PAYMENT

$2150.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

EARLY BIRD DISCOUNT

If you register at least thirty days in advance you will receive a $200 discount on the course.

ADDITIONAL DISCOUNTS

Contact us at 610-648-7550 or info@cfpie.com for additional discounts on multiple registrations.

CANCELLATION POLICY

All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CFPIE reserves the right to alter the venue, if necessary.

Substitution Policy - Classroom Courses

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

ABOUT CfPIE

Learn from the Leader

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

HOW TO REGISTER

1.

Go to http://www.cfpie.com

2.

Go to "Training" and select your course.

3.

Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
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http://www.CfPIE.com

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European Regulatory Procedures - Comprehensive Overview of EMA and National Requirements

April 3-4, 2017
Malvern, PA

COURSE DESCRIPTION

This course will give participants the necessary overview of the application procedures and regulatory filing pathways used within Europe to grant marketing authorisations for medicinal products, and of the agencies and institutions that control the regulatory process. Special focus will be given to the European Medicines Agency (EMA) and the Centralised Procedure (CP), with the role of the national health authorities and other EU bodies in the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) explained also. Factors affecting the choice of procedure will be discussed, as well as best practice in the management of the procedures.

A workshop session will engage participants in a case study evaluating the options for submission of a marketing authorization application.
The course will also outline how variations to the marketing authorisation, as well as authorisation of specific groups of products such as orphan, paediatric, advanced therapy and herbal medicinal products are handled in the EU. The transparency of EU regulatory decision making will be demonstrated via review and navigation of EU regulatory websites. The impact of key emerging trends already affecting or likely to impact on European pharmaceutical registrations in the future will be discussed.

INSTRUCTOR CREDENTIALS

Mary Rafter is a pharmaceutical professional with experience across regulatory affairs, regulation of medicines, quality and scientific support. She is currently a consultant contributing to academic education programs.

Following a period in pharmaceutical quality control for Rice Steele & Co., Ms. Rafter joined the National Drugs Advisory Board (forerunner of the Irish Medicines Board) in 1983. There, she spent fourteen years as a pharmaceutical assessor. In this role, she was involved in clinical trials and the quality assessment of EU and national applications. In that time, she also developed a specialization in inhaler technologies.

In other roles, Ms. Rafter served as Technical and Marketing Services Manager for Cahill May Roberts, EU-Qualified Person in batch release with Wyeth and as Senior Regulatory Affairs Manager for Pfizer (formerly Wyeth Medica Ireland). There, her responsibilities included scientific support, training and coordination of several major regulatory projects.

She received her Bachelor of Science Degree in Pharmacy from University College Dublin and her Master's of Science Degree in Pharmaceutical Medicine from Trinity College. She also maintains her status as a registered pharmacist with the Pharmaceutical Society of Ireland.

Ms. Rafter has represented the Irish Medicines Board at CPMP/CHMP/EMEA as a pharmaceutical expert. She was also a delegate to the EU Working Party on Strategy for CFC Inhaler Phase-out and member of the EU Working Group on the Implementing Guidelines for Clinical Trials Directive.

WHO SHOULD ATTEND

An experienced ex-regulator will deliver this course and provide a comprehensive overview of the regulatory filing requirements in Europe. The course will be of value to both those who are new Regulatory Affairs in the pharmaceutical, biopharmaceutical and generic drug industries, as well as experienced professionals wishing to refresh their regulatory knowledge. Personnel whose responsibilities require knowledge of the EMA and European country regulatory environment, such as Project Managers and those in Clinical, Non Clinical, Manufacturing and Quality areas will also find this training highly relevant.

HOTEL INFORMATION

The Berlin Hilton, Berlin, Germany (CfPIE room rate of Standard Single Room is €179.00 and Double Occupancy is €199.00 inclusive of VAT and Breakfast if booked 4 weeks in advance.)

FIRST DAY

Legal Basis for the European Regulation of Medicinal Products

- Historical perspective
- EU Pharmaceutical Legislation Overview
- Review of the key EU Directives and Regulations governing medicinal products
- Legal basis of marketing authorization applications and how data requirements are met
- Main features of the EU Marketing Authorisation (MA)

Understand the EU Institutions for Pharmaceutical Regulation and How they Interact

- European Commission (EC)
- European Medicines Agency (EMA)
- European Directorate for the Quality Of Medicines (EDQM)
- National Competent Authorities and interactions via Heads of Medicines' Agencies/CMDh
- EU Agreements and Co-operation-International, Tripartite, Bilateral and Regional

Regulatory Pathways – the Centralized Procedure

- Overview of the Centralised Procedure (CP)
- Mandatory versus Optional Scope
- Consultations with EMA and Pre-submission activities
- Managing procedural phases up to adoption of the final CHMP opinion, including written and oral presentations
- The CHMP opinion and post-opinion activities – possible outcomes and their implications

Review and Navigation of the European Medicines Agency Website

- This interactive session will give ample opportunity to ensure participants are familiar with locating available guidances and procedural documentation on the EMA website as well as exploiting the publicly available product-specific information to view the decision-making procedures used by the EMA in assessing and reaching its opinion.

Decentralized and Mutual Recognition Procedures-Practical Considerations

- Key features and differences of DCP and MRP
- Role of the Reference Member State (RMS) and booking your RMS slot
- The role of the Co-ordination Group – CMD(h)
- Planning and managing MRP and DCP
- Referrals (Article 30 and 31)

SECOND DAY

Variations to the EU Marketing Authorization (Post-Approval Changes)

- Background and key elements of the variations procedure
- Implementing texts and guidelines
- Options for filing "unforeseen" changes
- Grouping and Worksharing
- Role of the CMDh

EU Regulatory Innovations for Specific Groups

- Orphan medicinal product incentives
- Paediatric development incentives – the PUMA and extension to patent protection
- Traditional Herbal Medicinal Products Certification– a simplified registration scheme
- Advanced Therapy Medicinal Products (ATMPs)-additional provisions governing these
- Conditional Marketing Authorisation, Exceptional Circumstances and Accelerated Review

Workshop on developing an EU Regulatory Filing Strategy

- This interactive workshop session will engage participants in a case study, to evaluate the various options for the submission of a marketing authorization application, in order to inform the corporate regulatory strategy for the compound in the EU

Challenges to Global Submissions Management: EU versus US Key Differences

- Regional differences in Common Technical Document Administrative information
- Role of Module 2 summaries
- Incorporation of additional EU technical requirements, use of CEPs
- Presenting EU Product Information: SmPC, Package Leaflet, Labeling
- Managing divergence in EU procedures, e.g. national MAs, MRP/DCP referrals

Emerging Trends Impacting on EU Pharmaceutical Registration, including

- Emerging topics presented are updated continually e.g. Health Technology Assessment, Prescription to non-prescription switches, EMA Reflection papers, etc.