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Academy

Preparing the Quality Module of the CTD

Online Course: Understanding and preparing the quality and pharmaceutical module of the global CTD Dossier

29 January - 1 March 2024 | 6 May -7 June 2024 | 2 September - 4 October 2024

5-week online course | 10 Modules | 2 hours per week

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Online Program

Course Information

Key Learning Objectives

- Understand the different levels of requirements in CMC during development and post-approval phase
- Get an overview of the structure of the CTD Module 3 and Quality Overall Summary (QOS)
- Understand the essential requirements for a drug substance and how to submit them
- Learn how to write the CTD sections on manufacturing and excipients
- Control on the finished product: learn how to set appropriate specifications and write the section
- Understand the requirements for packaging materials
- Get an overview of stability requirements

Who Will Benefit

CTD training will be valuable to any person involved in the preparation of the CTD Module 3, as well as people from pharmaceutical development and/or production. For example:

- Regulatory affairs
- Regulatory CMC
- Quality assurance specialists
- Product scientists
- R&D pharmaceutical project managers
- Analytical and stability laboratory managers (from R&D to GMP)
- Production technical experts

Course Information

About the Course

Preparing the registration dossier for the Marketing Authorisation application is a critical milestone of drug development. This course focuses on key regulatory requirements for the content and structure of the quality module of the Common Technical Document (CTD Module 3).

This CTD course provides knowledge on the scientific data that are required on the quality of the drug product and helps you understand the expectations of regulatory authorities worldwide in terms of content and level of detail.

Meet Your Course Director

Sophie Nageotte
Regulatory CMC Expert

Sophie has over 20 years of experience in the pharmaceutical industry. She gained her Master's degree in analytical chemistry from Manchester University and her Chemical Engineer degree from Montpellier School of Chemistry. She went on to work in pharmaceutical development and post-marketing CMC regulatory compliance in companies such as Bayer, Stragen, PregLem and Laboratories Galderma. She gained a strong experience in the worldwide regulatory environment for the manufacture and control of the medicines.

She now runs her own consultancy, delivering consultancy and support in writing IMPDs, CTD Module 3 and QOS, preparing variations and answering questions from health authorities.

Sophie also delivers training courses on European regulations for pharmaceuticals, writing of the Module 3, how to achieve global regulatory compliance, managing transfers of manufacturing sites and preparing variations for the ASEAN region.

"The course trainer was friendly and clearly very knowledgeable. I found the flexibility of the course and the structure very useful to fit around my schedule."

Regulatory Affairs Specialist, Liqvor CJSC

Course Outline

Module 1:
CMC IN THE DRUG DEVELOPMENT PROGRAMME

- What is CMC?
- Introduction to drug development.
- Considerations for CMC Data Requirements at different stages of drug development.
- Other considerations impacting CMC and Drug Development.

Module 2:
CTD MODULE 3 & QUALITY OVERALL SUMMARY

- What does CTD mean?
- Module 3 Structure and Quality Overall Summary (QOS).
- Purpose and content of module 3 and QOS
- QOS strategy
- Future perspective

Module 3:
PREPARING THE DRUG SUBSTANCE SECTION OF THE APPLICATION

- Analysing the needs for the section
- How to submit information – Drug Master Files, Certificates of Suitability, other methods
- Detailed information requirements for the section

Module 4:
ESSENTIAL INFORMATION FROM API SUPPLIERS

- Identify essential data requirement
- Understand the essential requirements from API suppliers/manufacturing section
- Impact on finished products

Module 5:
MEETING MANUFACTURING AND INSPECTION REQUIREMENTS

- Regulatory compliance and manufacturing issues in relation to the application
- Clarifying manufacturing licence criteria
- Preparing for pre-approval inspection
- Examining the relation between GMP and CTD Module 3

Module 6:
WRITING THE SECTION ON THE MANUFACTURE OF THE DRUG PRODUCT AND PROCESS VALIDATION

- Examining the content of the section: How much information to provide
- Defining the difference between process development and validation
- Post-approval commitments
- Writing the sections on excipients
- Examining the content of the section

Module 7:
WRITING THE SECTIONS ON CONTROL OF THE FINISHED PRODUCT

- Examining the content of the section
- Control of the drug product

Module 8:
MODULE 7 SPECIFICATIONS

- Identify and understand the writing of specifications Dossier Requirements.
- Adjusting specifications during development.
- Justification of specifications.

Module 9:
STABILITY SECTION

- Examine the content of the section
- Evaluation of stability data and the impact on shelf-life
- QbD and Stability

Module 10:
Pharmaceutical packaging

- Regulatory requirements for pharmaceutical packaging
- How to reflect requirements in the dossier
- Quality and suitability of packaging
- Packaging specifications

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Easy Ways to Register

www.informaconnect.com/academy | +61 (02) 9080 4399 | training@informa.com.au

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Course Code	Location/ Format	Course Dates	Standard Price	
P24GO51ON	Online Program	29 January - 1 March 2024	$2,095 + $209.50 GST	**$2,304.50**
P24GO51ON02	Online Program	6 May - 7 June 2024	$2,095 + $209.50 GST	**$2,304.50**
P24GO51ON03	Online Program	2 September - 4 October 2024	$2,095 + $209.50 GST	**$2,304.50**

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Informa Connect Academy

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