

## Advanced Level Trainings

### 1 eCTDmanager

#### 1.1 Regulatory Basics

##### 1.1.1 eCTD Specification

Code	S_ ICH_01
<b>Title</b>	<b>ICH eCTD Specification V 3.2.2</b>
Content	<ul style="list-style-type: none"> <li>• Implementation of ICH eCTD Specification V 3.2.2 requirements in eCTDmanager</li> <li>• Implementation of selected requirements of ICH Annex 1-4 and 7</li> </ul>
Duration	3 hrs

##### 1.1.2 Dossier & Submission Types

Code	S_ DOS_02
<b>Title</b>	<b>Dossier Types</b>
Content	<ul style="list-style-type: none"> <li>• Learn about different dossier types in eCTDmanager</li> <li>• eCTD (Regions: EU, FDA, Canada, Japan, Switzerland, China, TW, ZA,JO)</li> <li>• EAEU</li> <li>• IMPD / CTA / generic dossiers</li> <li>• Re-use of manually created structures</li> </ul>
Duration	2 hrs

Code	S_ SBMT_02
<b>Title</b>	<b>EU Marketing Authorization Procedures &amp; eCTD Submission types in eCTDmanager</b>
Content	<ul style="list-style-type: none"> <li>• Centralized Procedure</li> <li>• National Procedure</li> <li>• MRP/DCP</li> </ul>
Duration	2 hrs

Code	S_ MOD_01
<b>Title</b>	<b>eCTDmodules</b>
Content	<ul style="list-style-type: none"> <li>• Specifics in eCTD Modules 1-5</li> <li>• Reference to EU-CTD (NTA, Vol. 2B)</li> </ul>
Duration	2 hrs

### 1.1.3 Regional-specific eCTD's

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

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

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

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

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