IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Chemistry, Manufacture and Control (CMC) - Regulatory Requirements for Biological Drug Products

22-23 April 27
+ 18-19 October 27

The regulatory requirements for Biological drug products are complex, and pharmaceutical companies are continuously under pressure to ensure regulatory compliance from drug discovery to post-marketing surveillance.
This course has been designed to help you navigate the complex regulatory requirements for biological drugs, including ATMPs. It will clearly depict the differences between small and large molecules and the development approaches which reflect the type of molecule. It will address the key aspects of the CTD, look at the CMC regulatory requirements during different stages of development, and discuss the importance of change control.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Overview

The regulatory requirements for Biological drug products are complex, and pharmaceutical companies are continuously under pressure to ensure regulatory compliance from drug discovery to post-marketing surveillance.

Information regarding chemistry, manufacturing and controls (CMC) for drugs is an important and detailed section in the dossier to support clinical studies and marketing applications. This data must be updated as more information is gained throughout a drug's lifecycle.

The quality module of the Common Technical Document (CTD) presents the CMC data in the submission dossier for small and large molecules. Compiling the CMC regulatory material is challenging; however this needs to be completed with efficiency and accuracy to gain fast approval.

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This is a key opportunity to learn from an expert in the field of CMC requirements and compliance, and discuss the complexities involved.

Please note, it is recommended that attendees have some experience with Module 3 of the CTD.

Who Should Attend

- Regulatory, Quality Assurance and Manufacturing personnel
- Managers of a CMC area
- CMC Project Managers
- Quality Assurance Managers for Biological Products
- Individuals who are new to drug companies

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

22-23 April 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17112*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 25 Feb**
18-19 October 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17424*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 23 Aug**

How to book

Online:
ipi.academy/2593

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 wanted to understand more about source documents, and my general development. A lot of great information was shared, some of which I did not expect, like new guidance and very good training.

Kinga Zuk
Global Regulatory CMC Lead
Swedish Orphan Biovitrum
Apr 23 2026

★★★★★

I was hoping to gain knowlwdge on biologics, since it is my career goal and it definitely happened. Everything was very clear. There was a lot of information but i totally understood the way of thinking, the logic and the things that really matter. The refernce to the new ECTD was highly appreciated. Difference between small molecules and biologics was clear. I will keep every note and every slide to help me in the future. Thank you!

Anastasia Basta
CMC Specialist
Private Individual
Apr 23 2026

★★★★★

The speaker had lots of clarity in his explanations, making the course very easy to follow and understand, even with deep topics.

Bernardo Diaz
Regulatory Affairs Manager
Bioeq AG
Feb 29 2024

★★★★☆

Good webinar, presentation and excellent speakers

Nor Hazwan Ali
Head of Regulatory Affairs

Jun 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:



ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



Harry ALTAMONT
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