IPI Academy

MANAGEMENT forum




*Presented by*
**Management Forum**

# US FDA - Understanding Key Factors When Working with the FDA

**19 January 27**
+ 7 July 27

This course has been designed to provide an essential overview of the critical factors when working with the FDA (Food and Drug Administration). For those short on time this course is for you, as you will receive a focused and comprehensive overview of the key strategic considerations when making applications to the FDA.

**Format:**
Live online

**CPD:**
6 hours for your records

Certificate of completion

# Overview

**This course has been designed to provide an essential overview of the key factors when working with the FDA.** It will equip senior managers and project managers with pivotal information to enable them to interact with their teams and ask critical questions to ensure the best outcomes when making applications to the FDA.

The programme will provide an overview of the US FDA's organisational divisions and examine the drug development regulations. It will provide a valuable guide through the review options and discuss the New Drug Application (NDA) process and how the FDA deals with Generics and Biosimilars.

For those short on time this course is for you, as you will receive a focused and comprehensive overview of the key strategic considerations when making applications to the FDA.

## Benefits of Attending

- **Learn** the critical factors involved when embarking on product development for the US market
- **Understand** how to communicate effectively about US activities throughout the organisation
- **Know** the structure of the FDA and how it works
- **Understand** how to comply with the regulations and requirements
- **Discover** the best review process for your application
- **Learn** the requirements and processes for biologics and advanced therapies
- **Review** the key differences between the EU and FDA applications for Generics (ANDA) and Biosimilars (315k)
- **Get the opportunity** to understand the complexities and discuss best approaches with an expert in this area

## Who Should Attend

- Pharmaceutical and Biopharmaceutical Starts-ups
- Pharmaceutical Executives
- Senior Management
- Business Development Managers
- Regulatory Strategists
- Project Managers
- All those who wish to broaden their knowledge on working with the FDA

# Programme

**Overview of the US Food and Drug Administration (FDA)**

- Brief history of the FDA and Regulations and how we got to where we are today
- Review the FDA's organisation by division

**Examining the Drug Development Regulations in the US**

- Clinical trials and Investigational New Drug (INDs)
- Discover who is involved in development and the types of INDs
- Basic understanding of the IND content and timings

**FDA Meetings**

- Review the various FDA meetings in accordance with PDUFA VII (Prescription Drug User Fee Admendments)

**Evaluation of FDA Review Options**

Understanding the following FDA review options:

- Fast track / Priority review / Accelerated review / Breakthrough status
- Understand the importance of Cell and Gene Therapy in FDA and Regenerative Medicine Advanced Therapies (RMAT) Process / Interact

**Reviewing the New Drug Application (NDA) process / Biologics Licensing Application (BLA) Process**

- Defining full NDAs / BLA
- Examining the NDA categories
- Explaining abbreviated NDAs and 505 (b) (2)

**Understand ANDA (Generics) and 351K (Biosimilars) Applications**

- Review of key differences to EU
- Overview of regulatory positions
- US strategies for development

**Review the Importance of Lifecycle Management in the US**

- Annual reports
- Change being Effective
- Prior Approval Supplements
- Comparison to EU variation regulation

# 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 dates

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| **19 January 27** | **Live online**<br>09:00-17:00 **UK (London)** (UTC+00)<br>*Course code 17165* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 24 Nov** |
| **7 July 27** | **Live online**<br>09:00-17:00 **UK (London)** (UTC+01)<br>*Course code 17518* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 12 May** |

## How to book

**Online:**
ipi.academy/2649

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

★★★★☆

**Did a great job trying to keep everyone engaged - a challenge when all remote and so much content to cover.**

**Hannah Swayze**
Sr Dir ClinOps
Lindus Health
Nov 26 2025

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★★★★☆

**Thomas Lehmann Falck**
Novo Nordisk Denmark
Nov 27 2024

## 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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