IPI Academy

MANAGEMENT forum

Presented by
Management Forum

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

20-21 October 2025

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.

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.

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

Programme

Day 1

Understanding Biologics

- Understanding what a Biological Product is
- Defining ATMPs
- The difference between small and large molecules

CMC Regulatory Guidelines for Biological Drug Products - Part 1

- Relevant laws, main guidelines & monographs, specifically for biologics (i.e. ATMP guideline and other relevant guidelines for mRNA products)
- ICH guidelines specific to different modalities (i.e. recombinant proteins, ATMP0
  - Brief background on ICH (e.g., countries belonging to ICH, full membership, observers etc.)
  - Q1-Q6B (no focus on New Chemical Entities (NCEs))
  - Q7-Q12 (requirements due to Q12 revision)

CMC Regulatory Guidelines for Biological Drug Products - Part 2 (continued)

Understanding the Key CMC Aspects of the Common Technical Document (CTD) - Part 1

- Quality Overall Summary (QOS)
- Examining the structure and content of the CMC sections – developing a CTD Roadmap
- Overview of the Drug Substance Sections for biologics
- Examine the linkage to the Drug Product Section
- Examine some basic rules for Q11 development and manufacture of drug substances
- Significant differences between EU & US & JP (e.g. P.3.5 FDA expectation)

Understanding the Key CMC Aspects of the CTD - Part 2 (continued)

CMC Regulatory Requirements During Differenct Stages of Development - Part 1

- Understand the definition and requirements at different stages of development (early stage, linked to clinical trials) as well as for different modalities (mRNA vs. Cell and gene)
  - QbD elements: QTPP, CQA, Process Characterization and Validation, Control Strategy
  - Starting materials: MCB and WCB (monoclonality, characterization, follow-up batch qualification)

CMC Regulatory Requirements During Different Stages of Development - Part 2 (continued)

- Potency assay: development, inter-assay comparability, critical reagent
- Reference standard: Primary & working standard (re- & follow-up qualification)
- Stability requirements & resulting concept (accelerated development): development batch, technical batch, pre-validation batch, PPQ batches
- Comparability exercise for biologics according to ICH Q5E
  - Extended characterization: early versus late phase development
  - Orthogonal methods

Day 2

CMC Regulatory Requirements During Different Stages of Development - Part 3 (continued)

- The Review dimensions of the dossier
- Clinical stages and linkage to formulation / analytical development
- Develop strategies to overcome challenges

Building the Pharmacuetical Sections of the Dossier

- Examining the importance of development biologics/ATMPs
- Review of the sections on development biologics/ATMPs (P2 and S26)
- Understanding the reviewer's perspective, highlighting methods to ensure we answer the reviewer's questions

Understanding Source Documents

- Overview of source documents
- Understanding the reviewer's perspective (Using analytical data as an example)
- Highlight the needs of internal teams versus external reviewers
- Reviewer's questions to be answered

Change Control for Biological Products

- Change control and the impact of your dossier
- The importance of comparability
- Practical exercise on change control

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

20-21 October 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 15020*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 15 Sep**

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

★★★★★

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

★★★★★

The webinar had enough information for anyone to start their CMC biologics career or who is interested to do so. Or even for someone with biologics experience is looking to have additional knowledge and information can attend this training. Andrew's knowledge and experience was proven very well.

Vineet Gavankar
Manager, Regulatory Affairs
PharmaLex UK Services Limited
Jul 6 2023

★★★★☆

The content was thorough. The presentation was informative. The speaker was very knowledgeable, helpful and friendly.

Sheena Singadia
Scientist II
Arecor
Jul 6 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