IPI Academy

MANAGEMENT forum



Presented by
Management Forum

EU Pharmaceutical Regulations and Strategy

1-2 March 27
+ 4-5 October 27

The course will provide an up-to-date overview of the current European pharmaceutical regulatory environment including procedures for obtaining marketing authorisation and post-approval obligations. Political agreement on the proposed changes to the EU pharmaceutical legislation has been reached and projected implementation and transition timelines will be discussed in the relevant sections and impact on strategic considerations for obtaining and maintaining marketing authorisations. Procedures for obtaining marketing authorisations in the UK will be discussed.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

In the highly regulated field of pharmaceuticals, staying abreast of regulatory affairs is invaluable for ensuring compliance, maintaining market authorisations, and effectively managing drug development and post-approval obligations. Navigating the complexities of regulatory processes, particularly in the context of evolving legislation, can be challenging.

Creating and coordinating an effective regulatory strategy is an important part of the work of a regulatory affairs department and can save valuable time and money. It is therefore necessary to be aware of potential changes and new procedures and methodologies which may impact on planning and strategy.

This interactive course will provide an overview of the current European pharmaceutical regulatory environment, procedures and obligations. Political agreement on changes to EU pharmaceutical legislation has been reached. Implementation and transition timelines will be discussed.

The programme will cover the legal basis of EU regulation, development strategies and the importance of pre-submission activities, a brief overview of the format for presentation of data, the registration procedures for obtaining marketing authorisations and post-authorisation obligations and strategic considerations. The increasing use of AI in product development, manufacturing and post-authorisation activities will be considered in the relevant sections.

The UK is no longer part of the EU but it is a major pharmaceuticals market and knowledge of interactions and collaboration with the EU and other regulatory agencies are important for obtaining and maintaining marketing authorisations in the UK.

Case study sessions will explore options and strategies for key regulatory activities and provide an opportunity for discussion and the sharing of experiences with our expert trainer and other delegates.

Benefits of attending

- **Understand** the legal basis of the current EU regulatory environment
- **Outline** the background to and the proposed EU pharmaceutical legislation changes in the identified key areas
- **Discuss** development strategy and pre-submission activities and the use of AI
- **Review** procedures for applying for a marketing authorisation in the EU/EEA and in the UK
- **Discuss** post-authorisation strategic considerations and obligations

Who should attend?

The course is designed primarily for regulatory affairs personnel, however it will also be of value to those who interact with the regulatory affairs function and would benefit from an understanding of action timelines and information requirements. It will be particularly relevant to all those working in:

- Regulatory affairs
- Project management
- Business planning
- Commercial management
- Manufacturing and QA
- Labelling and artwork
- Medical information
- Clinical
- Pharmacovigilance

Programme

Day 1

EU regulatory environment: background and legal basis

- Proposed EU pharmaceutical legislation changes, current status and implementation
- Key regulations, directives and guidelines with discussion of proposed changes for specific product categories

Information sources

Case study one

Development and strategy including the use of AI

- Drug discovery
- Scientific advice

Development process

- Pharmaceutical R&D
- Non-clinical tests
- Clinical studies

EU Clinical Trials Regulation

Types and categories of marketing authorisations

Adaptive marketing authorisation procedures

The Common Technical Document (CTD)

- Brief overview of Structure and content of the EU CTD

Procedures for obtaining a marketing authorisation in the EU and the EMA

- The EMA
- Current procedure and proposed changes

Other EU centralised procedures

- Referral and arbitration

Day 2

Other procedures for obtaining a marketing authorisation in the EU

DCP, MRP and National (includes UK)

Managing product labelling

Case study two

Abridged applications and Generics

- Types and Requirements

Product life cycle; post approval

Patents and SPCs

Parallel trade

Post-authorisation obligations; pharmacovigilance, variations and renewals

Pharmacovigilance

- Safety reporting
- PSURs

Licence variations

- Type I and Type II variations and timelines
- Procedures and timelines

Extensions

Case study three

Renewals

Sunset clause

Phase IV clinical studies

Classification change

Generic development

Strategic considerations (summary)

- Line extensions
- Classification switch
- Parallel trade

Criteria for successful products

Current status of EU proposed legislation changes and implementation timelines

Presenter



Norah Lightowler

Norah Lightowler is a partner in Lightowler Associates, an independent consultancy offering regulatory advice and support to pharmaceutical companies in or proposing to enter the European market for human pharmaceuticals. They are in their twenty fourth year of successful business. She has wide experience in the pharmaceutical and related nutraceutical, herbal and devices industries as a pharmaceutical assessor with the UK regulatory authority and as associate director of European regulatory affairs with an international pharmaceutical company. She is experienced in organising and presenting courses on European regulatory control systems, including requirements, procedures and strategy.

Course dates

1-2 March 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17021*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 04 Jan**
4-5 October 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17382*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 09 Aug**

How to book

Online:
ipi.academy/2239

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Overall, it was a wonderful webinar and has helped me further expand my knowledge on the EU/UK regulations. I look forward to participating in future webinars.

Iva Martinovic
Medical Information Professional
Teva
Feb 10 2025

★★★★☆

Very Good. I wanted to get an overview of EU Pharmaceutical Regulations and to understand regulatory strategies to bring new products quickly into the market. The course covered everything I needed and even more.

Chitra Saxena
Senior Manager Regulatory Affairs
Lupin Healthcare (UK) Limited
Feb 10 2025

★★★★★

Excellent presenter! Truly professional!

Anastasios Stylianos Karountzos
Regulatory Affairs Officer
Pharmathen
Oct 16 2023

★★★★☆

Good overview of the Pharmaceutical Legislation and interesting summary of future changes in the legislation framework. Case studies were a good opportunity to discuss regulatory strategies.

Adriana Lopes
Regulatory Affairs
Bluepharma Indústria
Oct 16 2023

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



Harry ALTAMONT
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com