IPI Academy

MANAGEMENT forum

Presented by
Management Forum

EU Proposed Pharmaceutical Legislation Changes

18 September 2024

On 26 April 2023, the European Commission proposed a new directive and regulation to revise and replace current pharmaceutical legislation. This course will provide an up-to-date overview of current European pharmaceutical legislation and the proposed changes. The potential regulatory impact of the proposed changes on company planning and strategy will be considered and discussed.

Format:
Live online

CPD:
3 hours for your records

Certificate of completion

Overview

It is essential that companies are aware of proposed changes to pharmaceutical legislation in the EU and the potential impact on company planning and strategy.

The UK is no longer a member of the EU but knowledge of interactions and collaboration with the EU are important for obtaining and maintaining marketing authorisations in the UK and the EU.

The programme will cover the current legal basis of pharmaceuticals regulation in the EU and proposed changes in pharmaceuticals legislation. The proposed changes in procedures for obtaining marketing authorisation in the EU and post-authorisation data and marketing protection will be considered. The changes in the role and responsibilities of the EMA will be discussed.

The format will provide opportunities for discussion and for sharing of concerns and experiences with our expert trainer and other delegates.

Benefits of Attending

- **Understand** the legal basis of the EU regulatory environment
- **Discuss** proposed changes to EU Pharmaceuticals legislation
- **Review** current and proposed procedures for applying for a marketing authorisation in the EU/EEA and in the UK
- **Consider** post-authorisation data and marketing protection
- **Learn** about proposed changes to the EMA responsibilities and function

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 strategic factors. It will be of interest to personnel working in:

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

Programme

Introduction of presenter and participants

Aim of course

Background

- Background to proposed EU legislation changes
- EU regulatory environment
- Proposed changes to EU pharmaceuticals legislation

Pre-submission

- Development advice
- Discussion re adaptive procedures

Submission procedures

- EU procedure for obtaining marketing authorisation and proposed changes
- Centralised Procedure (CP)

Submission procedures (continued)

- Decentralised Procedure (DP)
- Mutual Recognition Procedure (MRP)
- National procedures

Post-authorisation

- Post-authorisation data and marketing protection and proposed changes
- Post-authorisation obligations and proposed changes

Institutional and wider issues

- The EMA
- One Health
- Environmental protection

Q & A and discussion

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 date

18 September 2024

Live online
13:30-17:00 **UK (London)** (UTC+01)
Course code 14270

GBP **299** ~~349~~
EUR **429** ~~499~~
USD **501** ~~579~~
Until 14 Aug

How to book

Online:
ipi.academy/2705

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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

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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