

Training: EURS Standard User Training – One Day

Duration

One day

Agenda

Timetable	Topic
09:00 - 10:00	Session 1: Introduction to EURS <ul style="list-style-type: none"> ➤ EURS Introduction: Getting familiar with EURS Interface <ul style="list-style-type: none"> ➤ Start the application: „EURS Start Page“ ➤ Parts of the User Interface: Explorers and Menus
10:00 – 10:45	Session 2 <ul style="list-style-type: none"> ➤ Some Theory of eCTD ➤ Technical Aspects of an electronic Submission <ul style="list-style-type: none"> ➤ How to read an Applicant’s Validation Report, where can I find it later? ➤ How to interpret warnings? ➤ What to do with errors? ➤ EURS Story 1: The content of the initial Submission <ul style="list-style-type: none"> ➤ Open the Validation Report in EURS ➤ Reviewing the Structure of the submission (eCTD Module M1)
10:45 – 11:00	Coffee break
11:00 – 12:30	Session 3 <ul style="list-style-type: none"> ➤ EURS Story 1: The content of the initial Submission (continued) <ul style="list-style-type: none"> ➤ Reviewing the Structure of the submission <ul style="list-style-type: none"> • Specific Sections • Node Extensions • Document Viewer
12:30 – 13:30	Lunch
13:30 – 14:15	Session 3 (continued) <ul style="list-style-type: none"> ➤ EURS Story 2: Reviewing the initial Submission <ul style="list-style-type: none"> ➤ Search documents <ul style="list-style-type: none"> • Collect documents for reviewing • The reviewing tools
14:15 – 15:15	Session 4 <ul style="list-style-type: none"> ➤ EURS Story 3: Import and Review follow-up submissions <ul style="list-style-type: none"> ➤ Check the Validation Report of 0001 ➤ See the changes ➤ Filters and Views ➤ eCTD document Life Cycle: color code <ul style="list-style-type: none"> • Compare document versions in the Life Cycle • See annotations of previous submissions ➤ Working with Regulatory Activities
15:15 - 15:30	Coffee break
15:30 – 16:30	Session 5 <ul style="list-style-type: none"> ➤ EURS Story 4: Need assessment assistance? <ul style="list-style-type: none"> ➤ Several ways to get document information out of EURS ➤ EURS Story 5: Report Creation <ul style="list-style-type: none"> ➤ Creating an electronic Assessment Report
16:30 – 17.00	Questions & Answers