



CTD Quality Consulting

Helping the Pharma Industry Stay Current with the CTD

New Course:

Easing the Transition to CTD/eCTD for INDs/NDAs

CTD Quality Consulting assists your transition to the CTD and eCTD from phase 1 IND to NDA/BLA marketing application, including maintenance of updates (life cycle management). With a focus on authoring, in this course you will discover how to:

- Expand the content of standard CTD submissions sections from phase 1 through marketing and post-approval to gain efficiencies in the drug development process.
- Create submission-ready documents from the start that fit into the CTD submissions, eliminating time-consuming, tedious re-works.
- Optimize the use of navigation tools such as bookmarking, hyperlinks, and tables of contents to reduce FDA review time.
- Plan appropriate eCTD granularity for ease of life cycle management and management of submission content revisions.
- Assess and improve submission processes, workflow, and teamwork to achieve less stress and cost to the organization.
- Transition from paper to eCTD and explore the various options that ease that transition, working with an extended team of electronic publishing experts to quickly ramp up electronic submissions.
- Plan CTD submissions early to accelerate the final preparation, publishing, and filing with FDA to reduce time to market.

Suggested for:

- Submission authors and technical report generators
- Regulatory Affairs and Regulatory Publishing/Operations
- R&D, Clinical and Nonclinical Development, and Operations
- Program Executives and Project Managers
- Anyone interested in gaining efficiencies and improving team work in the submissions process.

Improve workflow efficiency in preparation of IND and NDA submissions

Facilitate acceleration of drug development and approvals

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Suggested Course Outline:

Session 1: Overview of the CTD and eCTD (2 hours)

- What's new and different – Modules 1-5
- Regional differences
- Expanding from IND to NDA
- Submission-Ready Documents
- Benefits of eCTD
- Life Cycle Management
- eCTD considerations
- Key needs and tools

Session 2: Authoring the CTD/eCTD, special considerations for each module (2 hours)

Module 1 - Administrative

Module 2 - Summaries

Module 3 – Quality (CMC)

Module 4 – Safety (Nonclinical)

Module 5 – Efficacy (Clinical)

Note: This could be expanded into a 2-day course, or advanced training delivered as needed

Session 3: Process is Key – The Submission Team and Workflow (2 hours)

- Planning Process – Strategy, defining roles, project management, mapping source documents to the submission
- The Submission Team – extended team, communication
- Authoring Process – writing standards, granularity, cross-referencing
- Review Process – review tools, meetings
- Publishing Process – paper or eCTD
- Life Cycle Management, Granularity

Session 4: Considerations in Using CTD/eCTD Tools

(Can be co-taught with eCTD vendor or electronic publishing group)

- Templates
- Navigation – hyperlinks, bookmarks, TOC
- eCTD Compilation and Verification
- eCTD Viewing
- SPL Structured Product Labeling, structured content
- Life Cycle Management
- Document Management Systems, version control, repositories
- Secure Electronic Gateway (FDA)
- Action Items