

CERTIFICATE IN ESSENTIALS OF BIOPHARMA & CHEMICAL MANUFACTURING

(QQI Level 5 - Special Purpose Certificate 60 FET)

This programme is designed to meet a growing industry demand for increased knowledge of pharmaceutical manufacturing operations, involved in both chemical synthesis and bio-processing applications.

This programme is specifically designed for learners seeking a qualification that will enable them to either progress within their current employment or take up employment in a manufacturing operations industry.

Aims and Objectives

The aim of this course is to provide participants with the necessary knowledge and skills to be successful in the bio-pharmaceutical and chemical industries in order to gain employment in production operations. The programme provides learners with an understanding of regulatory compliance and quality control in this highly regulated sector. Learners will gain a foundational understanding of the of the theory and practical applications which are essential for both of these manufacturing sectors, equipping them with a broad base skill set to gain entry level positions within these sectors. Learners can choose one of two elective modules, focusing their skills development in either bioprocessing or chemical processing.

Learning Outcomes

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

- Identify and describe the importance of regulatory compliance and quality control standards to ensure the production of pharmaceutical products meet established quality criteria.
- Describe the concepts of Continuous Improvement, Value Creation and Lean Thinking in a modern regulated, digital environment.
- Explain key elements of a quality management system in the context of organisational structure, responsibilities, procedures, processes, and resources.

PROGRAMME DELIVERY

This part time programme runs over 9 months.

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

PROGRAMME CERTIFICATION

QQI Level 5 Special Purpose Certificate in Essentials of BioPharma Manufacturing (60FET)

ENTRY REQUIREMENT

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

CHANGE DIRECTION, ADVANCE YOUR CAREER

- Recall and outline common biopharmaceutical laboratory techniques and procedures.
- Define the essential skills of cleanroom operations and cGMP (current Good Manufacturing Practice).
- 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.
- Utilise concepts of computer science to digitise processes and propose potential optimisations
- Identify Personal Development Skills to enhance productivity, improve well-being and increase resilience.
- Understand essential topics in chemistry relevant to the pharmaceutical industry for chemical processing.
- Understand the fundamental concepts and techniques involved in harnessing biological systems for industrial applications.

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)
- 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 and Conclusion

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

Learners may complete additional Innopharma Education QQI Micro-Credential programmes and work towards completing a

- X
- Y

For more information on this course contact Pauline Flusk (Programme Lead) on: T: +353 (0) 1 264 5570
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