ONLINE COURSE

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PREPARING THE QUALITY MODULE OF THE CTD

Understanding and preparing the quality and pharmaceutical module of the global CTD Dossier

5-week online course | 10 Modules | 2 hours per week 2 May - 3 June 2022 | 5 September - 7 October 2022

Our Expert Course Instructor

Sophie Nageotte, Regulatory CMC Expert

Sophie has over 22 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.

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

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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).

It 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 details.

WHO WILL BENEFIT

Any person involved in the preparation of the CTD Module 3, but also 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

Would You Like To Run This Course On-Site?

Informa Corporate Learning: On-site & Customised Training

If you have **8+** interested people, an onsite course can be an ideal solution. Speak with **Anton Long** on **+61 481 995 653** or **Holly Baldwin** on **+61 450 866 597** to discuss your customised learning solution, or email **training@informa.com.au**

EXPERT COURSE INSTRUCTOR

Sophie Nageotte
Regulatory CMC Expert

With over 22 years of experience in the pharmaceutical industry, Sophie has a strong experience in the CMC Regulatory field. 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, PregLem and Laboratoires Galderma.

She gained a strong experience in the worldwide regulatory environment for the development, manufacture, and control of the medicines. Since 2015, she runs her own consultancy, delivering advice in pharmaceutical development strategies and providing support in writing IMPDs and INDs, CTD Module 3 and QOS, preparing variations and answering questions from health authorities. Her experience covers a wide range of products (small molecules and biologics) and pharmaceutical forms.

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.

BENEFITS OF LEARNING ONLINE

Informa Corporate Learning's online courses are new digital, interactive and engaging educational experience designed to maximise learning for professionals with busy schedules and/or small training budgets.

Our online courses are perfect opportunity for busy professionals as they require just 2 hours per week of your time and include an interactive forum for you to ask direct questions about challenges you are facing to expert course leaders.

Modules are released on a weekly basis, so you can pace yourself alongside your peers and you will have access to a comprehensive set of assets to support your learning such as video content, quizzes and case studies.

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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

- Module 3 structure & 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 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

WHAT OUR CLIENT SAY

"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

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Easy Ways to Register

1. **Web**
   www.informa.com.au/ctd
2. **Telephone**
   +61 (02) 9080 4395
3. **Email**
   training@informa.com.au

Preparing the Quality Module of the CTD

Course Code	Location	Course Dates	Standard Price		4+ Dels Discount
P22GO51ON	Online	2 May - 3 June 2022	$1,695 + $169.50 GST	**$1,864.50**	**Great Savings:** When you book **4 or more** participants! **Call us** today on **+61 (02) 9080 4395** or email **training@informa.com.au** to take advantage of the discount offer.
P22GO51ON02	Online	5 September - 7 October 2022	$1,695 + $169.50 GST	**$1,864.50**	

If you're an international customer based outside of Australia, the GST will be excluded.

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Informa Corporate Learning – On-site & Customised Training

Informa Corporate Learning has a long-standing track record of delivering very successful customised learning solutions achieving real and measurable value for our clients through our senior training consultants.

If you have 8+ interested people, an on-site course can be the ideal solution – giving you the opportunity to customise our course content to your specific training needs, as well as attracting significant savings compared to public course costs.

Why Choose On-site With Informa Corporate Learning?

1. **Custom design** – Together, we will identify the best blended learning solution for your culture, your people and your training objectives.
2. **Quality Assured** – We design market-leading training programs, concepts and methodologies, with a 400+ course portfolio. Our rigorously selected 900+ instructor faculty are recognised experts in their field. Quality of their content and delivery methods is assured through continuous monitoring and evolution.
3. **On-site training** is a cost effective way to train your people and achieve your defined outcomes.

Our Long Standing Clients Include:

Rio Tinto, Siemens, Yarra Trams, Oz Minerals, Southern Program Alliance, SBS, Sarawak Government, Petronas, Boehringer Ingelheim, Glencore, Bluescope Steel, Baker Hughes, ActewAGL, Ambulance Victoria, ANU, Arrow Energy, Australian Super, Barrick, BHP, Chevron Australia, ConocoPhillips, CSIRO, Dalrymple Bay Coal Terminal, Department of Education, Department of Planning, Electricity Generating Authority of Thailand (EGAT), ENI Australia, EY, Fortescue Metals Group, Health Purchasing Victoria, IBM, IP Australia, Jemena, Metro Trains, Origin Energy, Public Transport Authority – WA, QGC – BG Group, Queensland Rail, Rio Tinto, Romgaz, South Australia Health, Woodside and more...

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