



# CTD Quality Consulting

Helping the Pharma Industry Stay Current with CMC

*Improving Regulatory Documentation Efficiencies for  
Accelerating Time to Market*

## **NEW: CTD Quality IND/NDA Templates**

CTD Quality Consulting provides training and assistance in writing high quality CTD Quality sections (drugs or biologics) of your IND (investigational) or NDA/AND/BLA (marketing) applications and/or Drug Master Files in CTD (Common Technical Document) format (*required by Europe and Canada, and highly recommended by FDA*).

CTD Module 3 templates are customized for each client's product to:

- Assist authors in writing the IND/NDA/ANDA/BLA on pre-formatted templates by providing instructions on content and format of each section of Module 3, with recommended table shells for data, information, and question-based review features requested by FDA.  
*Note: IND templates include Modules 1-5 of the CTD.*
- Provide organized format and content that assists/speeds FDA review.
- Assist project management by facilitating 1) management approval of key content and format of the submission prior to writing, 2) gap analysis, and 3) tracking of outstanding items.
- Save time, money, and stress to the organization in preparing IND/NDA/ANDA/BLA sections by cutting down on formatting and re-writing;
- Easily expand Module 3 of the IND during development in preparation of IND CMC amendments and the CMC section of the NDA/ANDA/BLA.

CTD Quality Consulting also provides training (*see course description on next page*), expert authoring and review, preparation of the Quality Overall Summary, mapping of source documents to the CTD, and gap analysis of Chemistry, Manufacturing, and Controls (CMC) documents. Michelle Herrera Foster, Ph.D. Chemistry, has more than 20 years experience in the pharmaceutical industry, with more than 15 years experience in preparing regulatory submissions and in providing CMC regulatory training.



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## *Preparing CMC Submissions in CTD Format from IND to NDA*

### ***NEW COURSE: CTD Quality Submissions Training***

This course provides in-depth training in the content and format of Chemistry, Manufacturing, and Controls (CMC) submissions and also presents proven processes for expediting and achieving shorter sustainable submission cycles, with lower cost, less preparation and review time, and more efficient use of resources, with less stress to the organization. Courses can be customized for your product(s) and needs.

Participants will learn:

- In-depth review of FDA and ICH requirements for IND, NDA, ANDA, BLA, and DMF CMC submissions in the CTD format.
- Preparation of “submission-ready documents” prepared in the IND phase in a modular format for global submissions and the eCTD.
- The use of CTD templates and model documents to assist the authoring process.
- Product development planning with continuous gap analysis and life cycle management.
- Cross-functional team building and development and use of contract manufacturers/vendors, to streamline DMF and NDA technical information.
- The strategy for and preparation of CMC supplements and annual reports following FDA regulations and SUPAC guidance documents.
- Examples from case studies in small and large pharmaceutical organizations.

#### ***Day 1***

Content and format of the CTD Module 3 and the Quality Overall Summary from a regulatory perspective, with submission planning and tools such as submission-ready documents, product development planning, life cycle management, and gap analysis

#### ***Day 2***

The technical aspects and details of FDA and ICH guidelines related to each section of Module 3, and CMC strategy, with case studies.

#### ***Day 3 (optional)***

Interactive workshops and client document reviews (which can also be interspersed with lecture time over the three days.)

See [www.ctdquality.com](http://www.ctdquality.com) for course outlines, bios of Michelle Herrera Foster, Ph.D. and Mukund Chorghade, Ph.D., and updates on courses. See previous page for information on customized IND/NDA templates that assist authors in writing CMC submissions.