IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Biosimilars

15-16 March 27
+ 20-21 September 27

A two-day course providing an essential overview of biosmilars and how they differ from the original biological product.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Prepare for the biosimilar market growth as some of the world's best-known biologics face patent expiration in the coming years.

In today's pharmaceutical landscape, the rise of biosimilars presents a pivotal shift in therapeutic options, offering more affordable alternatives to biologics whose patents are expiring. With major biologics facing patent expiration in the near future, the biosimilars market is poised for substantial growth, driving increased interest and investment in this sector.

This course delves into the critical distinctions between biosimilars and their reference biologics, addressing the complex regulatory pathways and challenges in both the EU and US markets.

Participants will gain insights into essential dossier requirements specific to biotech products compared to pharma products, alongside strategies for successful biosimilar development. Moreover, the course emphasises key biological considerations and the concept of totality in biological reviews, discussing unique aspects of biosimilars compared to small molecule generics.

This course will equip attendees with comprehensive knowledge essential for navigating the evolving biosimilar landscape.

Benefits of attending

- **Discuss** global considerations and definitions of biotech/biosimilar products
- **Gain** an invaluable overview of the regulatory pathways for biosimilars in the EU and US
- **Understand** the key Module 3 dossier requirements for biotech products versus pharmaceutical products
- **Learn** how to develop effective strategies for development of biosimilar products

Who should attend?

This course is perfect for pharmaceutical professionals working in regulation, quality assurance, pharmaceutical development, and R&D, including:

- Regulatory affairs professionals
- Medical affairs professionals
- Clinical development managers
- Quality assurance personnel
- Legal and compliance officers

Programme

Day 1

Biologics introduction

- Technical and legal definitions
- Examples of biologics
- The complexity of biologicals
- The challenges with development of biologics

Biosimilars vs generics

- How the process is the product
- A simple excursive to be reminded of the difference between biosimilars and generics
- Creating a copy with limited and imperfect tools

The (e)CTD

- International council of harmonization (ICH)
- The common technical document
- CMC explained (incl. quality by design, specifications)
- Why the CMC section for biologics is more extensive (as compared to small molecules)

The (e)CTD continued

Day 2

The registration process

- A review of EMA and FDA biosimilar guidelines
- Biosimilar development as a step-wise approach
  - Quality
  - Non-clinical
  - Clinical
- Non-comparable biologics
- Other regulatory topics
  - Interchangeability
  - Naming
  - Labelling
  - Pharmacovigilance

Module 3 for biosimilars - section by section

- In-depth review of module 3 documentation with special remarks regarding biologics and biosimilars specifically

Challenges for biosimilar sponsors

- Global development
- Costs
- Uncertainty

Main players in the biosimilar field

- A review of the current situation

Strategic considerations

- A summary of key points to consider when (starting to) develop biosimilars

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 dates

15-16 March 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 17050*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 18 Jan**
20-21 September 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17342*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 26 Jul**

How to book

Online:
ipi.academy/2438

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

★★★★★

Everything was great, presentation, speaker and content: it met my expectations

Veronica Mendel
Regulatory Affairs Manager
LABORATORIOS RECALCINE S.A.
Oct 1 2026

★★★★★

The content was great and very informative. Andrew was so kind, nice explanator and joyful.

Sujey Palma
Regulatory Specialist
LABORATORIOS RECALCINE S.A.
Oct 1 2026

★★★★★

The course was very interesting and highly informative. A lot of information was presented in a clear, pleasant, and easy-to-understand way by the lecturer, which made the course feel engaging and not overwhelming despite the amount of material covered.

Rana khleif
QP
unipharm
Oct 1 2026

★★★★☆

The speaker was quite dynamic, even though he had to present a large amount of content in a short time. He also was receptive to our questions, which is always good.

Cecilia Matito
Patent Advisor
Neuraxpharm Pharmaceuticals
Sep 30 2025

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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