IPI Academy

MANAGEMENT forum

Presented by
Management Forum

The FDA Drug Approval Process

7-8 October 2025

A comprehensive overview of FDA procedures, requirements for marketing authorisations and recent developments affecting the drug approval process in the US

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

The US is the largest market globally for pharmaceutical sales, so having a good understanding of FDA procedures is vital for those submitting in this challenging region. This course will help clarify the US regulatory process, giving you a practical insight into FDA requirements and ensuring that you are fully up to date with all the latest developments.

The comprehensive programme will cover procedures for submission of INDs, NDAs, ANDAs and 505(b)(2), provide a useful insight into the organisation and structure of the FDA and its review processes, and highlight recent changes. The course will emphasise areas of interest to innovative manufacturers, but will also deal with issues relating to generic and over-the-counter drugs.

There will be ample opportunity for discussion with our expert trainer as well as other delegates and a practical workshop session to optimise learning.

Benefits of attending:

- **Review** the latest FDA regulatory requirements for drug development
- **Understand** FDA regulatory strategic needs
- **Ensure** that you comply with FDA requirements for NDAs, ANDAs and 505(b)(2)
- **Discuss** recent changes and developments with an industry expert and Improve your communication and interactions with the FDA

Who should attend?

This programme will be especially beneficial to those responsible for preparing US registration documents (INDs, NDAs, Biologics License Applications, etc), regulatory affairs personnel, lawyers and others responsible for advising companies on strategies for developing new drugs for the US market.

Programme

Day 1

Pharmaceutical Medicine and Documents

- The role of regulatory affairs
- The purpose of the Common Technical Document (CTD)

FDA History and Organisation

- Review of FDA centers
- Organization of the CDER and CBER
- Differences between CDER and CBER

Legal Basis (Patent Exclusivity PDUFA, GDUFA, BsUFA)

- 21st century cure act
- Patent and exclusivity
- PDUFA
- GDUFA
- BsUFA

Legal Basis Continued

Application and Submissions Types

- Investigational new drugs (IND)
- New drug applications (NDA)
- Abbreviated new drug applications (ANDA)
- Over the counter drugs (OTC)
- Biologics license applications (BLA)
- Orphan drug designations

Refusal to File

- Reasons for refusal
- The regulatory process

Investigational New Drug (IND) Applications

- Review of the content of an IND

Getting Products to the Market Faster

- Review of expedited programs in the US
  - Fast Track designation
  - Breakthrough Therapy designation
  - Accelerated Approval
  - Priority Review designation

FDA Meetings and Documentation

- FDA communication philosophy
- Different meeting types
  - Scope
  - Format
  - Procedure

CTD Content - Setting the Scene

- Lean authoring to ensure possible document re-use for multiple purposes
- A review of the different modules

CTD Content - M1

Day 2

CTD Content - M3 and Corresponding M2

CTD Content - M4 and Corresponding M2

CTD Content - M5 and Corresponding M2

Submission Format and Methods

- Study tagging files
- Datasets
  - Case report forms
  - Bioresearch monitoring (BIMO) clinical data

US Amendment Procedures

- A review of US amendment procedures (incl. annual reports, minor/major changes)

High Level Comparison US vs EU

- A review of the main differences in terms of dossier content and procedures

Case Study

Presenter

Andrew Willis

Andrew Willis is an independent consultant providing expert advice and training on global regulatory solutions and pharmaceutical development. Previously, he worked for Catalent Pharma Solutions as VP Regulatory Affairs & Consulting Services, where he was head of a team of internal and external regulatory affairs consultants.

He qualified as a Chemist from the University of Glamorgan, after which he furthered his understanding of pharmaceutical development, working as a research chemist with Parke Davis. He had 10 years manufacturing and analytical experience prior to entering regulatory affairs as a Senior Executive Officer with responsibility for submission of European MAAs and project management of development programs. He has over 30 years' pharmaceutical experience with extensive knowledge in the development and manufacture of sterile, solid oral, inhalation, topical and biotech pharmaceutical products. These experiences have allowed knowledge of many biotech products requirements with experiences of growth hormones and multiple cancer treatments, including development and clinical registration of the first genetically modified live bacterium for such treatment.
He has extensive experience of major European and US regulatory projects, in the clinical and marketing authorisation stages, and has significant experience in coordinating and managing meetings with European and US Health Authorities.

Course date

7-8 October 2025

Live online
09:00-17:00 **UK (London)** (UTC+01)
Course code 15109

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 02 Sep

How to book

Online:
ipi.academy/2133

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 hoping to gain a better understanding of the US approval process as I currently work on EU registrations but am moving to a more global role. The webinar covered the US process really well and I don't feel there was anything missed.

Susan Scanlan
Principal Scientist
Dechra Limited
Jun 12 2024

★★★★☆

[Speaker] answered all the questions, and the discussions were super helpful. Very satisfied. Would recommend.

Camila Tavares
International Medical Manager
Novo Nordisk
Dec 2 2024

★★★★☆

A good, detailed process of FDA drug approval process

Richa Dcruz
Regulatory Affairs officer
Shorla Oncology
Oct 2 2023

★★★★☆

Very good webinar I am glad I was able to attend.

Magdalena Olszewska
Sr. Director RA EMEA
Bausch Health Poland Sp. z o.o.
Jun 14 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

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