docuBridge Standard Document Management and Submission Training

Location:
New Horizons CLC Frankfurt AG
Ludwig-Erhard-Str. 30-34
65760 Eschborn

Fee:
2250 € / 3 days
(The fee includes complete set of material, refreshment breaks and lunch.)

Description:
Participants will learn how to effectively upload content files into docuBridge, organize them using custom attribute entries, and distribute them via defined custom procedures. In addition, participants will practice updating their content by versioning their documents from both within and outside of docuBridge.

Participants will learn how to create new submissions and the basics of compilation in each of the eCTD modules including how to deal with repeatable sections, compile study reports and setup their selected region's Module 1.

Participants will continue to learn about the functionality needed to finalize their initial sequence as well as manage the lifecycle of their applications.

Agenda

Day 1

9:00 - Introduction to dB
- Uploading Single Files and Related Documents
- Quality Controlling Uploaded Files – Editing Attributes and Deleting Duplicates
- Uploading Multiple Files
- Access Control – Distributing Files
- Creating and using Searches
- Versioning Documents
  o Editing Files in dB
  o Uploading Files from external Source
- Administrative Procedures and Hiding of Documents
- Object Audit Trail – Audit Trail Reports

12:30 - 13:30 – LUNCH BREAK

- Using Searches for Application Compilation
- Creating and Distributing a New Application
- Compilation Basics – 1 to 1 Compilation
- Repeatable and 1 to many Compilation
- Multiple user editing

16:00 – End of Day 1

Day 2

9:00 - Compiling Study Reports – Nonclinical and Clinical, STF or Non-STF
 - Compiling Regional Content – Administrative Information and Module 1 (1 Region)
 - Application Viewer – Layout and Navigation
 - Application Processing – Annotations – Highlights and Notes

12:30 - 13:30 – LUNCH BREAK

 - Application Processing – Hyperlinks
 - Working with Bookmarks
 - Application Processing – Quality Control – Update Version; Find Nodes (eCTD Attributes)
 - Publish as Single File
 - Publish as Combined Document
 - Reference Node & Cross Application Referencing

16:00 – End of Day 2

Day 3

9:00 - Initial Publishing – eValidation and Publishing Error Correction
 - Application – Merging and Cloning
 - Application Cloning for another Country – Part Submissions
 - Lifecycle Management – NEW, REPLACE and DELETE Operations
 - Lifecycle – Dealing with Hyperlinks
 - Multiple Sequence Editing

12:30 - 13:30 – LUNCH BREAK

 - Submission Replication
 - Importing Submissions and Elevating Internal Objects – SCM (Submission Content Management)
 - Incremental Publishing
 - Content Planning

16:00 – End of Day 3

Additional Topics:
 - Paper Production – Volumes
 - Paper Production – Page Inserts, Headers & Footers, TOCs and Printing
 - NeeS and VNees
 - Working with imported Applications
 - Additional Documents (documents placed in the Submission Outline, but these documents will not be published) – Working Documents EU
 - Search Management
 - Template Management