

# Training eSUBmanager/EURSnex 4 Standard – half Day

## Duration:

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

## Agenda Day 1

09:00 - 10:00	<p>Introduction: Electronic Submission Management &amp; the CTD Background</p> <ul style="list-style-type: none"> <li>➤ Connect to eSUBmanager</li> <li>➤ The elementary terminology of eSUBmanager</li> <li>➤ Handling the eSUBmanager User Interface, end eSUBmanager</li> </ul>
10:00 - 10:30	<p>eSUBmanager as Reviewing Tool</p> <ul style="list-style-type: none"> <li>➤ Some Theory of eCTD</li> <li>➤ Technical Aspects of an electronic Submission (optional) <ul style="list-style-type: none"> <li>➤ How to read an Applicant's Validation Report?</li> <li>➤ How to interpret warnings?</li> <li>➤ What to do with errors?</li> </ul> </li> </ul>
10:30 - 10:45	<i>Coffee Break</i>
10:45 - 11:30	<p>eSUBmanager Story 1: The Initial Submission</p> <ul style="list-style-type: none"> <li>➤ The content of the initial Submission</li> <li>➤ Reviewing the Structure of eCTD Module M1</li> <li>➤ Reviewing the Structure of the submission (M2-M5) <ul style="list-style-type: none"> <li>➤ Specific Sections / Node Extensions</li> <li>➤ Document Viewer</li> </ul> </li> <li>➤ US only: SPL and STF</li> </ul>
11:30 - 12:00	<p>eSUBmanager Story 2: Reviewing the initial Submission</p> <ul style="list-style-type: none"> <li>➤ Search in a Dossier</li> <li>➤ Search in documents</li> <li>➤ The reviewing tools <ul style="list-style-type: none"> <li>➤ Annotations, Highlights, Scratch Book</li> <li>➤ Copying text and Graphics</li> </ul> </li> </ul>
12:00 - 12:30	<p>eSUBmanager Story 3: Review follow-up submissions</p> <ul style="list-style-type: none"> <li>➤ Navigating in the Hierarchy Explorer</li> <li>➤ Working with Favorites</li> <li>➤ The follow-up submission 0001 <ul style="list-style-type: none"> <li>➤ See the changes</li> <li>➤ Filters and Views</li> </ul> </li> <li>➤ eCTD document Life Cycle: color code</li> <li>➤ compare document versions</li> </ul>
12:30 – 12:45	<p>eSUBmanager Story 4: Need assessment assistance?</p> <ul style="list-style-type: none"> <li>➤ Several ways to get document information out of eSUBmanager</li> </ul>
12:45 - 13:00	Final questions & closing

**Booking:** Please contact [training@extedo.com](mailto:training@extedo.com) or +49 89 189454 – 144 if you want to book this training.