IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Biotechnology for the Non-Biotechnologist

9-11 July 2025
+ 10-14 November 2025

An ideal course for non-scientists and scientists who need to understand the basic theory, principles, techniques and potential of biotechnology.

Format:
Classroom, Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

The importance of the biotech industry has increased significantly over recent years and biotech companies now dominate the new drug pipeline. The industry is gaining momentum and advancements in biomedical science and increased innovation hold vast potential for the growth of the biotech market.

This intensive course will provide an overview of how biotech products are being developed and manufactured, and discuss the scientific and regulatory environment. The interactive programme will cover the latest advances in regulation, including biosimilars and advanced therapies, and address the role and importance of patents within biotech, including what actually can be patented.

Benefits of attending

- **Gain** an introduction to the fundamental principles of biotechnology
- **Improve** your understanding of the key techniques used by biotechnologists
- **Understand** the key regulatory considerations for biopharmaceuticals
- **Discuss** advances in regulation – biosimilars and advanced therapies
- **Learn how** to identify potential patents, and why and how they must be protected

Who should attend?

This course is ideal for non-scientists and scientists needing to understand the basic theory, principles, techniques and potential of biotechnology.

It will be relevant for anyone needing either an overview or refresher, particularly those working in:

- Quality assurance
- Regulatory affairs
- Legal and IP
- Business development
- Sales and marketing
- Engineering
- Finance
- Clinical
- Training
- Project management

Programme

Introduction to biotechnology

- Historical perspective
- Diversity of biotechnology products
- Impact on society
- Product development overview

Introduction to molecular biology

- DNA, RNA, genes, plasmids and vectors
- Protein synthesis – transcription and translation

Re-expression of proteins

- Recombinant DNA techniques
- Monoclonal antibodies – from mouse to human
- Transgenic animals and plants

Development of production organisms

- Transfection
- Selection
- Preservation

Fermentation technology and large-scale production

- Types of fermenters
- Fermentation basics
- Modes of operation
- Process development

Process optimisation and scale-up

- Scale-up strategies
- Strain improvement
- Media improvement
- Process improvement

Analysis of biopharmaceuticals

- Biological activity
- Physicochemical characterisation
- Purity, impurities and contaminants

Formulation design of biopharmaceuticals

- Factors affecting degradation
- Choice of excipients
- Prolonging shelf life

Product recovery and purification

- Cell harvesting and removal
- Clarification – intracellular and extracellular proteins
- Chromatographic techniques

Process economics

- Drug development and bioprocess economics
- Optimising bioprocess economics
- Manufacturing make or buy
- Future manufacturing alternatives

Patenting biotech inventions

- What is a patent?
- What are the basic criteria for patentability?
- What can be patented?
- Can you patent genes, proteins, hybridomas, and stem cells?

Patent workshop

- How to recognise what is patentable
- Drafting claims to biotech inventions
- Maximising protection for an invention
- Understanding the examination process
- Enforcing patents

Regulatory considerations of biopharmaceuticals

- General principles
- Product quality and control
- Pre-clinical safety

Application of regulatory principles

- What do regulators want?
- Specifications
- Product characterisation
- Assessment of process change
- Comparability guidance and strategy

Advances in regulation: biosimilars

- Comparability, equivalence and biosimilarity
- Biosimilars guidance
- Guidance vs practice – a case study

Advances in regulation: advanced therapies

- Gene therapy
- Cell therapy
- Tissue-engineered products

Presenters

Adekunle Onadipe

Dr Adekunle Onadipe is an Associate Research Fellow in Bioprocess R&D, Cell Line Development at Pfizer Inc. USA. He leads a group of scientists responsible for the construction, development and characterization of mammalian and microbial cell lines for biotherapeutics and vaccines production. His group is also involved in the scale-up of bioprocesses from bench top to pilot scale bioreactors and process development for the establishment of cell banks to support the manufacture of biopharmaceutical products for early phase clinical trials.

Kunle joined Pfizer Limited in the UK in 2005 in Discovery Biology with responsibility for optimizing cell culture processes for the production of cell-based assay reagents. Prior to this he worked for 15 years at Lonza Biologics plc., in Slough UK where, as a Principal Group Leader in cell culture process development, he was responsible for constructing and developing production mammalian cell lines and culture processes, subsequently transferring them to full-scale production for clinical trials.

A microbiologist by training, Kunle has been involved in the production of biopharmaceuticals for more than 30 years and has a broad experience of microbial and mammalian cell culture methods. He obtained his PhD in Microbiology from the University of Surrey, Guildford UK.

Philip Webber

Dr. Philip Webber obtained his first degree from Cambridge University, UK (Natural Sciences, Genetics) and then carried out research on the regulation of brain-specific genes at Warwick University, UK, where he obtained his PhD.
He qualified as a UK Chartered Patent Attorney and European Patent Attorney with Dehns (formerly Frank B. Dehn & Co.) London and Oxford, and is now a partner in their Life Sciences Group. He has a worldwide client-base including clients from the UK, Scandinavia, the US and Japan. Amongst other things, his work involves the preparation and filing of patent applications in Europe and throughout the world; acting for his clients in opposition procedures at the European Patent Office; and searching for and advising his clients on the relevance of competitors' patents. He is an active member of the Life Sciences Committee of the UK Chartered Institute of Patent Attorneys (CIPA). He has spoken at a number of European conferences and on BBC Radio on the patenting of biotech inventions, as well as publishing a number of papers in this area.

Adrian Haines

Dr Adrian Haines is a Senior Process Manager within MSAT at Sobi (Swedish Orphan Biovitrum). Adrian has extensive experience in generating mammalian cell lines suitable for the GMP production of biologics and is extensively involved in the scientific oversight of both upstream and downstream process development, and process characterisation studies prior to regulatory filings. He joined the company (then Novimmune, Switzerland, subsequently acquired by Sobi) in 2015 and prior to this he worked at Lonza Biologics in the UK working on projects to develop new technologies and processes for generating manufacturing cell lines. Before that he worked for ML Laboratories/Cobra Research developing UCOE technologies for the expression of proteins in mammalian cells and at Therexsys Ltd, developing antibody targeted gene therapies. Prior to this he worked at Celltech Research Ltd, generating radiolabelling and cross-linking technologies for antibodies. A biochemist by training, he has been involved in the protein chemistry and production of monoclonal antibodies ~30 years, starting with his PhD where he generated monoclonal antibodies (using hybridoma technology) for the diagnosis of prostate cancer. He received a biochemistry degree from Imperial College, London, and his PhD from St Thomas' Hospital Medical School, University of London. He is currently based in the UK.

Presenters

Robert Alvarez

After completing his degree in molecular biology at the University of Reading, Robert Alvarez has been at Lonza Biologics for 17 years, of which 14 were spent working in the product stability group and 2 as Head of Business Planning and Innovation within Analytical Services (AS). Most recently he has accepted a new role as Site Head of Digital Transformation spearheading Lonza's digitilisation strategy. Within AS he was a Subject Matter Expert responsible for the design and implementation of forced degradation and formulation studies, directing stability programs for multiple products and establishing standards for stability, as well as supporting stakeholders and customers. As analytical lead for mAb and non-mAb programs, he has provided technical and advisory support for CMC development of biopharmaceuticals from pre-clinical through to clinical phases, including successful BLA licence applications.

Rhydian Howells

Rhydian Howells, associate director of regulatory affairs at Diamond Pharma services a Propharma group company. 20 years' experience in the industry, 10 years at a large contract manufacturer developing manufacturing processes and analytical offerings for biological products followed by 10 years in regulatory CMC roles supporting clients with clinical development and marketing authorisation activities for large molecules and advanced therapies.

Mardon McFarlane

Mardon McFarlane currently works as a Director of External Manufacturing for the gene therapy company AAVantgarde Bio. Mardon is a co-founder of a consultancy, Taxo Bioscience, that specialises in supporting pre-clinical and clinical stage biotech companies, by ensuring they make the correct, impactful decisions early in their journey to bring life-changing therapies to patients. Mardon specialises in the CMC aspect of drug discovery and has been involved in notable drug approvals during his 18+ years in the industry. His experience in the biotechnology sector started with biologics but over the last 11 years he has migrated to the cutting-edge sector of cell and gene therapy. Mardon's career has been focused on the processing aspects of drug manufacture and has spanned process development, technology transfer, scale up and large-scale manufacturing. Mardon holds an MEng in Biochemical Engineering from University College London.

Lekan Daramola

Lekan Daramola is an independent consultant who specialises in supporting biotech companies during the critical early drug development activities, enabling successful preclinical and clinical decisions as they develop new drugs for patients.

Lekan has extensive experience working in the biopharmaceutical industry, with over 26 years contribution to different areas of biologics drug development. Lekan's experience spans lead drug molecule selection to regulatory submission. His expertise includes molecular biology, mammalian recombinant protein expression technologies, cell line development and early CMC support. In addition, he also has expertise in the development of novel drug modalities like nucleic acid drugs/vaccine (RNA, DNA) as well as AAV (viral vector) production platform development.

Prior to his current role, Lekan was a Senior Director at AstraZeneca, managing mammalian expression activities, the development of nucleic acid and AAV production capabilities to deliver preclinical and clinical drug development goals. Lekan hold a M.Sc. in Medical Microbiology from the University of Surrey.

Course dates

9-11 July 2025	**Classroom** London *Course code 14946*	GBP **1,899** ~~2,199~~ EUR **2,659** ~~3,079~~ USD **3,051** ~~3,519~~ **Until 04 Jun**
10-14 November 2025	**Live online** 12:00-17:00 **UK (London)** (UTC+00) *Course code 15117*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 06 Oct**

How to book

Online:
ipi.academy/1585

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 **15% 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

★★★★★

All of the speakers were very knowledgeable, well prepared and presented the topics in a structured and comprehensible manner. A session I thought would be rather arid turned out to be entertaining and instructive at the same time. The seminar gave a very complete overview of the topics.

Max Hofferberth
DSTL
Hoffmann LaRoche
Dec 2 2024

★★★★★

I wanted to get a good overview of biotechnology: history, development, science, processes, regulations and future and this goal was 100% fulfilled. All lecturers were highly competent in terms of content and style of presentation.

Andy Bossert
CQV Engineer
Lonza
Dec 2 2024

★★★★★

Content flow is well designed and good. [Parts I particularly liked were] process economy , Upstream and Downstream scale up.

Arindam Gupta
Global Category Procurement Manager
Servier Monde
Sep 25 2024

★★★★★

Excellent, I am so please a colleague mentioned to IPI to me.

Julie Bailey
CFO
ILC Therapeutics Ltd
Sep 25 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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