

ECTDMANAGER WORKSHOP GREECE

11-12 MARCH 2020

Duration:

Two Days (ca. 09:00-17:00h)

Agenda Day 1: Best Practice Workshop – Hands-On

09:00 - 09:15	Welcome / Agenda / Training Environment
09:15 - 10:30	Session 1: <ul style="list-style-type: none"> ➤ Start eCTDmanager, User Interface ➤ Create Dossier/Submission: EU Regional Part (Module 1 v 3.0.1) ➤ EU M1 specifics: EU envelope, the eAF ➤ Adding Documents
10:30 - 10:45	<i>Coffee Break</i>
10:45 - 11:30	Session 2: <ul style="list-style-type: none"> ➤ eCTD Specific Sections and Node Extensions ➤ More ways to work with documents
11:30 - 12:30	Session 3: <ul style="list-style-type: none"> ➤ Creating Hyperlinks
12:30 - 13:30	<i>Lunch</i>
13:30 - 14:15	Session 4: <ul style="list-style-type: none"> ➤ Validation/Finish/Export 0000 ➤ Validate Business Rules ➤ Submission Lifecycle ➤ Edit Envelope Information in Follow-Up sequences
14:15 - 15:00	Session 5: <ul style="list-style-type: none"> ➤ Document Lifecycle ➤ The cumulative Submission
15:00 - 15:15	<i>Coffee Break</i>
15:15 - 16:30	Session 6: <ul style="list-style-type: none"> ➤ From a National Procedure to an MRP" ➤ Non-eCTD Dossiers
16:30 – 17:00	Final Questions and Closing

The trainees can bring their own laptops for practical exercises. Up to ten machines can be connected to the EXTEDO training server via a WiFi network. There's no software installation required, we will not leave dummy data in your system! So the requirement for the laptops are very simple:

- The used laptops/notebooks should be Windows systems, equipped with Win XP or higher, but no "Home" versions. Apple/MAC's are not recommended, as they don't support the right mouse button.
- Minimum required display size: 15", resolution 1280x720 or better
- Laptops must allow access to a WiFi network; the users must have the permission to change the WiFi (to connect to the training WiFi) and execute "Microsoft Remote Desktop connection".
- Ideally each Laptop should have a separate mouse. According to our experience working with a mouse is more comfortable than with the build-in touchpad.

Agenda Day 2: Advanced Topics

Agenda

09:00 - 09:15	Welcome / Agenda
09:15 - 10:30	Session 1: Global regulatory update <ul style="list-style-type: none"> ➤ Status of e-Submissions in the regions (EU, US FDA, China ...)
10:30 - 10:45	<i>Coffee Break</i>
10:45 - 12:30	Session 2: EU eCTD submissions <ul style="list-style-type: none"> ➤ Regulatory Information on <ul style="list-style-type: none"> ○ Procedure Types (NP, MRP, DCP, CP) ○ Submission Types (e.g. MAA, Variations) ➤ CESP ➤ What should you do in case of Brexit?
12:30 - 13:30	<i>Lunch</i>
13:30 - 15:00	Session 3: eCTD Readiness <ul style="list-style-type: none"> ➤ From a single document to the eCTD submission ➤ How to setup electronic submission in your company? ➤ What are the tools you need? ➤ Word templates
15:00 - 15:15	<i>Coffee Break</i>
15:15 - 16:15	Session 4: <ul style="list-style-type: none"> ➤ Best practice of electronic submissions ➤ Common errors in electronic submissions
16:15 - 16:45	Session 5: eCTDmanager add-ons <ul style="list-style-type: none"> ➤ Configuration Options ➤ eCTDmanager goes Cloud ➤ Roadmap
16:45 - 17:00	Final Questions and Closing