COBBLESTONE

COURSE ID 1989

CMC Writing and Submission Strategies: A Global Regulatory Approach

DIRECTED BY

Shrinivas (Cheenu) Murti, Ph.D. MBA, Head, Global Regulatory Affairs - CMC Business Process Excellence and Devices, Takeda Pharmaceuticals

12 Hours

ACCREDITED COURSE

- Prerequisite Online Course Access
- Drug Substance and Drug Product Data in Clinical Trial and Marketing Applications
- Regulatory CMC Strategies for Global Filings Consideration
- Case Studies

about the course

The required prerequisite online course provides an overview of the regulations, guidelines, and procedures of major health authorities. By understanding the ICH Common Technical Document (CTD) and supporting documents, participants will be ready to move into the intensive online training with a clearer understanding of agency requirements.

The CTD is the basis of drug, biologic, and drug-device combination registration applications. A proper understanding of CTD writing strategy and health authority expectations can greatly aid a company in gaining approval. With the prerequisite complete, this 12-hour accredited training, will provide in-depth instruction on Chemistry, Manufacturing, and Controls (CMC) requirements and review processes for clinical trial, registration, and post-approval drug applications in the US, Europe, and Japan. Additional considerations and integrative approaches for other key country submissions (Canada, Australia, China, Brazil, Korea, etc.) and Most of the World markets will be presented. Development, manufacturing, analytical testing, controls, and stability issues will be discussed for solids, parenteral and other dosage forms. Overviews of Quality by Design (QbD) submissions and Drug Master Files will be presented. Successful regulatory filing strategies and best practices will be illustrated with examples and case studies.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

This course is intended for individuals responsible for R&D/technical writing/quality management/original and post-approval submissions in pharmaceutical companies, especially those in:

- Regulatory Affairs
- Process Chemistry
- Analytical Chemistry
- QA/QC
- Scale-up and Technology Transfer
- Preformation and Formulation Development

learning objectives

Upon completion of this course, you will be able to:

- Describe the regulatory review processes and health authority expectations through the product lifecycle
- Analyze and compile CMC data to support CTD clinical trial applications, registration files, and post-approval submissions in the US and Europe
- Explain special writing strategies for Quality by Design marketing applications, Drug Master Files, and "Most of the World" registration dossiers
- Identify regulatory compliance issues in agency inspections

course outline

Prerequisite Online Training:
To maximize the in-person training experience, participants are required to access and attend the following online segments prior to the start date of the course. (Detailed instructions will be sent with the registration confirmation package.)

Unit 1 (pre-course recording; approximately 1 hour): Regulatory Agencies and Processes

- Key regulatory agencies and ICH: organization and roles
- Regulations/directives/CMC-relevant guidelines
- Marketing authorization procedures
- Regulatory intelligence & agency interactions

Unit 2 (pre-course recording; approximately 45 mins): Regulatory Document Basics

- The Common Technical Document
- Drug Master Files
- GMP support documents (licenses, CEPs, etc.)

Unit 3–Review of Learning Objectives/Course Introduction

Unit 4–Clinical Trial Applications: CMC Content and Strategies
Regulatory and GMP considerations for INDs/IMPDs/CTAs

- Content issue for drugs and biologics
- Globalization strategies

Unit 5–Marketing Applications: CTD Module 3

- Rational writing for NDAs, MAAs, BLAs, ANDAs, etc.
- Agency review expectations and experiences

Unit 6–Fundamentals of Strategy Development

- CTD authoring and content harmonization
- Storyboarding
- Regulatory CMC strategy plan
- Commitment sections

Unit 7–Special Submission Elements

- CTD Module 2.3 (quality overall summary)
- Question-based review
- EU and Japan submission Considerations

Unit 8–Quality by Design

- ICH Q8/Q9/Q10/Q11

Unit 9–Post approval CMC Changes

- US and EU post-approval guidelines and filing strategies
- ICH Q12

Unit 10– Agency Inspections and GMP

- Relating regulatory content to preapproval inspections

Unit 11– Select CMC Strategy Issues Topics may include but are not limited to:

- Regulatory starting materials
- Drug-device combinations
- Bridging strategies/biowaivers
- Comparability protocols
- Batch size flexibility
- Analytical issues for drugs and biologics
- Patient-centric specification setting
- Stability for drugs and biologics

Unit 12–Key Most of the World Market Submissions

- Countries may include, but are not limited to Australia, Brazil, Canada, China, India, Korea, Mexico, Turkey, and South Africa

Unit 13– Effective Writing

- Interactive Workshop
- Parking lot topics
- Case Studies

Question and Answer Session

Assessment Opportunity

course instructor

Shrinivas (Cheenu) Murti is Head of Global Regulatory CMC Submissions & Business Process Excellence at Takeda Pharmaceuticals, Cambridge, MA, USA. He has a B. Pharmaceutical from the University of Bombay, India, a Ph.D. in Pharmaceutical Sciences from the University of Missouri, and an MBA from Rutgers University.

Cheenu previously worked at Merck & Co., Schering-Plough, and Organon including 3 years in The Netherlands. He has over 20 years of experience in Global Regulatory CMC with the clinical trial application, global registration, post-approval responsibilities, and management for small molecules, biologics, and drug-device combinations. He has interacted with global health authorities, leading many topics of regulatory strategy, and has given invited presentations in the US, Europe, and India.

Cheenu has been affiliated with several professional associations and served on cross-industry working groups including AAPS, PhRMA, CASSS, the IQ Consortium, ISPE, and the Combination Products Coalition. He has developed and taught Cobblestone courses on CMC submissions and strategies in the US, The Netherlands, Spain, and Turkey since 2009, and lectured at several universities in an adjunct faculty or advisory role. He is a past President of the American Association of Indian Pharmaceutical Scientists (AAiPS).

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 12 contact hours or 1.2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS-established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.