TRAINING ECTDMANAGER STANDARD – TWO DAYS

Duration:
Two days (ca. 09:00-17:00h)

Agenda Day 1

Time	WS	Content
09:00 - 09:45		**Introduction: Electronic Submission Management & the CTD Background** ❯ The elementary terminology of eCTDmanager ❯ Starting eCTDmanager ❯ *Optional: eCTDmanager and MS Access* ❯ Handling the eCTDmanager User Interface, end eCTDmanager

09:45 – 10:30	WS 1 EU	**eCTD Story 1: your first Submission**
		❯ Create a new Dossier with EU M1
		❯ Working in the EU M1 Structure
		❯ Adding Documents
		   o The "electronic Application Form" eAF
		   o EU Labelling

10:30 – 10:45		*Coffee Break*
10:45 - 11:30	WS 2	**eCTD Story 2: Add Content and Structure!** ❯ eCTD Specific Sections ❯ Managing Documents ❯ Node Extensions ❯ Copy Branch
11:30 - 12:30	WS 3	**eCTD Story 3: Create Hyperlinks** ❯ manually ❯ Automatic resolution of externally created hyperlinks ❯ "Create Hyperlinks from Text"
12:30 – 13:30		*Lunch*
13:30 – 14:30	WS 4	**eCTD Story 4: Validate and Finish an eCTD submission** ❯ Validation, Task Tracking, Finish submission **eCTD Story 5: Export of an eCTD submission** ❯ Export submission ❯ Validate Business Rules after Export
14:30 - 15:15	WS 5	**eCTD Story 6: Additional Features in higher Submissions!** ❯ Submission Lifecycle & M1 Modifications ❯ Document Lifecycle ❯ Hyperlinks and Document Lifecycle ❯ The Cumulative Submission
15:15 – 15:30		*Coffee Break*
15:30 – 16:45	WS 5	eCTD Story 6: Additional Features in higher Submissions (contd.)
16:45 – 17:00		Final questions & closing

Agenda Day 2

Time	WS	Topic
09:00 - 09:45		Repetition and Wrap up of day 1
09:45 – 10:30	WS 6	eCTD Story 7: Import of eCTD Submissions
10:30 – 10:45		*Coffee Break*
10:45 – 11:30	WS 7	eCTD Story 8: Submission Staging and Regulatory Activities
11:30 - 12:30	WS 8	eCTD Story 9: MRP/DCP principles and tools ❯ From National Procedure to MRP ❯ Working with EU envelopes ❯ Tracking Table ❯ Export country filter
12:30 – 13:30		*Lunch*
13:30 - 15:15	WS 9	Additional Functionality ❯ Additional Features 　❯ Document Viewer 　❯ Tools on Submission Level 　❯ Tools on Document Level ❯ Reviewing 　❯ Search Functionality 　❯ Internal Communications: Annotations, Highlights, TOC Annotations, Scratch Book 　❯ Generating Reports ❯ Other Output Options 　❯ Paper Publishing 　❯ eCTD with consistent headers & footers
15:15 – 15:30		*Coffee Break*
15:30 – 16:00		WS 9 continued
16:00 – 16:45	WS 10	Basic Administration Features of eCTDmanager ❯ Licensing ❯ User Management: Roles, Creating/editing user credentials, Permissions ❯ Basic Maintenance features ❯ User Documentation ❯ add-ons to eCTDmanager (Configurable / Licensed add-ons)
16:45 – 17:00		Final questions & closing