LIQUENT INSIGHT®
2016 COURSE CATALOG
PAREXEL's Education Services is committed to creating a learning environment that stimulates the participant's interest and encourages discussions and questions. This environment is established by implementing results oriented training by qualified instructors.

By participating in training, students gain confidence and develop skills. Education Services accomplish this by offering:

- Hands on examples of business applications
- Opportunities for independent exercises designed to reinforce instruction.
- Time for questions and answers
PAREXEL's Education Services is a comprehensive eRegulatory training service to assist our clients and users in developing their knowledge and skills in using and building our products and applications.

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THIS CATALOG LISTS ALL COURSES AVAILABLE. FOR ADDITIONAL INFORMATION, PLEASE EMAIL EDUCATIONSERVICES@PAREXEL.COM.

TRAINING DELIVERY INSTRUCTOR-LED TRAINING (ILT) DELIVERY

ILT features traditional classroom instruction, allowing for face to face interaction with the instructor, resulting in a student-centered, dialogue-driven learning environment.

ILT can be delivered through the following methods:

ON-SITE CLASSES:
Training for any course can be delivered at your site by our instructors. Email EducationServices@PAREXEL.com for more information.

PUBLIC CLASSES:
Schedules of courses available at https://www.parexel.com/solutions/informatics/education-services

PRIVATE CLASSROOM TRAINING:
Private Classroom training allows companies to schedule an entire classroom for exclusive use in either of our Education Centers: in Horsham (PA), or Uxbridge (UK).

Training features virtual demonstration and discussion by the instructor as well as student exercises and opportunities to practice skills acquired during the classes.

TRAINING DEVELOPMENT

CUSTOMIZED TRAINING

PAREXEL’s Education Services can create customized training to match your business processes and environment. Staff can learn specific features and functions and how the company plans to use InSight in each environment. Highly qualified PAREXEL Instructional Designers are available to produce training courses using your documents, data, templates and business processes.

CONFIGURED TRAINING

LIQUENT’s Configured Training program consists of materials and classes developed in partnership with the Client. The materials are based on standard LIQUENT training materials but using CLIENT terminology and screenshots, no consideration of specific CLIENT process is included. This training and development uses CLIENT configurations and the CLIENT training database.
ONLINE LEARNING

eLEARNING

Through our Learning portal, clients can access personalized online learning programs and learning resources.

Education Services currently offers a suite of online courses. These courses are designed as a series. Individual courses are also available for learners who wish to personalize their learning experience to a specific component or unit of instruction. All courses and packages are accessible to the student within a certain time period; Select from 30 days or 60 days. To inquire about current course offerings for all online courses delivered through the Education Services Learning Management System, please contact your Account Executive.

Benefits of eLearning:

• Users can learn at their own computer, without leaving the work site.
• Training may be completed in bite-size chunks, when and where it is needed.
• eLearning satisfies the training needs of a geographically dispersed workforce, without large investments in travel and living expenses.
• Training can be completed at the learner’s own pace.
• Interactive training activities allow users to develop and practice skills easily.
• Users are provided with a Certificate of Completion.

CUSTOM DEVELOPMENT

Education Services can customize your eLearning experience by designing courses for your business. Custom course development is available for all delivery styles including self-paced online modules, blended live and online courses. Custom courses can be deployed in your environment using: HTML, CD, AICC, SCORM 1.2 or single file executable. To inquire about custom development options, please contact EducationServices@PAREXEL.com.
REGISTRATION

Please register online at www.PAREXEL.com/liquent/courses. For questions about course availability, please email Education Services at EducationServices@PAREXEL.com.

Pre-registration is required, confirmation of registration will be sent via email.

RESCHEDULING/CANCELLATION

Course fees are refundable with at least 10 business days notice prior to start of class. Other cancellations are subject to a 50% cancellation fee. Substitutions may be made up to the start of class. PAREXEL reserves the right to cancel any training course due to insufficient enrollment or other events beyond our control by providing notice at least 5 business days prior to scheduled start date. The client understands and agrees that PAREXEL shall not be held responsible for any costs, including loss of airfare or other transportation, hotel costs, or any other expenses incurred.

Course dates, pricing and course locations are subject to change.

PAYMENT

PAREXEL provides three alternatives for payment:

Option One: Invoice. A purchase order is required for an invoiced registration. Please include all relevant purchase order information, as well as an accounts payable contact name, on the registration form.

Option Two: Payment by Check.

Option Three: Credit card. Registration is held until confirmation is received from your credit card company. We accept Visa, MasterCard and American Express.

Course fees will be charged in the currency of the training venue. Registrations in the U.S. may be subject to state sales tax. European registrations may be subject to local tax rates.

CLASS LOCATIONS

PAREXEL has two Education Centers:

United States: Horsham, Pennsylvania [the northern suburbs of Philadelphia].

Europe: Uxbridge, United Kingdom.

Information on local accommodations can be found at www.PAREXEL.com/liquent/courses.

CERTIFICATES OF COMPLETION

Students will receive a signed certificate at the completion of the course.

Note: PAREXEL will NOT be able to issue certificates due to student absence or for students who do not complete the full course.
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<td>LIQUENT InSight for XEVMPD®</td>
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LIQUENT INSIGHT®
FOR REGISTRATIONS
LIQUENT InSight® for Registrations

**PREREQUISITES**

- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Working knowledge of Microsoft Internet Explorer 9.0 or higher.

**PRIMARY AUDIENCE**

Clients responsible for tracking data associated with a planned pharmaceutical, medical device or veterinary registrations in a country or countries. Clients responsible for compliance with agency guidelines for existing product registrations.

**COURSE DESCRIPTION**

This interactive one and a half day course will introduce students to the features of the LIQUENT InSight for Registrations module. Students will learn to create key entities and enter data necessary to track the registration process for new and existing pharma, veterinary or medical device products.

**Topics**

- Understanding the InSight Data Structure
- Navigating InSight
- Working with Product Families
- Creating Products, Components and Active Ingredients
- Creating Applications, Events and Sequences
- Managing Event Status Values
- Post Approval updates to Applications
- Querying InSight

**DURATION/PRICING**

<table>
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<tr>
<th>One and a Half Day Class</th>
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*Prices will be charged in the local currency of the training venue, and may be subject to taxes.*
## LIQUENT InSight® Product Detail Management

<table>
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<tr>
<th>PREREQUISITES</th>
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</table>
| • Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.  
• Working knowledge of Microsoft Internet Explorer 7.0 or higher. | Clients whose responsibilities include tracking CMC and product details for approved, and pending approval, pharmaceutical, veterinary and medical device products. |

## COURSE DESCRIPTION

This interactive one-day course is only offered in conjunction with the 1.5 day InSight for Registrations module training. It introduces students to the features of the InSight Product Detail Management module, to create and track the granular, product information associated with Registrations.

### Topics
- Understanding the InSight Data Structure
- Product Detail Set Overview
- Creating PDS Templates
- Creating Component, Product Details
- Package Set Registration
- Managing Changes to PDS
- Querying InSight

## DURATION/PRICING*

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**LIQUENT InSight® for European Union Applications**

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<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
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| • Prior training in InSight for Registrations or InSight for Submissions.  
• Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.  
• Working knowledge of Microsoft Internet Explorer 7.0 or higher. | Clients whose responsibilities include planning and tracking multi-country European Applications. |

**COURSE DESCRIPTION**

This interactive half-day course introduces students to the management of European Applications in InSight. It introduces students to multi-country Applications, country and product tracking, Package Set Registrations registrations and the Sunset Clause report.

**Topics**

• Creating a Centralised Procedure (CP) Application  
• Creating and maintaining a Mutual Recognition Procedure (MRP) / Decentralised Procedure (DCP)  
• Tracking country status using Event-Country functionality  
• Package Set Registrations and Sunset Clause querying  
• Creating a European Clinical Trial Authorisation Application (CTA)

**DURATION/PRICING**

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# LIQUENT InSight® for Commitments & Correspondence

## PREREQUISITES

- Prior training in InSight for Registrations or InSight for Submissions.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Working knowledge of Microsoft Internet Explorer 7.0 or higher.

## PRIMARY AUDIENCE

Clients whose responsibilities include tracking agency commitments and correspondence, managers and employees who will assign/be assigned tasks in InSight, users who will create and maintain Notifications in InSight.

## COURSE DESCRIPTION

This interactive half-day course introduces students to the Commitments and Correspondence capabilities of the InSight for Registrations, Registration Planning and Tracking and InSight for Submissions modules. It introduces students to InSight’s Reference, Task and Notification functionalities which allow users to track and assign commitments and other tasks that support regulatory objectives.

### Topics

- Creating links to external content using References
- Creating and copying assignments in InSight using Task functionality
- Creating Task Progression Workflows
- Creating InSight E-mail alerts using local and global Notifications

## DURATION/Pricing*

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### LIQUENT InSight® Advanced Planning & Tracking

#### PREREQUISITES
- User training in InSight for Registrations, InSight Product Detail Management or InSight for Submissions.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Working knowledge of Microsoft Internet Explorer 7.0 or higher.

#### PRIMARY AUDIENCE
- Clients responsible for regulatory data changes that affect multiple Applications and product lines.
- Clients familiar with basic InSight functionality.

#### COURSE DESCRIPTION
This interactive one and a half day course will introduce students to advanced features in the InSight system: creating and managing Global Project Plans (GPP) and Event Plans. These functionalities address the needs of users of InSight for Registrations, and Product Detail Management modules who manage pharmaceutical, veterinary and medical device product data.

**Topics**
- Creating and applying Event Plans
- Creating Applications using GPP and Copy Application
- Creating Events using GPP and Copy Event
- Using GPP to Manage Product Details
- Withdrawing approved product data through GPP
- Creating Sequences and References in a project
- Using GPP to manage Event Statuses

#### DURATION/PRICING*

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What’s new with Registrations in LIQUENT InSight®

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<th>PREREQUISITES</th>
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<td>• Attendance in the course LIQUENT InSight Registration Planning and Tracking and Product Detail Management</td>
<td>Clients responsible for regulatory data changes that affect multiple Applications and product lines.</td>
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<td>• Working knowledge of the Microsoft Windows® XP or Windows 2003 interface.</td>
<td>Clients familiar with basic InSight functionality.</td>
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<td>• Working knowledge of Microsoft Word.</td>
<td>Clients whose responsibilities include tracking CMC and product details for approved, and pending approval, pharmaceutical, veterinary and medical device products.</td>
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COURSE DESCRIPTION

This half-day interactive course will introduce students to the new features of LIQUENT InSight for Registrations.

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## Executive Overview for LIQUENT InSight® for Registrations

### PREREQUISITES
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Working knowledge of Microsoft Internet Explorer 7.0 or higher.

### PRIMARY AUDIENCE
Managers and executives needing a high-level overview to InSight Registration functionality.

### COURSE DESCRIPTION
This interactive half-day course introduces executives and managers to the scope of functionality and capabilities available in InSight: creating product records, using Global Project Planning (GPP) to create and maintain multiple Applications and regulatory objectives simultaneously, managing new and approved product details. It also exposes students to InSight commitment tracking and electronic Notification functionality.

### Topics
- Creating product data
- Creating Timeline / Event Plans for regulatory objective records (Events)
- Creating and maintaining a Project to track Applications and regulatory objectives
- Creating and managing Package Set Registrations
- Managing changes to product details
- Tracking commitments and correspondence and creating electronic alerts

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Publishing with LIQUENT InSight® for eCTD, Paper and NeeS

**PREREQUISITES**

- Working knowledge of the CTD and eCTD Specifications.
- Working knowledge of Microsoft Windows®
- Basic working knowledge of a document management system and/or file system – including the ability to: Save files, delete files, and navigate folder structures.
- Working knowledge of Microsoft Internet Explorer 5.5 or higher.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

**PRIMARY AUDIENCE**

This course is designed to enable submission planners and publishers with the tools necessary to produce a NeeS and paper submission. Participants are provided with a publishing approach that leverages faster assembly techniques and methods to track the submission lifecycle.

**COURSE DESCRIPTION**

This three-day interactive course will introduce students to the features of LIQUENT InSight in order to create a non-eCTD electronic submission (NeeS) and a paper submission with InSight Publisher.

**Topics**

- LIQUENT InSight Suite
- Navigating in InSight
- Working with Applications
- Creating Assembly Trees
- Assigning Documents
- In Process Linking and Extracts
- Publishing and Reviewing eCTD, Paper and NeeS Output
- Managing the eCTD Lifecycle
- Applying Overlays and Variables
- Tables of Contents
- Paper Publishing Elements
- NeeS Publishing Elements

**DURATION/PRICING***

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Publishing with LIQUENT InSight® for eCTD and Paper

### PREREQUISITES

- Working knowledge of the CTD and eCTD Specifications.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Basic working knowledge of a document management system and/or file system – including the ability to: Save files, delete files, and navigate folder structures.
- Working knowledge of Microsoft Internet Explorer 5.5 or higher.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

### PRIMARY AUDIENCE

This course is designed to enable submission planners and publishers with the tools necessary to produce an eCTD, paper submission. Participants are provided with a publishing approach that leverages faster assembly techniques and submission lifecycle.

### COURSE DESCRIPTION

This three-day interactive course will introduce students to the features of LIQUENT InSight in order to create an eCTD and a paper submission with InSight Publisher.

**Topics**

- LIQUENT InSight Suite
- Navigating in InSight
- Working with Applications
- Creating Assembly Trees
- Assigning Documents
- In Process Linking and Extracts
- Publishing and Reviewing Output for eCTD and Paper submissions
- Managing the eCTD Lifecycle
- Applying Overlays and Variables
- Tables of Contents
- Paper Publishing Elements

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Publishing with LIQUENT InSight® for eCTD and NeeS

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<td>• Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.</td>
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**COURSE DESCRIPTION**

This three-day interactive course will introduce students to the features of LIQUENT InSight in order to create an eCTD and NeeS submission with InSight Publisher.

**Topics**

- LIQUENT InSight Suite
- Navigating in InSight
- Working with Applications
- Creating Assembly Trees
- Assigning Documents
- In Process Linking and Extracts
- Publishing and Reviewing eCTD and NeeS Output
- Managing the eCTD Lifecycle Applying Overlays and Variables
- Tables of Contents
- NeeS Publishing Elements

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Publishing with LIQUENT InSight® for Paper

**PREREQUISITES**

- Working knowledge of the CTD Specification.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Basic working knowledge of a document management system and/or file system – including the ability to: Save files, delete files, and navigate folder structures.
- Working knowledge of Microsoft Internet Explorer 5.5 or higher.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

**PRIMARY AUDIENCE**

This course is designed to enable submission planners and publishers with the tools necessary to produce paper submissions using CTD as an example format. Participants are provided with a publishing approach that leverages faster assembly techniques of the submission.

**COURSE DESCRIPTION**

This two day interactive course will introduce students to the features of LIQUENT InSight in order to create a paper submission with InSight Publisher.

**Topics**

- LIQUENT InSight Suite
- Navigating in InSight
- Working with Applications
- Creating Assembly Trees
- Assigning Documents
- In Process Linking and Extracts
- Publishing and Reviewing Output
- Applying Overlays and Variables
- Tables of Contents
- Paper Publishing Elements

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# Publishing with LIQUENT InSight® for eCTD

## PREREQUISITES

- Working knowledge of the CTD and eCTD Specifications.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Basic working knowledge of a document management system and/or file system – including the ability to: Save files, delete files, and navigate folder structures.
- Working knowledge of Microsoft Internet Explorer 5.5 or higher.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

## PRIMARY AUDIENCE

This course is designed to enable submission planners and publishers with the tools necessary to produce an eCTD. Participants are provided with a publishing approach that leverages faster assembly techniques and methods to track the submission lifecycle.

## COURSE DESCRIPTION

This two-day interactive course will introduce students to the features of LIQUENT InSight in order to create an eCTD with InSight Publisher.

### Topics

- LIQUENT InSight Suite
- Navigating in InSight
- Working with Applications
- Creating Assembly Trees
- Assigning Documents
- In Process Linking and Extract
- Publishing and Reviewing Output
- Managing the eCTD Lifecycle
- Applying Overlays and Variables

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Report Level Publishing with LIQUENT InSight®

PREREQUISITES

- Working knowledge of the CTD and eCTD Specification.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Basic working knowledge of a document management system and/or file system – including the ability to: Save files, delete files, and navigate folder structures.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

PRIMARY AUDIENCE

This course is designed to enable submission planners and report level publishers with the tools necessary to produce reports. Participants are provided with a publishing approach that leverages faster assembly techniques and methods to create study reports.

COURSE DESCRIPTION

This two-day interactive course will introduce Publishers to the features of LIQUENT InSight in order to create and modify assembly structures that will contribute content in Modules 4 and 5 and enter and edit metadata used in report level publishing.

Topics

- Report Publishing Overview
- Navigating through InSight
- Managing Standalone Assemblies
- Creating Assembly Trees
- Using InSight Wizards
- Working with Special Data
- Applying Overlays and Variables
- Creating Tables of Content
- Publishing Clinical Study Reports
- Reviewing Published Output

DURATION/PRICING*

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# Advanced Publishing with LIQUENT InSight®

## PREREQUISITES
- Attendance in Publishing with LIQUENT InSight or What’s New with Publishing with LIQUENT InSight.
- 3-6 months prior practical application of the product.
- Working knowledge of the CTD and eCTD specification.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

## PRIMARY AUDIENCE
- LIQUENT InSight Publisher Users

## COURSE DESCRIPTION
This one-day interactive course is designed to present publishers with the knowledge necessary to perform sophisticated publishing tasks for eCTD creation. Participants are provided with an advanced approach to managing concurrently planned sequences, lifecycle applications, and regional submission variances. This course approach offers experienced publishers new techniques for faster assembly creation and alternative methods to tracking the lifecycle of a submission.

### Topics
- Automating Assemblies
- Changing Assembly Extensions
- Creating Study Reports
- Creating Templates with Variables
- Preparing Assemblies in the Lifecycle
- Lifecycle Linking

## DURATION/PRICING*

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Publishing with LIQUENT InSight®
Certified Professional Exam Preparation Course

**PREREQUISITES**

- 3-6 months of full-time LIQUENT InSight Publisher use; versions 5.0 and above.
- Attendance in the course Publishing with LIQUENT InSight.

**PRIMARY AUDIENCE**

Certified LIQUENT InSight Publishers are individuals who have demonstrated mastery in skills necessary to utilize LIQUENT solutions.

**COURSE DESCRIPTION**

The purpose of this half-day review class is to assist in the preparation for the Publishing with LIQUENT InSight Certified Professional Examination. At the beginning of each lesson, students will complete a skills analysis checklist. During the class, questions will be asked to measure students’ knowledge of publishing. In addition, they will have the opportunity to practice their publishing skills with hands-on exercises using LIQUENT InSight.

Students should bring in their training Manuals from the class: Publishing with LIQUENT InSight.

**Topics**

- InSight Entity Relationships
- Navigation
- Working with Applications
- Creating Assembly Trees
- Assigning Documents
- Creating Special Sheets
- Defining Overlays and Variables
- Building Tables of Contents
- In-Process Linking
- Reviewing a Publication
- Publishing
- Managing the eCTD Lifecycle
- Defining Overlays and Variables
- Building Tables of Content

**DURATION/PRICING***

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Publishing with LIQUENT InSight® Certified Professional Exam

**PREREQUISITES**

- 3-6 months of full-time Publishing with LIQUENT InSight; versions 5.1 and above.
- Attendance in the course Publishing with LIQUENT InSight.

**PRIMARY AUDIENCE**

Certified LIQUENT InSight Publishers are individuals who have demonstrated mastery in skills necessary to utilize LIQUENT solutions.

**COURSE DESCRIPTION**

LIQUENT InSight Publisher certification helps companies identify expert publishers who know how to use the tool and to distinguish themselves as leaders in their industry.

The Certified Publishing with LIQUENT InSight examination consists of two parts that are taken on the same day which consist of written and practical.

**Part One – 2 Hours – Written**

- Students will answer questions about the use of LIQUENT InSight. Included in this section are LIQUENT InSight publishing scenarios, matching, true/false, multiple-choice questions and explaining publishing terms.

**Part Two – 3 Hours – Practical**

- Students will create an eCTD submission. Alongside this the following areas will be incorporated:
  - Creating Applications/Events and Sequences
  - Creating Assemblies/Assigning Documents
  - In-Process Linking
  - Publishing
  - Managing the eCTD Lifecycle
  - Building TOCs
  - Creating Special Sheets
  - Defining Overlays and Variables

**Please Note:** Unless provided by the instructor, no study aids will be available for use during either part of the examination.

Students will be notified via email on scores approximately one week from completion of the exam. Certificates and a pin will be sent to students passing the exam.

**DURATION/PRICING**

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LIQUENT InSight® Administration for Publishers

PREREQUISITES

- Attendance in the following course: Publishing with LIQUENT InSight.
- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
- Basic working knowledge of a document management system and/or file system – including the ability to: Save files, delete files, and navigate folder structures.
- Working knowledge of Microsoft Internet Explorer 5.5 or higher.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

PRIMARY AUDIENCE

This course is designed to enable users with Administration responsibilities to manage permissions and data values. Publishing Administrators as well as IT Staff and LAN Administrators will also find this class useful.

COURSE DESCRIPTION

This one-day interactive course will introduce administrators to the system features of LIQUENT InSight in order to understand the role of an InSight Publisher Administrator.

Topics

- Architecture Overview
- Security Administration
- Data Administration
- Technical Administration
- Administration Reporting
- LES Rendering and Publishing Services
- Administrator Resources
- Troubleshooting

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## What’s New with Publishing with LIQUENT InSight®

### PREREQUISITES
- Attendance in the course Publishing with LIQUENT InSight.
- Working knowledge of the Microsoft Windows® XP or Windows 2003 interface.
- Working knowledge of Microsoft Word.

### PRIMARY AUDIENCE
LIQUENT InSight Submission Publishers.

### COURSE DESCRIPTION
This half-day interactive course will introduce students to the new features of LIQUENT InSight Publisher.

### DURATION/PRICING*

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LIQUENT InSight Submission Planning & Tracking®

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<td>• Working knowledge of the CTD and eCTD Specification.</td>
<td>Individuals who will be planning and tracking submission projects using InSight these individuals may also be responsible for creating tools to aid the submission process.</td>
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COURSE DESCRIPTION

This two day interactive course will introduce students to the features of InSight in order to use InSight tools to track the status and guide the production of a publishing project.

Topics

• InSight & InSight for Submissions overview
• Navigating through InSight manager
• Creating National Applications
• Creating Events and Sequences
• Creating Assembly Trees
• Using the Wizards
• European Applications
• Manipulating Assembly elements
• Managing commitments & correspondence
• Assembly management
• Automating Assembly creation
• Global Project Planning
• Working with reports
• Querying InSight

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Automating the Publishing Process with LIQUENT SmartDesk for PDF®

**PREREQUISITES**
- Working knowledge of Microsoft Windows® - including the ability to start an application; close/exit and application; open, close, minimize, maximize and move windows; and switch between applications and tasks.
- Working knowledge of the ICH Guidelines.
- Working knowledge of Adobe Acrobat.

**PRIMARY AUDIENCE**
This course is designed to instruct regulatory team members on preparing PDF documents in accordance with regulatory requirements before compiling an electronic submission.

**COURSE DESCRIPTION**
This one-day interactive course will introduce students to the features of LIQUENT SmartDesk for PDF in order to automate the publishing process, and help address publishing challenges in a simple and streamlined manner.

**Topics**
- PDF Security
- PDF Optimization
- PDF Page Verification – Margins, orientation & content
- Splitting & Merging PDF Files
- Scaling & Redacting PDF Files
- PDF Page Stamping – Header/Footer and Link Referencing
- PDF Link Tools
- Reversing Bookmark Order & Cloning Bookmarks
- Importing/Exporting Links & Bookmarks
- Linking the Table of Contents
- Modifying magnification Settings
- Verification & Resolution Tools for Document Information Fields, Navigational Items & Font Information

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# LIQUENT InSight Smartlink for Word

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| • Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.  
• Working knowledge of the ICH Guidelines. | Authors |

## COURSE DESCRIPTION

This half day interactive course allows authors and publishers to insert and edit these hyperlinks (or cross references) in Microsoft Word documents.

### Topics
- Use InSight Publisher’s SmartLink for Word to create links in a MS Word document.  
- Edit links in a Microsoft Word document.  
- Review links created using SmartLink for Word.

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Validating Submissions with LIQUENT InSight Validator®

PREREQUISITES | PRIMARY AUDIENCE
--- | ---
• Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks. • Working knowledge of the ICH Guidelines. | This course is designed to instruct students on validating eCTD submissions via LIQUENT InSight Validator

COURSE DESCRIPTION

This half-day interactive course will introduce users to the features of LIQUENT InSight Validator to effectively mitigate risks when validating eCTD submissions.

**Topics**

• Introduction to LIQUENT InSight Validator
• Accessing and Navigating LIQUENT InSight Validator
• Working on the Submissions Tab
• Working on the Reviewer Tab
• Working on the Validation Criteria Tab
• Accessing and Interpreting the Validation Report
• Working with Subsequent Submissions
• Working on the Preferences Tab

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Reviewing Submissions with LIQUENT InSight® for Viewing

**PREREQUISITES**

- Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize and move windows; and switch between applications and tasks.
- Working knowledge of Microsoft Internet Explorer 7.0 or higher.

**PRIMARY AUDIENCE**

The first half of this course is designed to instruct administrators on how to assign and establish permissions for reviewers of eCTD and Non-eCTD submissions. The second half of this course instructs users on how to access and view the eCTD and Non-eCTD submissions.

**COURSE DESCRIPTION**

This half-day interactive course will introduce students to the features of LIQUENT InSight for Viewing in order to create and manage user accounts, data repositories and application groups for the purpose of searching for and reviewing CTD and Non-CTD submissions.

**Topics**

**Part One – The Administrative Role**

- Managing Users, Data Repositories and Application Groups.
- Managing and Registering eCTD & Non-eCTD Applications.
- Content Indexing.

**Part Two – The Reviewer Role**

- Searching for Submissions – Content vs. Metadata.
- Reviewing the Submission’s Table of Contents, Document Properties and Lifecycle.
- Creating, Responding to, and Closing Comments
- User Settings & Preferences
- Running and viewing Reports: Comments, Review matrix by User and Auto Registration.

**DURATION/PRICING**

<table>
<thead>
<tr>
<th></th>
<th>Horsham, PA (USA)</th>
<th>Uxbridge, UK</th>
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<tbody>
<tr>
<td>Classroom Training</td>
<td>$325</td>
<td>€348</td>
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<tr>
<td>Onsite Training</td>
<td>Please email for pricing and scheduling information</td>
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</tbody>
</table>

*Prices will be charged in the local currency of the training venue, and may be subject to taxes.*
LIQUENT INSIGHT®
PLATFORM
LIQUENT InSight For Analytics®

<table>
<thead>
<tr>
<th>PREREQUISITES</th>
<th>PRIMARY AUDIENCE</th>
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</thead>
<tbody>
<tr>
<td>• Working knowledge of Microsoft Windows® – including the ability to:</td>
<td>This course is designed to provide users with advanced reporting and metrics</td>
</tr>
<tr>
<td>Start an application; close/exit an application; open, close, minimize,</td>
<td>from LIQUENT InSight data, including the ability to build your own ad hoc reports.</td>
</tr>
<tr>
<td>maximize, and move windows; and switch between applications and tasks.</td>
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<tr>
<td>• Working knowledge of Microsoft Internet Explorer 5.5 or higher.</td>
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COURSE DESCRIPTION

This one day interactive course will introduce students to the features of LIQUENT InSight for Analytics in order to provide advanced reporting and metrics from LIQUENT InSight data, including the ability to build ad hoc reports.

Topics

• Navigate within Analytics
• Understand Security permissions
• Run a predefined report
• Creating Charts from report results
• Understand and use Dashboard reports
• Understand and use Guided Ad Hoc reports
• Schedule a report
• Creating a Distribution List
• Create an adhoc report using InfoAssist
• Importing and exporting reports

DURATION/PRICING*

<table>
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# LIQUENT InSight Workflows®

## PREREQUISITES
- Working knowledge of Microsoft Windows®
- Basic working knowledge of a document management system and/or file system – including the ability to: Save files, delete files, and navigate folder structures.
- Working knowledge of Microsoft Internet Explorer 5.5 or higher.
- Working knowledge of Adobe Acrobat, Microsoft Word/Excel or other word processing/spreadsheet applications.

## PRIMARY AUDIENCE
- Regulatory team members who will be assigned activities /projects
- Administrators who will be assigning activities /projects to team members.

## COURSE DESCRIPTION
This half-day interactive course LIQUENT InSight Workflow Integrations module provides the functionality to utilize client specific workflows to meet process needs within LIQUENT InSight. Workflows are configured using XML which is processed by LIQUENT InSight at start-up. This functionality allows for workflows to contain multiple activities, with dependencies and defined preset fields, which guide processes within the system.

### Topics
- Associate a Workflow
- Pause/Resume a Workflow
- Delete a Workflow
- Work with Activities
- View Workflows and Activities
- Workflow administration
- Create a virtual group
- Modify a virtual group
- Delete a virtual group

## DURATION/PRICING*

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LIQUENT InSight for XEVMPD®

PREREQUISITES | PRIMARY AUDIENCE
---|---
• Working knowledge of Microsoft Windows® – including the ability to: Start an application; close/exit an application; open, close, minimize, maximize, and move windows; and switch between applications and tasks.
• Working knowledge of Microsoft Internet Explorer 5.5 or higher. | Individuals required to submit XEVMPD messages to the EMA, and upload received acknowledgement files.

COURSE DESCRIPTION
This half-day interactive course will introduce students to the features of LIQUENT InSight for XEVMPD in order to enter required XEVMPD data in InSight as well as create the message and process acknowledgement files from the EMA.

Topics
• XEVMPD data entry requirements
• Creation of the xml message for submission to the EMA
• Using the XEVMPD Submission Wizard
• Using the XEVMPD Acknowledgement Wizard
• Data Administration requirements

DURATION/PRICING*

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