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Academy

Fundamentals of EU Regulatory Affairs

Online Course: Gain a comprehensive understanding of the EU regulatory framework and explore strategies for dossier application to ensure speedy approvals.

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

5-week online course | 8 Modules | 2 hours per week

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Online Program

Course Information

Key Learning Objectives

- Gain a complete overview of the EMA and the various types of MAAs
- Understand the regulatory affairs throughout product development including R&D, manufacturing, clinical trials, and PV
- Learn the procedures for gaining clinical trial approval and appreciate the importance of GCP
- Gain an insight into the new CT Regulation and to prepare for future changes
- Discover what goes into a drug dossier application to ensure speedy approvals
- Examine the CTD with a detailed focus on the CMC/quality module, non-clinical study reports module and clinical study reports module
- Appreciate the difference between pharmaceutical and biopharmaceutical products and compare the key regulatory differences
- Understand the requirements of packaging and labelling pharmaceutical products in the EU
- Learn how to file for variations in your product post approval for efficient life cycle management
- Gain a solid grounding in pharmacovigilance and understand the importance of building a PV strategy to maintain patient safety

Who Will Benefit

Our EU regulatory affairs course benefits those new to regulatory affairs or wishing to update their knowledge on European regulatory affairs:

- Regulatory affairs professionals seeking to improve their skills in the regulatory environment
- Those moving into regulatory affairs from other areas within a pharmaceutical company (pharmacists, clinical trials, marketing, and others)
- Regulatory affairs, registration and documentation assistants/officers/managers
- Those in other areas of the pharmaceutical industry such as development or manufacturing
- Project managers who would find knowledge of the regulatory environment useful

Course Information

About the Course

Our EU regulatory affairs training course provides a grounding knowledge of regulatory frameworks in Europe. After over 5 weeks and 8 modules, you will gain a clear understanding of the EU regulatory structure and have a solid grasp of the submission process and the standards required by the regulators.

Gain an understanding of the regulatory framework the EU uses in evaluating marketing authorisation applications. Explore strategies for dossier application to ensure speedy approvals in clinical studies.

This EU regulatory affairs online course will give you a practical insight into the European regulatory environment throughout the whole product life cycle including non-clinical and clinical studies, the various submission procedures, labelling and packaging, post-MAA obligations, activities, and more.

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 online sessions allowed me flexibility to fit training into my busy work schedule."

Regulatory Publisher, Novo Nordisk

Course Outline

Each module contains approximately 1 hour of content.

Module 1:
OVERVIEW OF THE EU REGULATORY FRAMEWORK

- Regulatory bodies and competent authorities
- Legislative system
- The 4 main status for your products: medicine, medical device, food supplement and cosmetics
- Medicines: the EU pharmaceutical law and where to find it

Module 2:
PRODUCT DEVELOPMENT: NON-CLINICAL STUDIES

- The Target Product Profile
- Non-clinical development
- Toxicology
- Pharmacokinetics and toxicokinetics
- Environmental risk assessment

Module 3:
PRODUCT DEVELOPMENT: CLINICAL STUDIES

- The current clinical trial directive
- The new clinical trial regulation
- Regulatory and ethical approval guidance
- Good Clinical Practices (GCP)
- Special cases for children

Module 4:
MARKETING AUTHORISATION APPLICATION 1/3: THE REGULATORY PROCEDURES

- Centralised procedure
- Decentralised procedure
- Mutual recognition procedure
- Specific procedures: orphan drugs, paediatric medicines, advanced therapies, herbal medicinal products
- Scientific advice

Module 5:
MARKETING AUTHORISATION APPLICATION 2/3: THE REGISTRATION DOSSIER

- GxP and MA dossier
- Overview of the Common Technical Document (CTD)
- Requirements for the different modules:
  - Module 1 – Administrative data
  - Module 2 – Summaries
  - Module 3 – CMC/quality
  - Module 4 – Non-clinical studies
  - Module 5 – Clinical studies
- Electronic submissions: NeeS and eCTD

Module 6
MARKETING AUTHORISATION APPLICATION 3/3: LABELLING AND PACKAGING REQUIREMENTS

- Overview of the directives and guidelines
- Assess SmPC requirements
- Labelling requirements
- Examine Patient Information Leaflets (PILs) in Europe
- Overview of readability guidelines

Module 7
POST-MAA: FILING VARIATIONS AND RENEWALS

- Introduction to filing variations
- Variations requirements and procedures
- Compare the different types of variations: Type IA, IB and II
- Variations vs extensions
- Renewal legislation and procedures

Module 8
POST-MAA: PHARMACOVIGILANCE OBLIGATIONS

- Good pharmacovigilance practices
- Pharmacovigilance system
- Periodic safety update reports (PSURs)
- Risk management plan and post-authorisation safety studies (PASS)

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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	
P24GO06ON	Modular	29 January - 1 March 2024	$2,095 + $209.50 GST	**$2,304.50**
P24GO06ON02	Modular	6 May - 7 June 2024	$2,095 + $209.50 GST	**$2,304.50**
P24GO06ON03	Modular	2 September - 4 October 2024	$2,095 + $209.50 GST	**$2,304.50**

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ABOUT INFORMA CONNECT ACADEMY

Informa Connect Academy

Informa Connect Academy is a premier provider of global education and training solutions that caters to a diverse range of professionals, industries, and educational partners. We are dedicated to promoting lifelong learning and are committed to offering learners expert guidance, training, and resources to help them stay competitive in a rapidly changing world.

Our comprehensive range of courses and programmes are tailored to meet the needs of all professionals, from aspiring specialists to seasoned experts. We partner with elite academic organisations and industry leaders with unmatched expertise in their respective fields to deliver an exceptional learning experience.

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Informa Connect Academy 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 CONNECT ACADEMY?

1. **Custom design –** Together, we will identify the best blended learning solution for your culture, your people and your training objectives.
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3. **On-site training** is a cost effective way to train your people and achieve your defined outcomes.

Speak with **Sushil Kunwar** on **+61 (2) 9080 4370** to discuss your customised learning solution, or email **training@informa.com.au**