





Presented by Management Forum

Upstream and Downstream Manufacturing in the Biopharmaceutical Industry

12 September 2025 + 5 December 2025

In this talk, explore the fundamental concepts, techniques, and processes that make up the backbone of biomanufacturing, pharmaceutical production, and biotechnology. ریا Format: Live online ()

CPD: 1.5 hours for your records ്വ

Certificate of completion

Overview

Bioprocessing is the use of biological systems (such as cells, enzymes, or microorganisms) to produce valuable products, like pharmaceuticals, biofuels, or specialty chemicals. This process is typically broken down into two main stages: upstream processing and downstream processing. Both play vital roles in ensuring the efficient production, purification, and quality control of the final product.

Upstream processing encompasses everything that occurs before the actual production of the product, and it's primarily concerned with creating an optimal environment for microorganisms or cell cultures to grow and produce the target product.

Once the biological system has generated the product in upstream processing, the focus shifts to downstream processing, which involves purification and formulation to ensure the product is safe, pure, and suitable for commercial use.

Upstream and downstream processes are interconnected. The choice of cell culture methods, fermentation conditions, and media formulation can significantly affect the yield and purity of the product, which in turn impacts the complexity and cost of downstream processing.



Benefits of attending

Attending this session will not only deepen your knowledge but also equip you with the practical tools and strategies needed to enhance both upstream and downstream manufacturing processes, improve product quality, and navigate the complexities of the biopharmaceutical industry. The benefits of attending this session include:

- Learn about the latest industry trends, technologies, and strategies being employed to improve upstream and downstream processes. This can help you adopt cuttingedge practices to enhance operational efficiency and reduce production costs
- Understand key challenges and innovative solutions related to process optimisation, scale-up, and product consistency across both upstream and downstream stages. Knowledge in this area can help reduce bottlenecks and improve yield
- See best practices in maintaining product quality, with a focus on techniques like process validation, quality assurance, and regulatory compliance to ensure the safety and effectiveness of biologics
- Engage with experts, researchers, and other professionals in the biopharmaceutical field
- **Gain** insights into the regulatory requirements for both upstream and downstream biopharmaceutical manufacturing processes. This can help ensure compliance with FDA, EMA, and other regulatory bodies, minimising the risk of delays or regulatory hurdles
- Explore the latest technological advancements in biomanufacturing, such as automation, artificial intelligence, and continuous manufacturing processes, and how these can be integrated into both upstream and downstream operations to improve efficiency and scalability
- Discuss the factors that contribute to cost reduction in the production process, such as the selection of cost-effective raw materials, automation, and process optimisation techniques. This knowledge can help drive profitability without compromising product quality
- **Delve** into upstream and downstream processes and see how they fit into the larger context of the product life cycle, from discovery through clinical trials to commercial production

Who should attend?

- Bioprocess engineers
- Process development scientists
- Quality Assurance (QA) and Quality Control (QC) professionals
- Manufacturing supervisors and operators
- Regulatory affairs managers
- R&D (Research and Development) team members
- Project managers in biotechnology/pharmaceuticals
- Supply chain and logistics teams
- Senior leadership (e.g., CTOs, VPs of Operations)
- External consultants and contractors
- Finance and costing analysts
- Students and trainees in biotechnology and pharmaceutical sciences
- Environmental Health and Safety (EHS) personnel
- Automation and IT specialists

Presenter



Mustafa Edik

Mustafa Edik is an Independent GMP Consultant and Auditor.

After graduating as a Chemist from university, Mustafa began his 25 year plus career as a Laboratory Supervisor at Bayer, a German Pharmaceutical Company. After 15 years of working as a Quality Assurance Assistant Manager, Laboratory Supervisor, Pharmaceutical Quality Management Systems, and GMP Lead Auditor, he decided to continue his career as a Consultant. He has served the Turkish Atomic Energy Authority (TAEA) as Principal GMP Auditor and Consultant for 6 years. TAEA was audited by the Republic of Turkey Ministry of Health and granted GMP Certificate for 5 Radiopharmaceuticals. This success has won great acclaim from all health authorities and industry.

He has prepared and presented various training courses and workshops to more than 8000 individuals from 150 International and local Pharmaceutical, Medical Device, and Cosmetics companies on GMP, GDP and Pharmaceutical Quality Management Systems. He has taken part in several International Pharmaceutical Facility Establishment projects as GMP Consultant and has also set up various Quality Management Systems for Local Pharmaceutical and Medical Device Companies.

While he was the Vice President of Quality and Technical Operations at a Quality Academia Training and Consultancy firm, he acquired and converted it into a 100 % Turkish Company. As the only IRCA Certificated Pharmaceutical Quality Management Systems and GMP Lead Auditor in Turkey, he currently conducts API, Excipient, Packaging Materials Suppliers and Manufacturers, Third Party Logistics Service Providers, Sterile and Non-Sterile Manufacturing Facilities Audits according to FDA, EMA, PIC /S, TMMDA, MHRA, TGA Health Canada, and WHO regulations and guidelines.

He finished his second university degree in Biopharmaceutical Sciences BSc (Hons) at Atlantic Technological University - Ireland. He is the author of chapter 6 of the book published by PDA named "Good Distribution Practices" and his new book on 'GMP Audits in Pharmaceutical and Biotechnology Industires' will be published by Taylor & Francis in June 28, 2024.

Course dates

12 September 2025	Live online 12:00-13:30 UK (London) (UTC+01) <i>Course code 15520</i>	GBP 175 200 EUR 245 280 USD 280 320 Until 05 Sep
5 December 2025	Live online 12:00-13:30 UK (London) (UTC+00) Course code 15521	GBP 175 200 EUR 245 280 USD 280 320 Until 28 Nov

How to book

Online:

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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.

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