



PAREXEL® INFORMATICS

LIQUENT INSIGHT®

Regulatory Information Management



AN INTEGRATED REGULATORY INFORMATION MANAGEMENT PLATFORM

FROM RESEARCH TO RELEASE, LIQUENT INSIGHT® IS THE RIGHT CHOICE FOR REGULATORY INFORMATION MANAGEMENT

The LIQUENT InSight® platform is the only proven end-to-end, integrated Regulatory Information Management (RIM) platform available in the market today. LIQUENT InSight provides our clients with the robust submission planning, publishing, viewing and registration management capabilities necessary to quickly get their products to market and effectively maintain them throughout their lifespan. Each of the modules is a proven leader in its own right, and whether used in combination or as stand-alone applications, they offer robust and practical solutions that are firmly rooted in solving key problems faced by today's life sciences customers.

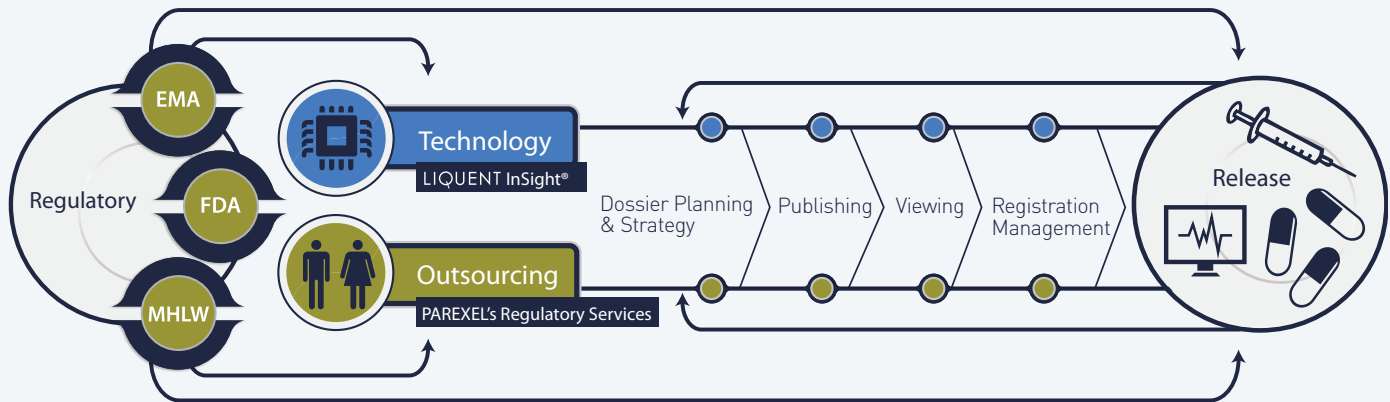
Since the market introduction of LIQUENT InSight in 2004, over 40 companies (including 10 of the top 20 pharmaceutical companies) have selected the LIQUENT InSight platform as their single, authoritative source of regulatory information. LIQUENT InSight is invaluable for regulatory planning, product detail management, dossier creation, dossier management, project planning and more.

Its publishing solutions offer the richest and most powerful tools to enable the rapid creation, review and submission of regulatory dossiers. LIQUENT InSight is built on high-performance, enterprise scale technologies, and its zero-footprint web interface streamlines installation.

LIQUENT INSIGHT RIM COMPONENTS:

- LIQUENT InSight for Submission Management™
- LIQUENT InSight for Registrations™
- LIQUENT InSight for Publishing™
- LIQUENT InSight for Viewing™
- LIQUENT InSight for XEVMPD™

Regulatory Information Management - Powered by LIQUENT InSight®



LIQUENT INSIGHT FOR SUBMISSION MANAGEMENT™

Simplifies the dossier planning process and accelerates regulatory submission development.

Features:

- Create submission plans that include document placeholders prior to authoring
- Assign new documents to the proper locations within the plan
- Define and view version binding rules for documents used in the submission
- Track the progress of submission content throughout the authoring phase
- Easily determine the submissions in which specific documents are used
- Define milestones for each submission sequence and track planned versus actual dates
- Order and group standard milestones to create Event Plans that ensure consistency, accuracy and on-time delivery
- Streamline processes and increase efficiency by publishing submissions directly from the plan

LIQUENT INSIGHT FOR REGISTRATIONS™

A one-of-a-kind application built specifically for the centralized collection, management and tracking of detailed product information, registrations and authorizations.

Features:

- Increase global coordination and collaboration between departments and affiliates by sharing a common authoritative information source
- Manage submission projects that span multiple applications-information is entered once and replicated as appropriate
- Track the status of the regulatory commitments and correspondence required to keep products on the market
- Leverage electronic notifications to alert users of critical information updates
- Gain visibility into registration activities and product detail information through robust querying and dashboard reporting
- Quickly and accurately answer questions regarding all regulatory activities



LIQUENT INSIGHT FOR PUBLISHING™

Provides comprehensive and scalable submission publishing capabilities, enables global simultaneous submissions, and produces output that is compliant with all current regulatory agency requirements.

Features:

- Leverage submission wizards to accelerate the creation of compliant submissions
- Quickly create the necessary submission components including ICH, STF and regional XML files, leaf files, folder structures, and other required navigation aids
- Create electronic (eCTD and NeeS) and paper submissions using a common user interface
- Easily manage subsequent amendments, supplements and variations within the context of the full application through the intuitive user interface
- Create multiple submissions in multiple regions using comprehensive built-in templates
- Automatically transform documents in multiple file formats into enhanced PDFs with bookmarks and hyperlinks

LIQUENT INSIGHT FOR VIEWING™

A unique application that supports the web-based collaborative review of regulatory submission content throughout the enterprise.

Features:

- Review legacy, non-eCTD submissions and eCTD submissions
- Quickly locate submission content using both document content and metadata via sophisticated indexing and searching functionality
- Simultaneously review submission output and provide commentary without the risk of making any unintentional changes to content files
- Search, report and distribute review comments for resolution-making true collaborative review a reality

“LIQUENT INSIGHT FOR SUBMISSION MANAGEMENT™ PROVIDES VISIBILITY INTO CRITICAL SUBMISSION AND CONTENT DEVELOPMENT ACTIVITIES- ALLOWING US TO IDENTIFY AND CORRECT POTENTIAL PROBLEM AREAS EARLY AND KEEP THE PROJECT ON TRACK.”

CLIENT QUOTE



LIQUENT INSIGHT FOR XEVMPD™

An application to maintain product data, create compliant submissions and process agency acknowledgements required by EMA pharmacovigilance legislation.

Features:

- Effectively maintain the product information and controlled vocabularies via an application that supports standard create, read, update and delete operations
- Standardize and harmonize data sets that meet EMA requirements using a high-performance, pre-configured Oracle database
- Create the XEVPRM ZIP files for both initial and update submissions and submit to EMA via your gateway using the web-based Submission Wizard
- Process the EMA acknowledgement files and update the corresponding EV codes within the LIQUENT InSight for XEVMPD™ database using the web-based Acknowledgement Wizard
- Filter, locate, and extract XEVMPD data from LIQUENT InSight for Registrations™ and load it directly into LIQUENT InSight for XEVMPD

We are always available for a conversation.

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*WHEREVER YOUR
JOURNEY TAKES YOU,
WE'RE CLOSE BY.*

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