Advanced Level Trainings

1 eCTDmanager

1.2 Dossier Management

Code	S_MRP3_01
Title	**The comprehensive MRP Model in eCTDmanager 3.0**
Content	• The MRP Goal • Business Case • Software Solution
Duration	2 hrs

Code	S_ASMF_01
Title	**Active Substance Master File in eCTDmanager**
Content	• 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	• *Parallel Sequences* are "*out-of-sequence submissions"* • 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	• 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	• Pass-/Fail: validation guideline • Current EU Validation Criteria for eCTD and NEES • Most common validation issues and their solution in eCTDmanager
Duration	2 hrs