LORENZ docuBridgeONE

Training Agenda - April 11, 2019

Description for the **docuBridge ONE** training

Participants will learn how to create a new application (US version 3.3) and will compile modules 1 (regional information), 2, 3, 4 and 5 (STFs). We'll look into hyperlinking and will make sure not to submit a document twice to the FDA by using the reference node option. Participants will re-use data by merging and cloning applications as well as manage the lifecycle of their applications.

Time	Topics
8:00 - 8:30 AM	Registration
8:30 - 9:30 AM	Creating new application DTD version 3.3 eCTD attributes/metadata module 2 – 5
9:30 - 10:00 AM	Building my submission: Compilation module 1 – 4
10:00 - 10:15 AM	**Break**
10:15 - 11:00 AM	Using manual filenames module 3 (analytical procedures) & compiling module 5
11:00 - 12:00 PM	Hyperlinking
12:00 - 1:00 PM	**Lunch**
1:00 - 2:00 PM	Lifecycle management
2:00 - 3:00 PM	Publishing and validation errors US FDA review - How does the reviewer see my application?
3:00 - 3:15 PM	Closing remarks, end of day

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Contact LORENZ: www.lorenz.cc/email - Phone: +1 914 584 1955

Please note that LORENZ reserves the right to modify the agenda.