® for Viewing

Together these modules form LIQUENT *InSight*®, the industry's leading regulatory management software solution.



# LIQUENT

## LIQUENT *InSight*<sup>®</sup> for Registrations

### KEY BENEFITS

- ➔ Effectively managing and tracking product registrations
- ➔ Sophisticated project planning tools
- ➔ 21 CFR Part 11 compliance, audit trail & configurable security features
- ➔ Automatically identify and initiate assemblies for all required submission updates
- ➔ Easy-to-use web interface with 'zero footprint' desktop install

LIQUENT *InSight*<sup>®</sup> for Registrations provides regulatory planning, product detail management and project planning.

LIQUENT *InSight*<sup>®</sup> for Registrations incorporates the planning and tracking of new and existing registrations, provides step-by-step guidance through the process of updating those registrations, offers a range of invaluable communication tools to assist in effectively managing and tracking product registrations, and includes an approval wizard guide and email notification system. In addition, LIQUENT *InSight*<sup>®</sup> for Registrations contains sophisticated project planning tools that help track, manage and analyze information to ensure regulatory submissions are compliant and delivered on time.

Before, during and after market approval, LIQUENT *InSight*<sup>®</sup> for Registrations is critical in enabling you to track the status of your documents. It incorporates the planning and tracking of new and existing registrations and provides step-by-step guidance through the process. Additionally, LIQUENT *InSight*<sup>®</sup> for Registrations offers a range of invaluable communication tools to assist in effectively managing and tracking product registrations, and includes an approval wizard guide and email notification system.

## LIQUENT *InSight*<sup>®</sup> for Submissions

### KEY BENEFITS

- ➔ Enhance your organization's efficiency, reduce your time to market
- ➔ Streamline your entire submission process by using a single assembly of documents to produce both your electronic and paper submissions
- ➔ Easily manage subsequent amendments, supplements and variations to your submissions using intuitive right-click menu options and simple drag and drop features
- ➔ Create multiple submissions in multiple regions using comprehensive, built-in templates

LIQUENT *InSight*<sup>®</sup> for Submissions simplifies, automates, and accelerates the entire regulatory publishing process enabling you to reduce your time to market. Offering the richest functionality, powerful tools, and a single, easy-to-use interface, it enables you to quickly and easily create, review, and amend regulatory dossiers and submit them for market approval.

The LIQUENT *InSight*<sup>®</sup> Platform system allows you to track the status of your regulatory submissions that often need to be amended to multiple regions and other subsequent submissions.

Submissions wizards enable you to streamline the initiation of submissions that comply with all current regulatory agency requirements, as stipulated in the eCTD guidelines and specifications, and supports NeeS (including vNeeS and ACTD). LIQUENT *InSight*<sup>®</sup> for Submissions contains a self-auditing database that has been specially designed for 21 CFR Part 11 compliance, as well as audit trail configurable security features and validation scripts.

## LIQUENT *InSight*<sup>®</sup> for Viewing

### KEY BENEFITS

- ➔ Easy to use interface
- ➔ Access to TOC and lifecycle history
- ➔ Intelligent caching, filters and refreshing techniques reduce load time
- ➔ Role-based security
- ➔ Filtering capabilities, which provide you to subset submission content

LIQUENT *InSight*<sup>®</sup> for Viewing is a unique submissions viewer solution that supports Web-based review, collaboration and information sharing of eCTD files allowing for each department involved to access their portion of a submission.

Throughout the entire organization, colleagues need to review and research currently-approved or currently-submitted regulatory submissions content — product representatives, agency liaisons, quality assurance professionals, legal and patent managers, and more. Although the eCTD format is technically complex, the intuitive and simple-to-use viewing platform of LIQUENT *InSight*<sup>®</sup> for Viewing makes it possible to distribute this information broadly and effectively.

LIQUENT *InSight*<sup>®</sup> for Viewing has a rich, easy-to-use Web interface that has a zero footprint desktop install and requires no plug-ins, ActiveX controls, or Java applets. It is driven purely by the eCTD's and other viewable submission types underlying XML backbone and regional XML files. LIQUENT *InSight*<sup>®</sup> for Viewing enables collaboration while making no modification or additions to the archived submissions.