EXTEDO's Basic Level Training Courses

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1 Basic Training Course eCTDmanager

Duration:
Two days (ca. 09:00-17:00h)

Agenda Day 1

Time	Topic
09:00 – 09:45	**Introduction: Electronic Submission Management & the CTD Background** ❯ The elementary terminology of eCTDmanager ❯ Starting eCTDmanager ❯ Handling the eCTDmanager User Interface, end eCTDmanager

09:45 – 10:30	**eCTD Story 1: your first Submission**
	❯ Create a new Dossier with EU M1
	❯ Working in the EU M1 Structure
	❯ Adding Documents
	    o The "electronic Application Form" eAF
	    o EU Tracking Table
	    o EU Labelling
	❯ Companion Folder for Working Documents

10:30 – 10:45	*Coffee Break*
10:45 – 12:30	**eCTD Story 2: Add Content and Structure!** ❯ eCTD Specific Sections ❯ Managing Documents ❯ Node Extensions ❯ Copy Branch
12:30 – 13:30	*Lunch*
13:30 – 14:30	**eCTD Story 3: Creating Hyperlinks**
14:30 – 15:30	**eCTD Story 4: Validate and Finish an eCTD submission** ❯ Validation, Task Tracking, Finish submission **eCTD Story 5: Export of an eCTD submission** ❯ Export submission ❯ Validate Business Rules after Export
15:30 – 15:45	*Coffee Break*
15:45 – 16:45	**eCTD Story 6: Additional Features in higher Submissions!** ❯ Submission Lifecycle & M1 Modifications ❯ Document Lifecycle ❯ Hyperlinks and Document Lifecycle ❯ The Cumulative Submission
16:45 – 17:00	Final questions & closing

2 Refresher Training Course eCTDmanager

Duration:
One Day (ca. 09:00-17:00h)

Agenda

Time	Session
09:00 – 09:15	Welcome, Introduction of the Participants, Agenda
09:15 – 10:30	Session 1: ❯ Start eCTDmanager, User Interface ❯ Create Dossier/Submission: EU Regional Part ❯ EU M1 specifics: EU Tracking Table, eAF, ❯ Companion Folder
10:30 – 10:45	*Coffee Break*
10:45 – 11:45	Session 2: ❯ Adding Documents ❯ Specific sections & Node Extensions
11:45 – 12:30	Session 3: ❯ Creating Hyperlinks
12:30 – 13:30	*Lunch*
13:30 – 14:00	Session 4: ❯ Validation/Finish/Export 0000 ❯ Validate Business Rules ❯ Submission Lifecycle
14:00 – 14:45	Session 5: ❯ Document Lifecycle ❯ Lifecycle Management Views ❯ Export Follow Up Submissions ❯ The cumulative Submission
14:45 – 15:30	Session 6: ❯ Importing Submissions
15:30 – 15:45	*Coffee Break*
15:45 – 16:15	Session 7: ❯ Enhancing an EU NP to an MRP
16:15 – 16:45	Session 8: ❯ Submission Staging: working with multiple open sequences
16:45 – 17:00	Final questions & closing

3   Basic Training Course eSUBmanager

Duration:

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

Agenda Day 1

09:00 - 09:45	**Introduction: Electronic Submission Management & the CTD Background** ❯ Start eSUBmanager ❯ The elementary terminology of eSUBmanager ❯ Handling the eSUBmanager User Interface, end eSUBmanager

09:45 - 10:30	**eSUBmanager Story 1: The Initial Submission**
	 ❯ The content of the initial Submission
	 ❯ Navigating in the Hierarchy Explorer
	 ❯ Reviewing the Structure of eCTD Module EU M1
	 ❯ Reviewing the Structure of the submission (M2-M5)
	   ❯ Specific Sections / Node Extensions
	   ❯ Document Viewer

10:30 - 10:45	*Coffee Break*

10:45 - 11:30	**eSUBmanager Story 2: Reviewing the initial Submission**
	 ❯ Search in a dossier
	 ❯ Search in a document
	 ❯ The reviewing tools
	   ❯ Annotations, Highlights, Scratch Book
	   ❯ Copying text and Graphics

11:30 - 12:15	**eSUBmanager Story 3: Review follow-up submissions**
	 ❯ Working with Favorites
	 ❯ The follow-up submission 0001
	   ❯ See the changes
	   ❯ Filters and Views
	 ❯ eCTD document Life Cycle: color code
	   ❯ Compare document versions in the Life Cycle
	   ❯ Compare any two documents
	   ❯ Working with Regulatory Activities

12:15 - 12:45	**eSUBmanager Story 4: Need assessment assistance?** ❯ Several ways to get document information out of eSUBmanager **eSUBmanager Story 5: your electronic Assessment Report!** ❯ Export all Annotations – the basis for your electronic Assessment Report
12:45 - 13:00	Final questions & closing

4   Basic Training Course EURS

Duration:
one day (ca. 09:00-17:00h)

Agenda

09:00 - 09:45	**Session 1: Introduction to EURS** ❯ EURS Introduction: Getting familiar with EURS Interface ❯ Start the application: „EURS Start Page" ❯ Parts of the User Interface: Explorers and Menus

09:45 - 10:30	**Session 2**
	❯ Some Theory of eCTD
	❯ Technical Aspects of an electronic Submission
	    ❯ How to read an Applicant`s Validation Report, where can I find it later?
	    ❯ How to interpret warnings?
	    ❯ What to do with errors?

10:30 – 10:45	*Coffee break*

11:00 – 12:30	**Session 3: EURS Story 1 - The content of the initial Submission**
	❯ Open the Validation Report in EURS
	❯ Reviewing the Structure of the submission (eCTD Module M1)
	❯ Reviewing the Structure of the submission
	    ❯ Specific Sections
	    ❯ Node Extensions
	❯ Document Viewer

12:30 – 13:30	*Lunch*
13:30 – 14:30	**Session 4: EURS Story 2: Reviewing the initial Submission** ❯ Search documents ❯ Collect documents for reviewing ❯ The reviewing tools

14:30 – 15:30	**Session 5: EURS Story 3: Import and Review follow-up submissions**
	❯ Check the Validation Report of 0001
	❯ See the changes
	    ❯ Filters and Views
	    ❯ eCTD document Life Cycle: color code
	❯ Compare document versions in the Life Cycle
	❯ See annotations of previous submissions
	❯ Working with Regulatory Activities

15:30 – 15:45	*Coffee break*
15:45 – 16:45	**Session 6:** ❯ EURS Story 4: Need assessment assistance? Several ways to get document information out of EURS ❯ EURS Story 5: Creating an electronic Assessment Report
16:45 – 17.00	Final questions & closing

5   Basic Training Course EURSnext

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

Agenda Day 1

09:00 - 09:45	Introduction: Electronic Submission Management & the CTD Background ❯ Start EURSnext ❯ The elementary terminology of EURSnext ❯ Handling the EURSnext User Interface, end EURSnext

09:45 - 10:30	EURSnext Story 1: The Initial Submission
	❯ The content of the initial Submission
	❯ Navigating in the Hierarchy Explorer
	❯ Reviewing the Structure of eCTD Module EU M1
	❯ Reviewing the Structure of the submission (M2-M5)
	   ❯ Specific Sections / Node Extensions
	   ❯ Document Viewer

10:30 - 10:45	*Coffee Break*

10:45 - 11:30	EURSnext Story 2: Reviewing the initial Submission
	❯ Search in a dossier
	❯ Search in a document
	❯ The reviewing tools
	   ❯ Annotations, Highlights, Scratch Book
	   ❯ Copying text and Graphics

11:30 - 12:15	EURSnext Story 3: Review follow-up submissions
	❯ Working with Favorites
	❯ The follow-up submission 0001
	   ❯ See the changes
	   ❯ Filters and Views
	❯ eCTD document Life Cycle: color code
	   ❯ Compare document versions in the Life Cycle
	   ❯ Compare any two documents
	   ❯ Working with Regulatory Activities

12:15 - 12:45	EURSnext Story 4: Need assessment assistance? ❯ Several ways to get document information out of EURSnext EURSnext Story 5: your electronic Assessment Report! ❯ Export all Annotations – the basis for your electronic Assessment Report
12:45 - 13:00	Final questions & closing

6   Basic Training Course SafetyEasy

Agenda Day 1: SafetyEasy Administration

Time		
09:00 – 09:15		Welcome, Agenda
09:15 – 10:30	Adm1	Administrative Features of Safety Easy – Part 1
		❯ Administrator's daily tasks – Change Password, Manage Users
	–.	❯ User's Management
		❯ Software's Management
		❯ Products Management
10:30 – 10:45		*Coffee Break*
10:45 – 12:30		Administrative Features of Safety Easy – Part 2
		❯ Workflow Admin
		❯ List Management
		❯ Case Management
		❯ Clinical studies Management
12:30 - 13:30		*Lunch*

Agenda Day 1: SafetyEasy Users

Time			
13:30 - 14:15		WS 1	SafetyEasy Introduction – Basic Operations
			❯ Starting SafetyEasy
			❯ Learn about the SafetyEasy Graphical User Interface (GUI)
			❯ How to use the views
			❯ Log Out of SafetyEasy
14:15 - 15:15		WS 2	SafetyEasy Data Entry: my first case
			❯ Creating a new case, Data Entry
			❯ Add Attachment to Case
15:15 - 15:30			*Coffee Break*
15:30 - 16:45		WS 3	SafetyEasy Data Entry: completing the first ICSR
			❯ Contacts and Query Form
			❯ Classification & MedDRA Coding: Case Coding View: MedDRA Coding
			❯ Case Narrative and Medical Assessment
			❯ Case Validation / Task View + Tracking
			❯ Use the workflow
			❯ Promote / demote workflows through the life cycle
16:45 – 17:00			Final questions & closing

Agenda Day 2 : SafetyEasy Users

Time	WS	Topic
09:00 - 09:45		Wrap-up Day 1
09:45 - 10:30	WS 4	SafetyEasy Case reporting ❯ Transmitting the case via gateway ❯ Exporting E2B XML Cases ❯ Other ways to send a Case ❯ Work on a Case, Follow-Up's ❯ Case Audit Trail
10:30 - 10:45		Coffee Break
10:45 - 11:15	WS 5	SafetyEasy – Working with Workflows ❯ Workflow View ❯ Workflow Status
11:15 - 12:30	WS 6	SafetyEasy - Creating a "special" case ❯ Literature Cases ❯ SUSAR's from clinical trials ❯ Pregnancy / parent-child cases ❯ How to deal with Non-serious cases from clinical trials
12:30 - 13:30		Lunch
13:30 - 14:30	WS 6	WS 6 continued
14:30 - 15:15	WS 7	SafetyEasy – Import ❯ Import a single Case ❯ Import Batches of Cases
15:15 - 15:30		Coffee Break
15:30 - 16:00	WS 8	SafetyEasy - Search and Reports ❯ creating a report ❯ Performing Complex Search Operations using the Reports Engine ❯ Creating a Chart
16:00 - 16:45	WS 9	SafetyEasy - Data Mining ❯ Advanced Search and Reporting ❯ Options Regulatory Reports
16:45 - 17:00		Points to consider, Question and Answers