

HIGHER DIPLOMA IN DESIGN AND MANUFACTURE OF BIOPHARMACEUTICALS

Overview

NFQ Level 8, Major Award

The Higher Diploma in Design and Manufacture of BioPharmaceuticals is a full-time programme taken over 12 months (September-August).

Programme Requirements

For information about modules, module choice, options and credit weightings, please go to Programme Requirements (p. 1).

Programme Requirements

Code	Title	Credits
Students take 60 credits as follows:		
<i>Core Modules</i>		
BC5004	Introduction to Human Molecular and Cellular Biochemistry	10
BC5005	SkillsBET-BioPharma (BioPharmaceutical Skills Based Education & Training)	5
BC5006	Technical and Professional Skills Training for BioPharma Workplace Employment	15
PE5004	Introduction to BioPharmaceutical Process Engineering	5
PF5003	Introduction to BioPharmaceutical Technologies and Processes	10
PF5001	Introduction to Pharmaceutical Process Design and Verification	5
PF5002	Biological Drug Manufacture: Intro to Regulatory and Sterility Requirements	10
Total Credits		60

Examinations

Full details and regulations governing Examinations for each programme will be contained in the *Marks and Standards Book* and for each module in the *Book of Modules*.

Programme Learning Outcomes

Programme Learning Outcomes for Higher Diploma in Design and Manufacture of BioPharmaceuticals (NFQ Level 8, Major Award)

On successful completion of this programme, students should be able to:

- Describe the fundamental principles of biochemistry and cell biology as they relate to health and disease
- Explain the development and design of major classes of biological drugs
- Describe an understanding Process Engineering principles as they relate to the production of BioPharmaceuticals
- Assess the key parameters to be considered in upstream processing, downstream processing and the formulation of biological drugs
- Describe the key concepts and principles of quality standards and regulations (eg. current Good Manufacturing Practices, cGMP) and

their integration in the production of a sterile BioPharmaceutical products.

- Demonstrate competence in the laboratory-scale production of a biological protein drug in accordance with written Standard Operating Procedures (SOP's).
- Design, implement and evaluate scientific investigations and assess, interpret and understand experimental data generated.
- Recognise and articulate personal and professional skills in the context of career planning, and demonstrate an ability to write an effective application.