IPI Academy

MANAGEMENT forum



*Presented by*
**Management Forum**

# An Overview of EU and UK Regulatory Affairs

**3-4 February 27**
+ 20-21 September 27

This two-day course provides an introduction to pharmaceutical regulatory affairs and the fundamentals of drug development. It is particularly valuable for those who are new to the regulatory function or work in a supporting or interactive role.

**Format:**
Live online

**CPD:**
12 hours for your records

Certificate of completion

# Course overview

**This interactive course provides an overview of pharmaceutical regulatory affairs and its key responsibilities and would be of value for those new to the function or in support or interactive roles.**

Navigating the complexities of regulatory processes, particularly in the context of evolving legislation, can be challenging.

Participants will gain knowledge of current and proposed EU legislation revision and of regulatory procedures available to register products in the EU and the regulatory activities required to maintain products on the market.

The UK is no longer a member of the EU but interactions and collaboration with the EU and other regulatory agencies for obtaining and maintaining marketing authorisations in the UK will be discussed.

Discussion sessions and practical case studies will help to consolidate learning, providing attendees with the skills and knowledge to be effective in their roles within the pharmaceutical industry.

## Benefits of attending

- **Understand** the background to EU legislation and proposed revisions
- **Gain** an understanding of the Common Technical Document
- **Discuss** how to apply for a marketing authorisation in the EU via the centralised, decentralised and mutual recognition procedures
- **Clarify** post-authorisation obligations - pharmacovigilance, variations and renewals
- **Contribute** to your Continuing Professional Development (CPD)

## Who should attend?

This course is designed for personnel wishing to gain an understanding of regulatory affairs in the pharmaceutical industry, including:

- Administrators
- Assistants
- Personnel new to regulatory affairs
- Those considering a role in regulatory affairs

It will also be of value to those who interface with the regulatory affairs function or support regulatory procedures and activities.

# Programme

## Day 1

**Current EU legislation**

- Background
- Proposed changes to EU legislation; background and key areas. (Other changes will be discussed in the relevant sections)

**Drug Development**

- Pharmaceutical R&D
- Non-clinical tests
- Clinical studies – Phase I to IV

**Clinical trials in Europe**

**Seeking scientific advice in Europe**

**Marketing Authorisations**

- Types of and categories for marketing authorisations

**Overview of the structure and content of a CTD**

**Procedures for Marketing Authorisation in the EU**

**EU centralised procedures**

- The EMA
- The Centralised Procedure (CP)
- Referral and arbitration

## Day 2

**Non-centralised procedures for marketing authorisation in the EU and in the UK**

- Co-ordination group
- Decentralised procedure (DCP)
- Mutual recognition procedure (MRP)
- National procedures
- Procedures in the UK

**Abridged applications and generics**

- Types and requirements

**Product life cycle; post approval**

**Parallel trade**

**Post-authorisation obligations**

**Pharmacovigilance**

**Licence variations**

- Types and timelines

**Extensions**

**Renewals**

**Sunset clause**

**Managing and supporting a regulatory affairs department**

# 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

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|---|---|---|
| **3-4 February 27** | **Live online**<br>09:30-17:00 **UK (London)** (UTC+00)<br>*Course code 17003* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 09 Dec** |
| **20-21 September 27** | **Live online**<br>09:30-17:00 **UK (London)** (UTC+01)<br>*Course code 17335* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 26 Jul** |

## How to book

**Online:**
ipi.academy/1112

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

★★★★☆

**I was a bit worried about not having a face-to-face course and discussions but it worked very well, it was really comfortable to do it from my home and we had no major connectivity issues.**

**Viktoria Vanyik**
Global Regulatory Affairs, Compliance Associate
GSK
Sep 29 2020

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★★★★★

**Highly recommended course for anyone wishing to learn more about their involvement within the regulatory affairs team at your particular company. The speaker, Norah, was very effective in her presentations and included each delegate and was able to highlight how certain areas were specific to them.**

**James Smith**
Regulatory Affairs Officer
Kyowa Kirin International
Mar 14 2019

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★★★★☆

**Great speaker**

**Ena Mrakužić**
Public Relations Associate
Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
Sep 23 2019

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★★★★☆

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Public Relations Associate
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Sep 23 2019

## 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:



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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.

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