IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmaceutical Development of ATMPs

13-14 October 2025

This course will provide a comprehensive overview of the regulatory, quality and GMP requirements to consider when developing ATMPs.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

This course has been designed to provide a comprehensive overview of the regulatory, quality and good manufacturing practice (GMP) requirements to consider when developing advanced therapy medicinal products (ATMPs).

Industry expterts will cover the regulatory landscape and the definition and classification of ATMPs and provide practical guidance on how to overcome quality and specific GMP challenges. The differences between GMP for ATMPs and conventional therapies will be discussed, as will the requirements for clinical trials and the preparation of the IMPD. Advice on the specific transportation requirements of these products will also be addressed.

This programme will be of benefit to all those involved with or considering developing an ATMP.

Benefits of attending:

- **Understand** the GMP requirements for clinical trials in US and Europe
- **Gain** a practical insight into other markets
- **Determine** critical quality attributes
- **Develop** a successful QC strategy
- **Examine** the major differences between GMP for ATMPs and conventional therapies
- **Overcome** potential pitfalls when manufacturing cells
- **Discuss** multi-manufacturing sites for autologous products
- **Consider** stability issues
- **Examine** risk analysis for biological materials and understand Annex 16
- **Gain** an introduction to GMO approval requirements

This seminar will be of benefit to all those involved with or considering developing an Advance Medicinal Therapeutic Product.

Who should attend?

- R&D personnel involved in research on cell or gene-based therapies
- Managers involved in the development and manufacture of ATMPs
- Quality assurance and quality control personnel responsible for quality aspects of ATMPs
- GMP managers responsible for implementing GMP in ATMP manufacture
- Regulatory personnel involved in inspections of ATMPs

Programme

Day 1

Introduction to ATMPs

- Definition of ATMPs and associated terms
- Classification of ATMPs

The Regulatory Landscape

- Examining the European regulatory landscape for ATMPs – detailed analysis of existing regulation 1394/2007
- Considering factors lying outside of the regulation's scope, e.g. combination products
- Links to related directives, eg Tissues and Cells Directives (2002/98/EC and 2004/23/EC); Medical Device Directive (93/42/EEC) and forthcoming regulation

Strategic Considerations

- Opportunities to meet with regulators to maximise approval chances
- ATMP-specific options in the EU: certification procedure, risk-benefit approach
- Accelerated access opportunities in EU and US
- Understanding breakthrough status/PRIME

Insight into Global Regulations and Requirements

- Examining key markets including Europe, US and Japan
- Evaluate the regulatory differences between regions to help you build a strategic approval route
- GMP requirements at Phase I in US and Europe – ramifications for your product

Overcoming Quality Challenges

- Overview of frequent quality concerns
- Potency assay development
- Determining critical quality attributes
- Developing a successful QC strategy for short-shelf-life product
- QP release: timing and logistical challenges for ATMPs

Understanding Clinical Trials

- EU clinical trial requirements
- The US IND

Risk-Based Approach for ATMPs

- Examining 3.2.A Adventitious Agents
- Level of data required EU/US

Day 2

GMP for ATMPs

- What is required: examine the major differences between GMP for ATMPs and conventional therapies
- Overcoming potential pitfalls when manufacturing cells
- Current GMP interpretations
- Multiple manufacturing sites for autologous products
- Point-of-care preparation devices

Stability and Logistics

- Considering stability issues
- Challenges in transporting cell therapies/cryopreservation
- Preparation on site

Clinical Trial Considerations

- Optimising materials for regulatory compliance – vendor qualification
- Risk analysis for biological materials
- The comparability concept and its importance in preparing for clinical trials
- Introduction to GMO approval requirements

Practical Considerations for the IMPD

- Terms and definitions
- Guidance on IMPD content for ATMPs
- Data requirements for first-in-human vs later clinical trials

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

13-14 October 2025	**Live online** 09:00-16:45 **UK (London)** (UTC+01) *Course code 14998*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 08 Sep**

How to book

Online:
ipi.academy/2290

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

★★★★☆

Presenter is very knowledgeable and is able to communicate that. [I particularly enjoyed] small group, presenter stimulated interaction.

Erik Gout
Senior Consultant CMC
Venn Life Sciences ED B.V.
Oct 14 2024

★★★★★

Structured and balanced approach in the order of CTD modules enabled a clear understanding on development and quality, regulatory expectations.

Ramanathan Srinivasan
Senior Director
Viatris UK
Jun 20 2023

★★★★★

excellent Andrew is very knowledgeable and helped us a lot in clarifying most of the ATMP dev processes which are very complicated to link without a given roadmap of the interlinked events.

Andrea Sirianni
Project Manager
Cell & Gene Therapy (CGT)
Feb 6 2023

★★★★☆

Andrew was very knowledgeable, provided clear answers with examples on any question he was asked and I consider his slides a treasure of information that one can continuously refer to in the future.

Panos Papoutsis
Project Manager
Cell & Gene Therapy (CGT)
Feb 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:

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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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