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Pharmaceutical Regulatory Affairs for EU

LIVE ONLINE TRAINING | 28 - 29 March 2024

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Course Information

LIVE ONLINE TRAINING	March 2024	Part 1	28 March	Part 2	29 March	4pm - 8pm AEDT

Key Learning Objectives

Regulatory Affairs for Europe (Module 1 and 2)

- Overview of regulatory bodies & competent authorities; EU legislative
- systems
- Clinical Trial regulations (data requirements, IRB; CTR 2014, ICH GCP; differences within EU)
- Clinical Trial Approval Process
- Product Development regulations (Non-clinical studies vs Clinical studies)
- CTD and eCTD
- Labelling and packaging regulations
- Marketing Authorisation Applications (CP, DCP, MRP, National Procedures)
- Post-MAA obligations, Pharmacovigilance and lifecycle management
- Understanding abridged applications

Case studies: biosimilars, oncology, OTC, generics

- Working effectively with EMA
- Legal issues (product recalls, CT violations, data manipulations, data privacy etc)

Meet Your Course Director

Dr. Salma Michor
(PhD, MSc, MBA, CMgr, RAC-Treasurer), CEO, Michor Consulting

Salma has advised numerous global clients across Pharmaceutical, Medical and Food industries, including J&J, Novartis, Pfizer and Shire and many more. She had previously worked for Torrex-Chiesi (Chiesi Farmaceutici S.p.A); Wyeth Whitehall Export, and Croma Pharma GmbH and had been the Director of Global Supporting Operations – Medical Devices and Pharmaceuticals (Ophthalmology & Orthopedics) where she was in-charge of technical and leadership of four departments – including Regulatory Affairs and Compliance; Medical and Vigilance; Change Control and Life Cycle Management; as well as Packaging and Pharmaceutical editing. Her duties included overall leadership & personnel management, budgeting and strategic planning, liaison with external contractors, doctors and customers in 60 countries worldwide. Here she also gained first-hand experience with submission of clinical trials phases:I-III as well as turnaround management of post-Mergers and Acquisitions integration operations.

Her experiences include:

- Post-acquisition phase-out and closedown after M&As
- Managing DCP registrations
- Consolidation of Multi-language labelling texts for pharmaceutical products and medical devices
- Forming clinical and registration strategies for medicinal products (combination, generics)
- Labelling compliance for drugs & food supplement
- Authoring CMC sections for drug products or drug/device combination products
- Preparing pharmaceutical and medical device companies for internal and FDA audits
- Managing large company-wide compliance projects (CAPA, GMP, ISO, etc)
- Preparing companies in 3rd countries for EMA, MHRA and AGES inspections and managing the whole biotech registration and clinical testing in the EU

Course Information

About the Course

In the heavily regulated, rapidly changing environment, staying informed with requirements and guidelines maintained by different authorities is crucial to pharma/biotech players. Complex and challenging, the success in clinical approvals, dossier submission, pharmacovigilance, product filing, among other operations, allow you to accelerate market access and achieve bottom line.

This live-online masterclass explores key touchpoints across European regulatory systems. The training offers attendees an in-depth examination into latest regulatory reforms, legislative developments, including data privacy, labelling & packaging, post-MAA obligations, import & manufacturing registrations, fast-track approvals, as well as key legal issues.

Course Outline

OVERVIEW OF EU REGULATORY FRAMEWORK

- Regulatory Bodies and Competent Authorities
- Legislative system
- EU pharma law

PRODUCT DEVELOPMENT – NON-CLINICAL STUDIES

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

PRODUCT DEVELOPMENT – CLINICAL STUDIES

- Clinical trial directive
- Regulations
  - Ethics Committees, IRB
  - Data requirements
  - CTR 2014
  - ICH GCP
  - Difference between EU countries
  - GCP
- Data protection

MARKETING AUTHORISATION APPLICATION

- Regulatory Procedures
  - Centralised procedure & decentralised procedure
  - Mutual recognition procedure

Case studies: *Orphan drugs, advanced therapies, etc*

  - Scientific advice
- Registration dossier
  - GxP and MA dossier
  - CTD and eCTD requirements
  - CMC module

LABELLING & PACKAGING REQUIREMENTS

- Packaging & labelling guidelines
- Patient information leaflets PILs in Europe
- SmPC
- Serialisation of Pharma Folding Cartons
- Track-and-trace solutions
- Readability guidelines

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

PHARMACOVIGILANCE OBLIGATIONS

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

PRACTICAL CONSIDERATIONS

- Working effectively with EMA
- Understanding abridged applications
- Legal issues

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Easy Ways to Register

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Course Code	Location/ Format	Course Parts	Course Dates	Standard Price	
P24GL36AUV	Live Digital	All 2 Parts	28 - 29 March 2024	$1,795 + $179.50 GST	**$1,974.50**

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