

TRAINING STANDARD – ONE DAY

Agenda (ca. 09:00-17:00h)

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| 09:00 - 10:45 | <p>Session 1:</p> <ul style="list-style-type: none"> ➤ Some Background Information! ➤ System Requirements and Installation ➤ Import Submissions ➤ User Management |
| 10:45 – 11:00 | <i>Coffee Break</i> |
| 11:00 - 12:30 | <p>Session 2:</p> <ul style="list-style-type: none"> ➤ Introduction to EURS ➤ The elementary terminology of EURS ➤ The Graphical User Interface ➤ The handling of basic EURS Objects ➤ TOC Items ➤ eCTD Lifecycle |
| 12:30 – 13:30 | <i>Lunch</i> |
| 13:30 - 15:00 | <p>Session 3:</p> <ul style="list-style-type: none"> ➤ The 7 Levels of the electronic Review Process: <ul style="list-style-type: none"> ➤ Level 1: Dossier/Submission check ➤ Level 2: Compare submissions ➤ Level 3: Collect, Search and Read Documents |
| 15:00 – 15:15 | <i>Coffee Break</i> |
| 15:15 – 16:15 | <p>Session 4:</p> <ul style="list-style-type: none"> ➤ The 7 Levels of the electronic Review Process: <ul style="list-style-type: none"> ➤ Level 4: Review Documents ➤ Level 5: Assess documents adding comments and annotations ➤ Level 6: Need assessment assistance ➤ Level 7: Create final report ➤ Support and Administration |
| 16:15 – 17:00 | Final questions & closing |

Pricing

On site: € 1850 + travel costs (max. 8 participants)

Classroom training in Ottobrunn (Munich area), Germany:

€ 500 per person. Classroom trainings will only be held if there are at least 4 confirmed participants for the training. EXTEDO reserves the right to cancel these trainings up to 1 week before the training day.

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