

CTD Quality Consulting

Helping the Pharma Industry Stay Current with CMC

NEW COURSE: CTD Quality Submissions Training

Preparing CMC Submissions in CTD Format from IND to NDA

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.

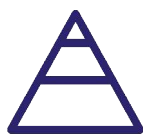
Learning Objectives

Participants will learn, in-depth, the regulatory and technical content / format of Chemistry, Manufacturing, and Controls (CMC) sections of investigational and marketing submissions and associated FDA and ICH guidelines from instructors who have combined experience of more than 40 years with CMC submissions and teaching courses on CMC submissions in the CTD format. Participants will learn to prepare submissions more efficiently and effectively by building cross-functional teams. The course focuses on preparation of submission-ready reports that can be written early in development and that can be inserted or expanded for the marketing applications. The use of CTD mapping and templates to facilitate gap analysis, project management, CMC strategy, and life cycle management will also be discussed in interactive sessions. Case studies presented throughout the course encourage discussions.

Who Should Attend

This course will benefit all involved in generation of data, writing, reviewing, and managing preparations of sections of CMC submissions in pharmaceutical and biotechnology companies of any size and clinical phase of development, including members of:

- ▶ Regulatory Affairs
- ▶ Chemistry
- ▶ Analytical
- ▶ Pre-formulation
- ▶ Pharmaceutical development
- ▶ Manufacturing
- ▶ QA/QC
- ▶ Project Management



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Course Description

This course provides an in-depth review of FDA and ICH requirements and easy to implement proven processes and tips for preparing the chemistry, manufacturing, and controls (CMC) documentation for the investigational new drug application (IND), the New Drug Application (NDA), the Drug Master File (DMF), pre-meeting packages, and other related CMC submissions using the Common Technical Document (CTD) content and format. Details of regulatory guidelines and regulations are presented for the technical data sections of submissions addressing manufacturing, pharmaceutical development, analytical, stability, chemical characterization, excipients, and sterility as they apply to the drug substance and drug. Training is also provided in:

1. Preparation of "submission-ready documents" prepared in the IND phase in a modular format for global submissions and the eCTD.
2. The use of CTD templates and model documents to assist the authoring process.
3. Product development planning with continuous gap analysis and life cycle management.
4. Building and using the submission team, including contract manufacturers and other vendors to get DMF and NDA technical information.
5. The strategy for and preparation of CMC supplements and annual reports following FDA regulations and SUPAC guidance documents.

Agenda

Day 1

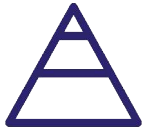
Content and format of the CTD from a regulatory perspective, with submission planning and tools such as submission-ready documents, product development planning, life cycle management, and gap analysis. An overview of the content and format of each section of the CTD Module 3 and the Quality Overall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

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 case reviews (which can also be interspersed with lecture time over the three days.)



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Customized Training

Customization of training for your particular product can also be pre-arranged to enhance learning for your on-site course. With a confidentiality agreement in place, a customized course allows for open discussions using actual data, issues, and solutions for a particular product. This also provides a unique opportunity to do bring the project team together to discuss strategy in the context of the training.

Instructor Bios

See www.ctdquality.com for bios of Michelle Herrera Foster, Ph.D. and Mukund Chorghade, Ph.D., course outlines, and updates on courses.