

Training

- ① Dossier defⁿ & brief introduction
- ② Input & Output

③ Flow (Normal)

- ④ Code Master & its validations
- ⑤ Submission plan & its validations
- ⑥ Attach files

→ ~~Observe~~ Observe diff. modules & sections.

→ Observe diff. attributes & applicable for different sections.

→ Observe different file extensions to different sections.

→ SPL section

→ Study applicable sections.

→ Observe eCTD filenames, actual & file title (validations).

→ Max. length of actual file allowed

⑦ Compile the submission (Preview)

⑧ Verify the submission

⑨ ~~Download~~ Download the submission

⑩ Observe different structures.

⑪ Observe when download is possible.

⑫ Define submission attributes

⑬ Submission plan Edit/Delete. (CSV validation)

⑭ Submission audit.

⑮ Observe folder structure (contents) → how folders are generated in different modules.

⑯ Read util folder documents.

⑰ STF → ~~def~~ⁿ use, tagging.

⑱ Observe different tags. → Tags having site identifiers.

⑳ Observe category related sections.

㉑ ~~Reset~~ Reset & Freeze

㉒ Higher versions.

㉓ Change in submission plan fields (high level & low level)

㉔ Concept of SSN, FRSN, MRSN. Active & inactive files, operations.

㉕ Attach links

㉖ Draft versions

㉗ Inherit Activity