



EXTEDO
eRegulatory Affairs

**EXTEDO's Advanced Level Training
Courses**

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1 eCTDmanager

1.1 Regulatory Basics

1.1.1 eCTD Specification

Code	S_ICH_01
Title	ICH eCTD Specification V 3.2.2
Content	<ul style="list-style-type: none"> ➤ Implementation of ICH eCTD Specification V 3.2.2 requirements in eCTDmanager ➤ Implementation of selected requirements of ICH Annex 1-4 and 7
Duration	3 hrs

1.1.2 Dossier and Submission Types

Code	S_DOS_02
Title	Dossier Types
Content	<ul style="list-style-type: none"> ➤ Learn about different dossier types in eCTDmanager ➤ eCTD (Regions: EU, FDA, Canada, Japan, Switzerland, China, TW, ZA,JO) ➤ EAEU ➤ IMPD / CTA / generic dossiers ➤ Re-use of manually created structures
Duration	2 hrs

Code	S_SBMT_02
Title	EU Marketing Authorization Procedures & eCTD Submission types in eCTDmanager
Content	<ul style="list-style-type: none"> ➤ Centralized Procedure ➤ National Procedure ➤ MRP/DCP
Duration	2 hrs

Code	S_MOD_01
Title	eCTDmodules
Content	<ul style="list-style-type: none"> ➤ Specifics in eCTD Modules 1-5 ➤ Reference to EU-CTD (NTA, Vol. 2B)
Duration	2 hrs

1.1.3 Regional-specific eCTD's

Code	S_CHVAR_02
Title	CH module 1 vs EU M1, Variations in EU & CH
Content	Specifics of Swiss M1 vs. EU M1 Galenic Form Swiss Procedure Types EU/CH Variations
Duration	2 hrs

Code	S_USCA_01
Title	US (FDA) Submission
Content	<ul style="list-style-type: none"> ➤ US (FDA) submission specifics: ➤ Module 1: forms, SPL ➤ Module 4 and Module 5 (US/CA): STF wizard, STF filetags view
Duration	2 hrs

Code	S_GCC_01
Title	GCC Module 1
Content	<ul style="list-style-type: none"> ➤ GCC submission specifics ➤ Module 1: special requirements of GCC ➤ GCC-specific documents
Duration	1 hrs

Code	S_ZA_01
Title	ZA Module 1
Content	<ul style="list-style-type: none"> ➤ ZA submission specifics ➤ Module 1: special requirements of ZA ➤ ZA-specific documents
Duration	1 hrs

Code	S_CHI_01
Title	eCTD to China
Content	<ul style="list-style-type: none"> ➤ The Chinese eCTD: Backbone, M1 ➤ Language / Translations? ➤ Module 1: special requirements of CHI ➤ CHI-specific documents
Duration	1 hrs

1.2 Dossier Management

Code	S_MRP3_01
Title	The comprehensive MRP Model in eCTDmanager 3.0
Content	<ul style="list-style-type: none"> ➤ The MRP Goal ➤ Business Case ➤ Software Solution
Duration	2 hrs

Code	S_ASMF_01
Title	Active Substance Master File in eCTDmanager
Content	<ul style="list-style-type: none"> ➤ Active Substance Master File guideline (CHMP QWP/227/02, Rev 3) ➤ Applicants & Restricted Part ➤ Preparation - Customer Specific Descriptor ➤ Set Section Attributes ➤ Publishing Parameters
Duration	2 hrs

Code	S_PARS_02
Title	Submission Staging & Regulatory Activities
Content	<ul style="list-style-type: none"> ➤ <i>Parallel Sequences</i> are “<i>out-of-sequence submissions</i>” ➤ Regulatory Activities help structuring submissions ➤ Handling of parallel submissions ➤ Creation and merging of parallel submissions ➤ Conflict handling ➤ Lifecycle and Regulatory Activity view
Duration	2 hrs

Code	S_NEES_01
Title	Create a NeeS based on an eCTD
Content	<ul style="list-style-type: none"> ➤ What Is NeeS? ➤ Differences to eCTD ➤ TOC documents & configuration ➤ Export & post-export modifications
Duration	1 hrs

Code	S_VAL_02
Title	EU Validation Criteria for eCTD and NEES
Content	<ul style="list-style-type: none"> ➤ Pass-/Fail: validation guideline ➤ Current EU Validation Criteria for eCTD and NEES ➤ Most common validation issues and their solution in eCTDmanager
Duration	2 hrs

1.3 eCTDmanager Enhancements

Code	S_DM2_01
Title	DOCmanager
Content	<ul style="list-style-type: none"> ➤ Concept ➤ Template Dossiers ➤ Creation & Update of child dossiers
Duration	2 hrs

Code	S_RLP_01
Title	RLPmanager
Content	<ul style="list-style-type: none"> ➤ Concept ➤ Studies ➤ Use of Studies in eCTD's
Duration	1 hrs

Code	S_MINI_01
Title	MiniDMS feature of eCTDmanager
Content	<ul style="list-style-type: none"> ➤ Concept ➤ Document life cycle ➤ Versioning
Duration	2 hrs

Code	S_PUB_01
Title	Enhanced Printing & Publishing in eCTDmanager
Content	<ul style="list-style-type: none"> ➤ Paper Publishing basics / repetition ➤ Format Template concept ➤ Re-useability for Format Templates ➤ Printers (requirements) ➤ ePaper
Duration	2 hrs for participants of basic training 4 hrs for beginners

Code	S_PUB_02
Title	Publishing Server in eCTDmanager
Content	➤ Publishing Server (optional)
Duration	2 hrs (can only be booked after S_PUB_01)

Code	S_PUB_03
Title	Using ToC / ToT / ToF in eCTDmanager

Content	<ul style="list-style-type: none"> ➤ Advanced Publishing options: ➤ Table of Contents ➤ Table of Tables ➤ Table of Figures
Duration	2 hrs (can only be booked after S_PUB_01)

1.4 Technics

Code	S_TECH_02
Title	eCTDmanager technical training
Content	<ul style="list-style-type: none"> ➤ eCTDmanager architecture & installation scenarios ➤ supported databases ➤ Archives (file system, DMS) ➤ Configuration of eCTDmanager.exe.config ➤ Licensing and User Management ➤ Attribute Type Descriptors ➤ internal mode ➤ publish service ➤ notification service ➤ Attribute Value Lists and Validation ➤ Troubleshooting and Support Request Information
Duration	4-8 hrs (depending on specific requirements)

2 EURS

2.1 EURS Enhancements

Code	S_AUTE_01
Title	EURS Automation Engine
Content	<p>EURS Automation Engine is a console-based application to automatize several specific 'EURS' functions from the command line (submission import, validation, indexing)</p> <ul style="list-style-type: none"> ➤ Key Features of the EURS Automation Engine ➤ Manual vs. batch Input Commands ➤ Preparing and Executing a Job File ➤ Importing and Remocing eCTD / NeeS Submissions ➤ Search Index Creation ➤ Shortcut Generator ➤ Create and Maintain Custom Attributes ➤ AE XML Logfiles ➤ Other Features: Available Validation Sets, Help Sets, Encryption
Duration	2-4 hrs (w/o practical work)

Code	S_EUDW_01
Title	EURS Distributed Working
Content	<p>Distributing EURS Services on multiple systems: Enhance EURS with “distributed working” options, i.e. to schedule and repeat jobs and to automatically queue and distribute jobs to run them simultaneously in order to gain performance.</p> <ul style="list-style-type: none"> ➤ Introduction: What are EURS Services? ➤ Managing and Administering Services with the EXTEDO Web Broker ➤ Job Details
Duration	1 hr (configuration and setup of Services and Broker is not included!)

2.2 Technics

Code	S_EUTT_01
Title	EURS technical training
Content	<ul style="list-style-type: none">➤ EURS architecture & installation scenarios➤ supported databases➤ Archives (file system, DMS)➤ EURS.ini➤ internal mode➤ Custom Attributes
Duration	2-4 hrs (depending on specific requirements)