

LIQUENT INSIGHT[®] MANAGER

A CENTRAL RESOURCE FOR PRODUCT REGISTRATION AND MANAGEMENT



WHERE YOU CAN USE IT

- Regulatory planning
- Product detail management
- Dossier creation
- Dossier management
- Project planning

WHAT YOU CAN DO

- Manage detailed product information
- Analyze worldwide product authorizations and registrations
- Track the regulatory compliance status of source documents
- Optimize resources
- Improve your time to market
- Decrease compliance risk
- Increase global coordination and collaboration
- Enhance your company's efficiency

IMPROVE AND SIMPLIFY REGISTRATION PLANNING AND TRACKING

Liquent InSight[®] Manager supports the entire regulatory product management lifecycle, from the early planning of registration targets through to product retirement. It contains a wealth of unique, invaluable communication tools to help you manage and track your product registrations effectively.

Through a single, central resource, you can easily maintain marketing authorization details for all current and planned products, including manufacturing and labeling details, commitments, licensing details, and registration status. E-mail notification features send reminders of approaching due dates and notify you that everything is progressing on schedule.

Liquent InSight Manager takes you step-by-step through the process of updating your registrations. An approval wizard guides you through every activity, marking them as complete and then creating or updating the registration license itself.

With *Liquent InSight Manager*, you can ensure your products are on track for market approval and are properly maintained over their marketing lifetime.

- Ensure that marketing launches and projected revenue are on schedule
- Track product or submission-specific correspondence
- Identify maintenance tasks
- Perform impact analysis of proposed or actual product detail changes to determine the effect on products and notification requirements
- Identify necessary submissions when product changes warrant action
- Maintain compliance as product, market, and regulatory conditions change

Liquent InSight Manager automates much of the project plan for you, so you can focus on tracking progress against plan, instead of worrying about the validity of the plan itself.



REGISTERED DOCUMENT ANALYSIS

Liquent InSight Manager enables you to create and keep track of multiple submissions in the post-approval environment, so you can benefit from considerable time and cost savings.

- Store and categorize all dossier and submission information relating to products, drug applications, business objectives, and submission sequences in a logical area
- Understand the historical composition of the sequences that make up a submission set
- Accurately determine the regulatory relevance of a source document to see if it should be used to initiate an update
- Quickly locate specific documents and answer agency enquires with confidence
- Identify which versions of which source documents are associated with registrations in each region
- Maintain compliance while reusing as many leaf documents as possible when making submissions in multiple markets
- Minimize the amount of manual data entry required for leaf attributes and associated XML files by having them automatically populated by the system
- Fully reuse all dossiers as templates or as the basis of new submissions
- Quickly import and export document collections and dossiers as virtual documents or XML

SECURE, EASY-TO-USE WEB INTERFACE

Liquent InSight Manager 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 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.

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