IPI Academy

MANAGEMENT forum



Presented by
Management Forum

EU Proposed Pharmaceutical Legislation Changes

18 January 27
+ 7 July 27

This course will provide an up-to-date overview of current European pharmaceutical legislation and the regulatory impact of the proposed changes.

Format:
Live online

CPD:
3 hours for your records

Certificate of completion

Course overview

In the dynamic and 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 and a comprehensive understanding of current and proposed revisions of pharmaceutical legislation is important.

The proposed changes, published by the Commission in April 2023, were followed by significant lobbying from the pharmaceutical industry. The European Parliament's position was published in March 2024, and the Council agreed its position on 4 June 2025. A political agreement between the Council, the European Parliament, and the Commission was reached on 11 December 2025.

The final text now requires formal endorsement by both the European Parliament and the Council before it can be published in the Official Journal, which is expected in Q2 2026. Implementation and transitional arrangements will follow.

Developing products is a lengthy process and the cost of developing new and modified products is increasing. It is therefore important that companies are aware of procedures and timelines for obtaining marketing authorisations and to know what if any post approval data and marketing protection will be available.

The background to and main objectives of the proposed changes in pharmaceuticals legislation will be outlined.

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

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

Please note:

This programme has been designed to reflect an understanding of the EU regulatory landscape for medicinal products, as well as the current status and implementation of proposed legislative changes. Content will be delivered using the most up-to-date information available at the time of presentation.

Attendees can expect a clear overview of the current position, along with discussion of implementation and transition timelines and the associated regulatory impact.

Benefits of attending

- **Understand** the legal basis of the EU regulatory environment
- **Learn** about the background to and reasons for the proposed revision of pharmaceuticals legislation in the identified key areas
- **Review** current and proposed modifications to procedures for applying for a marketing authorisation in the EU/EEA and in the UK
- **Consider** post-authorisation obligations and data and marketing protection

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 in obtaining and maintaining marketing authorisations.

It will be of interest to personnel working in:

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

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

18 January 27	**Live online** 13:30-17:00 **UK (London)** (UTC+00) *Course code 16963*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 23 Nov**
7 July 27	**Live online** 13:30-17:00 **UK (London)** (UTC+01) *Course code 17276*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 12 May**

How to book

Online:
ipi.academy/2705

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

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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