

Postgraduate Diploma in Entrepreneurship and Biopharmaceutical Manufacturing



- HCI funding available for the 2023/2024 and 2024/2025 academic years
- Pathway to Level 9 Master of Science Degree
- Industry-led content and guest speakers

This NEW Postgraduate Diploma is funded under the Human Capital Initiative, designed in conjunction with the Biopharmaceutical industry, aims to develop the necessary skills required to strategically support the development and manufacture of biopharmaceutical technologies. Learners will acquire cross skills in regulatory, advanced testing methods and entrepreneurship to meet the needs of the Medtech sector. The programme is aimed at graduates who have either a science or engineering background and are aiming to progress their careers in a leadership/managerial role.

Course Title	Credits	NFQ Level	Campus	Duration	Delivery
Postgraduate Diploma in Entrepreneurship and Biopharmaceutical Manufacturing	60	9	Galway City	One year	Blended Full-time



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an Atlantaigh

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Why Study?

This programme has been designed to meet the growing demands of companies in filling leadership and operational roles in the biopharmaceutical sector. The programme was developed based on industry needs, which was endorsed by the Western Regional Skillnets and the Human Capital Initiative programme.

The Postgraduate Diploma in Science in Entrepreneurship and Biopharmaceutical Manufacturing will provide students with a detailed understanding of bioprocessing technologies, six sigma management and validation for biopharmaceuticals. The programme will also cover topics such as quality management systems and regulatory affairs for biopharmaceutical products. In addition, the programme will include content on strategic marketing and communication; leadership and teams; managing innovation; finance and accounting.

Modules in strategic marketing and communication; leadership and teams; managing innovation; finance and accounting will deepen learners' understanding of business theories and strategies to support the manufacture of biopharmaceutical products. The programme will be delivered by academics and key experts through a flexible blended approach, with students expected to attend one day a month for on-site activities.

Human Capital Initiative (HCI) Funding will only be available for 2023/24 and 2024/25.

Course Content

Semester 1 Modules (Jan – May)

Strategic Marketing and Communications 5 Credits

Providing learners with the latest thinking and practice in strategic marketing and communications, with a particular twist on marketing of innovation, growth and sustainable performance.

Principles of Finance and Accounting 5 Credits

Introducing a detailed look at financial management in industry, its relationship to financial accounting and management accounting, the budgeting process, capital investment appraisal, the importance and management of working capital, and finance and investment decision-making based on accounting statements.

Six Sigma Management 5 Credits

Introducing the necessary skills to plan and implement a range of Six Sigma programme activities in a workplace environment. This module will focus on the tools & techniques required to reduce process variability, achieving Lean Six Sigma in manufacturing and ensuring continuous process improvement.

Validation for Biopharmaceuticals 5 Credits

Providing learners with a broad understanding of Validation in the Biopharmaceutical manufacturing context, including Process, Equipment, Cleaning, Automated System and Test Method Validation.

Advanced Biopharmaceutical Science 10 Credits

Exploring contemporary issues in biopharmaceutical science and examining novel emerging new technologies in this industry. It will evaluate and explore the current and emerging trends in Advanced Therapy Medicinal Products (ATMPs) such as cell therapies, complex antibodies, genetic vaccines, personalised medicines and 'omics'.

Semester 2 Modules (Sep – Dec)

Bioprocessing Technology *5 Credits*

The module will also focus on emerging trends in biopharmaceutical manufacturing such as continuous bioprocessing and the move towards the use of single use technology in biopharmaceutical manufacturing.

Quality Management Systems and Regulatory Affairs

5 Credits

Reviewing the key regulatory requirements for (bio) pharmaceutical product development, production and marketing, and addressing the role of quality management for efficacy, purity and safety, including ISO 9000 quality standard requirements and certification. It addresses the regulatory requirements of various regulatory authorities such as the FDA and EMA, National Authorities (i.e.HPRA) and the role of ICH guidelines in meeting regulatory requirements.

Managing Innovation *5 Credits*

Providing learners with an understanding of innovation at individual and firm level. An appreciation of the ever-changing macro and microenvironments and stakeholder interest for contemporary organisations will be integral to the module.

Leadership and Teams *5 Credits*

Effective leadership is needed to understand, predict, plan and communicate the nature of organisational change and manage the response. Learners will be equipped with the knowledge, skills and attitudes necessary to effectively lead and collaborate with teams in a variety of organisational settings.

Research Project *10 Credits*

Students will undertake a research project, which should take the form of a literature review and proposal for the development of medical technology (biopharmaceutical or medical device product) to prevent, treat or diagnose a specific medical condition.

What to Expect

The programme will be delivered in blended format. The average weekly contact hours for the proposed programme is 9/10 hours. Learners will be required to attend the Galway City campus one day each month with the remaining content delivered online. Lectures delivered online are recorded by the lecturer so that students can access the recorded version for study in their own time. This flexibility will allow students on the programme to manage their studies, work, and other commitments.

Graduates from the PG Diploma can progress to the MSc next year by completing the remaining 30 credits/ECTS.

What is HCI funding?

The Human Capital Initiative (HCI) Pillar 1 offers free and discounted full-time courses, designed to meet priority industry skills needs. Each year, the Higher Education Authority (HEA) approves courses for HCI funding, which covers 90%/100% of the courses' tuition fees.

This Level 9 course is HCI funded for the 2023/2024 and 2024/2025 academic years. If you are employed and enrol in this course, 90% of the tuition fee is funded and you are only required to pay the remaining 10% tuition fee, totalling €720. If you are unemployed, HCI will cover 100% of the tuition fee.

Visit springboardcourses.ie for more information.



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Entry Requirements

A H2.2 Bachelor (Hons) degree at level 8 in a cognate science discipline such as biochemistry, microbiology, biology, chemistry, biomedical science/engineering or equivalent, is the minimum entry requirement for this programme.

Applicants who do not hold the specified qualification, may apply through the ATU RPL (Recognition of Prior Learning) process for admission to the programme.

How to Apply

Applications should be made through the Springboard courses website **HEA - Springboard+ springboardcourses.ie**

**I want to know more.
Who can I talk to?**

Dr. Eugene McCarthy, Head of Department, will be happy to discuss the course detail further.

E Eugene.McCarthy@atu.ie

For **Springboard** enquiries, please contact:

Peter Butler **E** Peter.Butler@atu.ie

Or find out more at **www.atu.ie**

Career Opportunities

- Biotechnical production specialist
- Process Scientist
- Process engineer
- Technical Operations Specialist
- Team Leader Validation Specialist
Operations Lead/Manager Associate
Director
- Core Technology Operations Lead



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