AN INTEGRATED REGULATORY INFORMATION MANAGEMENT PLATFORM

LIQUENT InSight® components:

- Registrations
- Submission Management
- Content Management
- Publisher
- Viewing
- Analytics
- Workflows
- XEVMPD
- IDMP
FROM RESEARCH TO RELEASE, THE LIQUENT INSIGHT® PLATFORM 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.

Since the market introduction of the LIQUENT InSight® platform in 2004, companies (including 18 of the top 20 pharmaceutical companies) use LIQUENT InSight® platform as their single, authoritative source of regulatory information. The LIQUENT InSight® platform 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. The LIQUENT InSight® platform is built on high-performance, enterprise scalable technologies, and its zero-footprint web interface streamlines installation.

As the market leading Regulatory Information Management solution, the LIQUENT InSight® platform has become the trusted authority for both Headquarter and Affiliate usage through a streamlined user interface that drives user adoption, enables improved communications through an alert notification system and ultimately answers business critical questions via enhanced reporting and analytics capabilities.
The PAREXEL® Regulatory Cloud powered by LIQUENT InSight® Software

VISIBILITY AND REPORTING
Improves decision-making with high-quality data, allowing you to focus on the most pressing issues maximizing productivity to achieve key milestones.

- Metrics and Reporting through the InSight Analytics Module

EASE OF INTEGRATION
Eliminates inconsistent data and unnecessary time and resources spent on integrations.

Integrations with:
- DMSs – Documentum, LiveLink, etc.
- Source Systems – SAP, etc.
REGULATORY CLOUD
Giving clients the ability to build an end-to-end industry-leading Content Management and Regulatory Information Management solution deployed in a dedicated, private cloud environment. Clients can implement end-to-end all at once or iterate by building in the cloud over time. Clients will benefit from a tried-and-tested solution to simplify today’s complex Regulatory landscape.

FEATURES:
• Enhanced regulatory workflow
  - Single solution for document tracking and approval with powerful submission planning, publishing, archival, and registration management that supports the lifespan of your documents and products
  - Easily track progress of authoring, upcoming submissions, and plan for future workload within the submissions space
• Stay current for less
  - Get the security of Full Lifecycle System Maintenance
  - Eliminates the burden of upgrades and validation
  - Reduced computer system validation costs for IQ and OQ and reduced hardware, software, data center infrastructure spend
• Peace of mind that your data is safe and secure
  - Identity-based security ensures only authorized people get access to the infrastructure and application resources they require
  - The highest levels of Network Security, Physical Security, and Application Security to protect against today’s threats
  - Comprehensive Backup, Failover, and Disaster Recovery procedures to guarantee your data is protected if the unexpected happens
  - Increased performance through virtualization of IT infrastructure onto a Scalable and Fault tolerant platform
• Configurability
  - LIQUENT InSight® an be configured or integrated to meet client-specific requirements
  - Future migration of applications and data into the client’s IT environment if necessary

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 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.”

PUBLISHER

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
• Be prepared for future submission formats such as RPS / eCTD 4.0
• Validate eCTD and NeeS submissions using InSight Validator, in accordance with Regional Agency specifications, creating comprehensive PDF reports for review and action

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

FEATURES:

- Review eCTD and non-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
- Automatically register and update eCTD submissions from file system and/or EDMS repositories
ANALYTICS

Provides extensive industry leading reporting and dashboarding capabilities across all of your LIQUENT InSight Regulatory Information.

FEATURES:

• Leverage operational data captured in InSight to make better informed business decisions

• Visualize data based off role and drill down from executive dashboards to detailed record reporting

• Define business critical metrics and indicators in order to objectively measure performance
WORKFLOWS

Enable Workflows to match business processes within LIQUENT InSight.

FEATURES:

• Create predefined workflows to ensure business processes are followed when working with data inside LIQUENT InSight
• Define workflows at multiple levels within LIQUENT InSight
• Flexibility to assign work based on groups, reassign based on workload or vacations
• Manage workload, track progress, assignments, and increase efficiency
• Track actual work time to determine issues, increase efficiency, and enable better, more accurate metrics
XEVMPD

Provides the ability to maintain product data, create compliant submissions and process agency acknowledgments required by EMA pharmacovigilance legislation.

FEATURES:

- Effectively maintain the product information and controlled vocabularies via 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
- Fully integrated into the wider RIM capabilities, including reporting, task management, etc.
**IDMP**

End-to-end integrated solution to facilitate critical IDMP requirements.

**FEATURES:**

- Implemented with full ISO IDMP Medicinal Product Data Model
- User interface to allow manual input of data where needed
- Provides extensive integration capabilities, enabling Sponsors to leverage multiple datasets from a single source
- Tight integration between Registrations and IDMP, enabling users to perform the right tasks at the right time
- Generate IDMP messages through automated event triggers
- Process the returned acknowledgements and providing intuitive actionable reporting of the results
- Provides an agile solution that can be quickly updated to meet agency changes and new submission requirements
WHEREVER YOUR JOURNEY TAKES YOU, WE’RE CLOSE BY.

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