

# LIQUENT INSIGHT<sup>®</sup>

A CENTRALIZED, GLOBAL VIEW OF REGULATORY DOCUMENTS AND SUBMISSIONS



## WHAT YOU CAN DO

- Manage the entire regulatory information lifecycle effectively
- Increase teamwork, reuse planning and collaboration
- Improve organizational compliance
- Reduce compliance risk
- Manage internal or external documents
- Enhance internal delivery capability for eCTD
- Realize departmental efficiencies

## WHEN YOU BENEFIT

- Planning product registration and commercialization
- Creating and managing regulatory dossiers

## COVERS THE ENTIRE REGULATORY INFORMATION LIFECYCLE



*Liquent InSight*<sup>®</sup>, the latest generation of regulatory solutions from Thomson Reuters, provides a centralized, global view of product details, documents, and submissions to support collaboration, compliance requirements and the eCTD.

Together, these solutions help reduce compliance risks and provide maximum revenue opportunities by ensuring that products are on-track for market approval, and properly maintained over their lifecycle.

Each of the three components of the *Liquent InSight* suite — *Liquent InSight Manager*, *Liquent InSight Publisher* and *Liquent InSight Viewer* — can work independently, but are much more beneficial when integrated and deployed across your enterprise.

Together, they support the entire regulatory product management lifecycle from the early planning of registration targets through to product retirement.

## LIQUENT INSIGHT MANAGER

*Liquent InSight Manager* is invaluable for regulatory planning, product detail management, dossier creation, dossier management and project planning.

It 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, it contains sophisticated project planning tools that help track, manage and analyze information to ensure regulatory submissions are compliant and delivered on time.

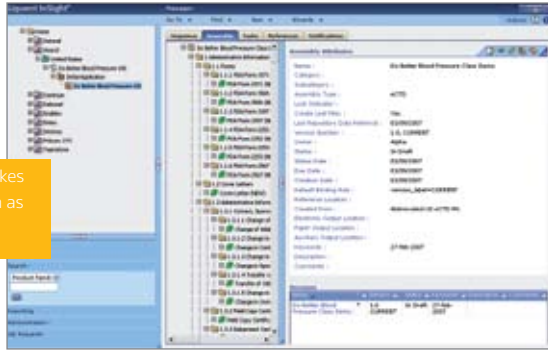
Before, during and after market approval, *Liquent InSight Manager* is critical in enabling you to track the status of documents and regulatory submissions that often need to be amended for multiple regions and other subsequent submissions. When changes to product characteristics occur, *Liquent InSight Manager* automatically identifies and initiates assemblies for all required submission updates.

*Liquent InSight Manager* has an easy-to-use web interface with 'zero footprint' desktop install — it requires no plug-ins, ActiveX controls or Java applets. It uses a self-auditing Oracle<sup>®</sup> database specially designed for 21 CFR Part 11 compliance, as well as audit trail, configurable security features and validation scripts.



The simple web interface of *Liquent InSight Manager* makes it quick and easy to navigate your submission tasks.



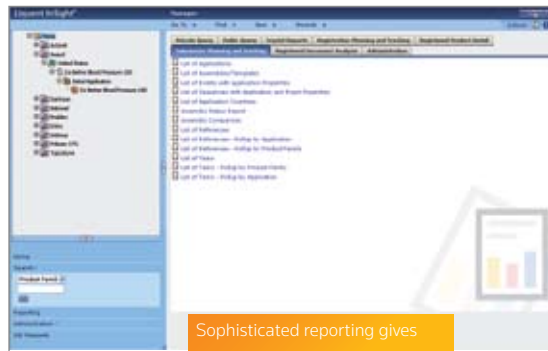


*Liquent InSight Publisher* takes the hassle out of tasks such as assembly and publishing.

### LIQUENT INSIGHT PUBLISHER

Built on industry-leading eCTD expertise, *Liquent InSight Publisher* addresses the complex details of lifecycle linking, XML creation, and paper requirements.

*Liquent InSight Publisher* addresses all the traditional submission product requirements you would expect, but also introduces new process advantages for smaller submissions and submission updates. For example, regionally related submissions (such as variation targeted to multiple markets) can be planned, assembled, published, and reviewed simultaneously.



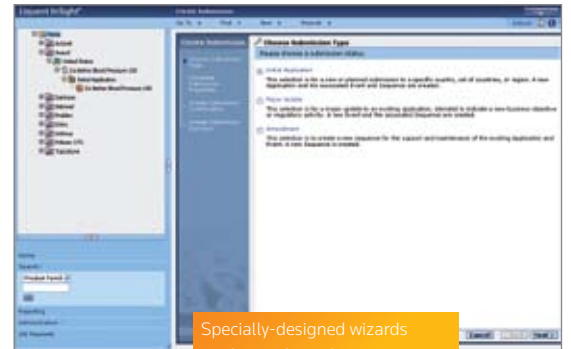
Sophisticated reporting gives you instant access to your current and archive submissions.

### LIQUENT INSIGHT VIEWER

*Liquent InSight Viewer* is a unique submissions viewer solution that supports Web-based review, collaboration and information sharing of eCTD files.

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 Viewer* makes it possible to distribute this information broadly and effectively.

*Liquent InSight Viewer* is driven purely by the eCTD's underlying XML backbone and regional XML files. It enables collaboration while making no modification or additions to the archived submissions.



Specially-designed wizards guide you through submission creation.

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