

TRAINING ECTDMANAGER REFRESHER TRAINING ONE DAY

Duration:

One Day (ca. 09:00-17:00h)

Agenda

09:00 - 09:15	Welcome Agenda
09:15 – 10:30	Session 1: <ul style="list-style-type: none"> ➤ Start eCTDmanager, User Interface ➤ Create Dossier/Submission: EU Regional Part ➤ EU M1 specifics: the eAF
10:30 – 10:45	<i>Coffee Break</i>
10:45 - 12:30	Session 2: <ul style="list-style-type: none"> ➤ Adding Documents (MiniDMS) ➤ Specific sections & Node Extensions ➤ Three options to create Hyperlinks ➤ Edit Bookmarks
12:30 – 13:30	<i>Lunch</i>
13:30 - 15:00	Session 3: <ul style="list-style-type: none"> ➤ Validation/Finish/Export 0000 ➤ Validate Business Rules ➤ Submission Lifecycle ➤ Document Lifecycle ➤ Export Follow Up Submissions
15:00 – 15:15	<i>Coffee Break</i>
15:15 – 16:00	Session 4: <ul style="list-style-type: none"> ➤ The cumulative Submission ➤ Batch Import
16:00 – 16:45	Session 5: <ul style="list-style-type: none"> ➤ Submission staging ➤ MRP / DCP
16:45 – 17:00	Final questions & closing