

CERTIFICATE IN ESSENTIALS OF PHARMACEUTICAL MANUFACTURING

Special Purpose Certificate 60 FET - QQI Level 5

Designed and developed by Innopharma Education and BioPharmaChem Skillnet, this programme is specifically targeted at learners seeking a qualification that will enable them to either progress within their current employment or take up employment in a manufacturing operations role.

Aims and Objectives

The aim of this course is to provide participants with the necessary knowledge and skills to be successful in operational roles within the bio-pharmaceutical and chemical industries.

Equipping participants with a broad skill base to gain entry level positions within these sectors, learners will gain a foundational understanding of the theory and practical applications of Cleanroom Operations, Quality Assurance, cGMP, Data/Digital Skills and Continuous Improvement/Sustainability. Learners can choose one of two elective modules, focusing their skills development in either bio-processing or chemical processing.

Learning Outcomes

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

- Recall and explain common biopharmaceutical laboratory techniques and procedures.
- Identify and describe the importance of regulatory compliance and quality control standards to ensure the production of pharmaceutical products meet established quality criteria.
- Define the essential skills of cleanroom operations and cGMP (current Good Manufacturing Practice).
- Recognise operational issues and deviations to identify root causes and potential solutions.
- Explain the importance of sustainable practices in a manufacturing operations environment.
- Utilise effective communication skills to convey technical information and collaborate with team members in a laboratory or production context.
- Identify personal development skills to enhance productivity, improve well-being and increase resilience.

PROGRAMME DELIVERY

This part-time programme runs over 12 months.

The programme is delivered in a blended format. Lectures are delivered online in the evenings, with a number of in-person lectures taking place on Saturdays throughout the programme.

PROGRAMME CERTIFICATION

Certificate in Essentials of
Pharmaceutical Manufacturing
Special Purpose Certificate 50 FET
- QQI Level 5

ENTRY REQUIREMENT

Proficiency in English Language
Required (B2+ level or equivalent on
the Common European Framework
of Reference for Languages (CEFR)
Age 18+

CHANGE DIRECTION, ADVANCE YOUR CAREER

Course Content

Cleanroom Operations & Plant Utilities/Facilities (15 FET)

- Facilities & Utilities
- Management Overview
- Building Management
- Total Productive Maintenance
- Introduction to Environmental
- Health & Safety Management
- Introduction to Regulations

Continuous Improvement & Sustainability (5 FET)

- Understanding the core elements of Business
- Foundational concepts of Quality
- Lean Thinking Principles
- Sustainability Principles
- Process Improvement Tools

Essentials of Quality Assurance (15 FET)

- Quality Management Systems (QMS)
- Quality Documentation
- Health & Safety

Personal Effectiveness & Transversal Skills (5 FET)

- Time Management, Goal Setting & Planning
- Academic & Professional Communication, Emotional Intelligence, Resilience & Stress Management
- Problem Solving & Critical Thinking
- Teamwork & Collaboration

Data & Digital Processing Skills (10 FET)

- Foundations of Data
- Data Management & Analysis
- Digital Processing & Visualization
- Advanced Data Handling Skills
- Practical Applications

Best Practices of Chemical Processing (10 FET/Elective)

- Chemical Principles & Applications
- Active Pharmaceutical Ingredient manufacturing process
- Batch vs Continuous API Manufacturing
- Quality Control

Principles & Best Practice of Bioprocessing (10 FET/Elective)

- Bioprocessing Overview
- Upstream Processing
- Downstream Processing
- Aseptic Techniques & Prevention of Contamination
- Regulatory Requirements

PROGRESSION OPPORTUNITIES

Graduates of this programme will be considered for progression onto Innopharma Education's higher education programmes at Level 6 (QQI).

This course is co-created with BioPharmaChem Skillnet, a Government funded organisation, providing subsidised Learning & Development solutions for the biopharmaceutical and chemical sector throughout the Republic of Ireland. They work with industry to understand their talent development challenges and provide enterprise-led, bespoke training solutions. Their collaborative ecosystem of industry, educational institutions and training providers work together to address industry challenges and foster innovation in the biopharma sector.