

Training EURSnext Standard – half Day

Duration:

half day (ca. 09:00-13:00h)

Agenda Day 1

09:00 - 10:00	<p>Introduction: Electronic Submission Management & the CTD Background</p> <ul style="list-style-type: none"> ➤ The elementary terminology of EURSnext ➤ Starting EURSnext ➤ Handling the EURSnext User Interface, end EURSnext
10:00 - 10:45	<p>EURSnext as Reviewing Tool</p> <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? ➤ How to interpret warnings? ➤ What to do with errors?
10:45 - 11:00	<i>Coffee Break</i>
11:00 - 11:45	<p>EURSnext Story 1: The Initial Submission</p> <ul style="list-style-type: none"> ➤ The content of the initial Submission ➤ Reviewing the Structure of eCTD Module M1 ➤ Reviewing the Structure of the submission (M2-M5) <ul style="list-style-type: none"> ➤ Specific Sections ➤ Node Extensions ➤ Document Viewer
11:45 - 12:15	<p>EURSnext Story 2: Reviewing the initial Submission</p> <ul style="list-style-type: none"> ➤ Search in documents ➤ The reviewing tools
12:15 - 12:45	<p>EURSnext Story 3: Review follow-up submissions</p> <ul style="list-style-type: none"> ➤ The follow-up submission 0001 <ul style="list-style-type: none"> ➤ See the changes ➤ Filters and Views ➤ eCTD document Life Cycle: color code
12:45 - 13:00	Final questions & closing

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