

TRAINING 4 STANDARD – TWO DAYS

Agenda Day 1 (ca. 09:00-17:00h)

09:00 - 09:45		<p>Introduction: Electronic Submission Management & the CTD Background</p> <ul style="list-style-type: none"> ➤ The elementary terminology of eCTDmanager ➤ Starting eCTDmanager ➤ <i>Optional: eCTDmanager and MS Access</i> ➤ Handling the eCTDmanager User Interface, end eCTDmanager
09:45 – 10:45	WS 1 EU	<p>eCTD Story 1: your first Submission</p> <ul style="list-style-type: none"> ➤ Create a new Dossier with EU M1 ➤ Working in the EU M1 Structure ➤ Adding Documents ➤ Validation / Task Tracking / Finish Submission ➤ Export Sequence 0000 ➤ Other Submission Functions
10:45 – 11:00		<i>Coffee Break</i>
11:00 - 12:30		<p>eCTD Story 2: eCTD Submission Lifecycle</p> <ul style="list-style-type: none"> ➤ Submission Lifecycle & M1 Modifications ➤ The “electronic Application Form” eAF
	WS 2	<p>eCTD Story 3: Add Content and Structure!</p> <ul style="list-style-type: none"> ➤ eCTD Specific Sections ➤ Managing Documents ➤ Node Extensions ➤ Copy Branch
12:30 – 13:30		<i>Lunch</i>
13:30 - 14:30	WS 3	<p>eCTD Story 4: Create Hyperlinks</p> <ul style="list-style-type: none"> ➤ manually ➤ Automatic resolution of externally created hyperlinks ➤ “Create Hyperlinks from Text”
14:30 – 15:15	WS 4	eCTD Story 5: Export of eCTD of Submissions
15:15 – 15:30		<i>Coffee Break</i>
15:30 – 16:15	WS 5	<p>eCTD Story 6: Additional Features in higher Submissions!</p> <ul style="list-style-type: none"> ➤ Document Lifecycle ➤ Hyperlinks and Document Lifecycle ➤ The Cumulative Submission ➤ Lifecycle of Specific Sections
16:15 – 16:45	WS 6	eCTD Story 7: Import eCTD of Submissions
16:45 – 17:00		Final questions & closing

Agenda Day 2 (ca. 09:00-17:00h)

09:00 - 09:45		Repetition and Wrap up of day 1
09:45 – 10:45	WS 7	eCTD Story 8: Submission Staging and Regulatory Activities
10:45 – 11:00		<i>Coffee Break</i>
11:00 - 12:30	WS 8	<p>eCTD Story 9: MRP/DCP principles and tools</p> <ul style="list-style-type: none"> ➤ From National Procedure to MRP ➤ Working with EU envelopes ➤ Tracking Table ➤ Export country filter <p>eCTD Story 10: Create a NeeS out of an eCTD</p> <ul style="list-style-type: none"> ➤ Module TOCs and ctd-toc
12:30 – 13:30		<i>Lunch</i>
13:30 - 15:15	WS 9	<p>Additional Functionality</p> <ul style="list-style-type: none"> ➤ Additional Features <ul style="list-style-type: none"> ➤ Document Viewer ➤ Tools on Submission Level ➤ Tools on Document Level ➤ Reviewing <ul style="list-style-type: none"> ➤ Search Functionality ➤ Internal Communications: Annotations, Highlights, TOC Annotations, Scratch Book ➤ An Introduction to Hyperlink Review Mode ➤ Generating Reports ➤ Other Output Options <ul style="list-style-type: none"> ➤ Paper Publishing ➤ eCTD with consistent headers & footers
15:15 – 15:30		<i>Coffee Break</i>
15:30 – 16:00		WS 9 continued
16:00 – 16:45	WS 10	<p>Basic Administration Features of eCTDmanager</p> <ul style="list-style-type: none"> ➤ 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

Pricing

On site: € 3700 + travel costs (max. 8 participants)

Classroom training in Ottobrunn (Munich area), Germany:

€ 1000 per person. Classroom trainings will only be held if there are at least 4 confirmed participants for the training. EXTEDO reserves the right to cancel these trainings up to 1 week before the training day.

Booking: Please contact support@extedo.com or +49 89 189454 – 144 if you want to book this training.