Preparing for the New eCTD Mandates
Mastering the Tools and Strategies

Agenda

DAY ONE

8:00 a.m. – 9:00 a.m. **Continental Breakfast/Registration**

9:00 a.m. – 9:15 a.m. **Introduction, Logistics and Overview of Day 1 Learning Objectives**

9:15 a.m. – 10:00 a.m. **What is an eCTD Submission for the US? (eCTD, SPL, CDISC)**

- What is new as a result of FDASIA 2012 and PDUFA V, MDUFA III, GDUFA and BsUFA?
- What are the steps for preparing to submit an eCTD?
- Communication with regulatory authorities
- eCTD pilot
- Electronic Submission Gateway (ESG) pilot
- What do regulatory authorities do with your eCTD?
- What are the consequences of submitting a noncompliant eCTD?
- At what phase in product development can I begin submitting eCTDs?

10:00 a.m. – 10:15 a.m. **Break**

10:15 a.m. – 12:00 p.m. **Where Do the Contents of an eCTD Come From?**

- Documents:
  - Inside authors
  - Outside suppliers (CROs, CMOs, contract writers)
  - Regulatory affairs
- Data:
  - Biostatistics and data management
  - Manufacturing quality control

    - CROs

- XML Overview — What a Sponsor Needs to Know About XML in the Context of eCTD
    - What is XML?
    - How is XML used in eCTD submissions, labeling and study reports?
    - Who produces XML and why?
    - What are a sponsor's responsibilities for the validity of the XML content of their submissions? When outsourcing submission publication? When publishing using in-house systems?
    - What is the impact of submission publishing workflow on XML validation?
    - Regulatory Product Submissions (RPS) — the next generation of XML for eCTD
- How do I integrate the eCTD culture within my company?

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:30 p.m. Issues About Content of eCTD Submissions

- FDA Automated Submission Receipt (ASR) process and the impact of noncompliance
- Top 10 errors FDA encounters with eCTD submissions
- Standards for document authoring
- Standards for data management and biostatistics workflow
- Electronic data capture and case report forms (CRFs)
- Standards for scanning
- Content review and approval, including electronic signatures
- Content management during the lifecycle of the drug development process
- Coupling regulatory strategy with document management and eCTD life cycle management

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:00 p.m. How to Produce Your eCTD

- Demonstration of an eCTD submission system
- Outsourcing
- Purchasing and implementing an in-house eCTD publishing system
- Combination
- Budget and timeline recommendations

- What if I don't have an electronic document management system (eDMS)?

4:00 p.m. – 4:30 p.m. **Q&A and Review Learning Objectives**

DAY TWO

8:00 a.m. – 9:00 a.m. **Continental Breakfast/Registration**

9:00 a.m. – 9:15 a.m. **Introduction, Logistics and Overview of Day 2 Learning Objectives**

9:15 a.m. – 10:00 a.m. **Best Practices in Use of MS Office — Including Demonstration on How to Use MS Word**

- Templates
- Cross references
- Tables of contents/tables/figures/listings/appendices
- Publication references

10:00 a.m. – 10:15 a.m. **Break**

10:15 a.m. – 12:00 p.m. **Best Practices in Use of Adobe Acrobat Professional**

- Characteristics of submission-ready PDF files
  - All agency requirements for PDF files
  - File format
  - Security
  - Open to bookmarks + page
  - Inherent zoom
  - Absolute path vs. relative path for intradocument cross references and bookmarks
  - Tables of contents
  - Page numbering
  - Levels of bookmarks
  - Amount of hyperlinking
- If you must scan to create PDF files?
- What are the consequences of noncompliant PDF files from the perspective of global health authorities?

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 2:30 p.m. Overview of Leading eCTD Submission Publishing Systems

- Vendors
  - Accenture/Octagon ViewPoint
  - Aspire
  - CSC/ISI eCTDXpress
  - Ennov eCTD
  - Extedo
  - Liquent Insight/S-Cubed
  - Lorenz
  - Mission3
  - TAKE Solutions
- Validation and Review tools for eCTD submissions
  - GlobalSubmit
  - Extedo GLOBALvalidator and EURS is Yours
  - Lorenz eCTD Validator
  - CDISC or SAS datasets review tools

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:00 p.m.

- **Break Out Session — Conduct an eCTD readiness assessment for your company and present your findings and recommendations**

4:00 p.m. – 4:30 p.m. Q&A and Review Learning Objectives