

ESSENTIAL SKILLS FOR BIOPHARMACEUTICAL MANUFACTURING

This programme equips participants with an in-depth overview of biopharmaceutical manufacturing.

The programme explores key areas of biopharmaceutical manufacturing including an over-view of Upstream and Downstream processing, cGMP Regulations, Quality Risk Management, Lean / Six Sigma, OpEx and Sustainability in Manufacturing.

Aims and Objectives

The aim of this course is to provide learners with the essential knowledge related to biopharmaceutical manufacturing processes.

Participants will understand the steps involved in key manufacturing processes (Upstream / Downstream), the importance of an aseptic environment in bioprocessing, quality management systems, regulatory compliance, cGMP, risk management and corrective / preventive

In addition learners will gain an awareness of new emerging technologies, the need for sustainable practices, as well as the principles of Lean, Six Sigma, and OpEx for improving efficiency.

PROGRAMME DELIVERY

10 x 2.5 hour lectures (online)

PROGRAMME CERTIFICATION

Innopharma Education Certificate of Completion.

WHO IS THIS PROGRAMME FOR?

This programme is aimed at employees working in biopharmaceutical manufacturing or those wishing to upskill and gain essential knowledge of biopharmaceutical manufacturing.

ENTRY REQUIREMENT

Courses are fully funded to both employed and unemployed applicants who are either living or working in the Midlands region (Longford, Laois, Offaly or Westmeath).

CHANGE DIRECTION, ADVANCE YOUR CA-

Learning Outcomes

On completion of this programme the learner should be able to:

- Identify key players, market dynamics, global impact of biopharma, career opportunities, and skills required in the biopharmaceutical industry.
- Describe emerging technologies, market trends, and sustainability practices shaping the future of biopharmaceutical manufacturing.
- List components and functions of quality management systems and regulatory compliance requirements in the biopharmaceutical industry.
- Define principles and methodologies of lean, six sigma, and Operational Excellence (OpEx).
- State essential elements of riskmanagement and Corrective and Preventive Actions (CAPA) systems, including handling complaints, audits, and compliance with ISO standards and regulations.
- Describe key elements of bioprocessing and contamination control, bioprocessing fundamentals, contamination control strategies, cleaning methods, cleanroom design and operation.
- Upstream processing
 - Introduction to biological systems
 - Cell line development
 - Bioprocessing techniques
 - Aseptic techniques in biopharmaceutical production
- Downstream processing
 - Purification methods for biopharmaceuticals
 - Separation techniques for biomolecules
 - Concentration and formulation

A PROFILE OF IRELAND'S ADVANCED MANUFACTURING SECTOR

Advanced Manufacturing accounts for
36.7% of GDP in Ireland

The sector employs
231,000 direct employees

9 out of the worlds top 10 STEM companies have a presence in Ireland

Ireland is the world's largest exporter of pharmaceuticals

Ireland's life sciences sector has a **global reputation** for operational and innovation excellence