

POSTGRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATORY SCIENCES

Overview

Status: Active

National Framework Of Qualifications (NFQ) Level: 9

NFQ Award Class: Minor Award

Duration Part Time: 1 Academic Year(s)

Total Credits: 30

Delivery Method: Blended

Connected Curriculum:

- Employability
- Global Reach
- Inter-and Transdisciplinary
- Research Based Teaching
- Sustainability

Sustainable Development Goals (SDGs):

- Good Health and Well-being
- Decent Work and Economic Growth
- Industry, Innovation, and Infrastructure
- Responsible Consumption and Production

Graduate Attributes:

- Creator, evaluator and communicator of knowledge
- Digitally Fluent
- Independent and creative thinker

Work-Integrated Learning (Including Placement):

No

The Postgraduate Certificate in Pharmaceutical Regulatory Sciences is a part-time programme delivered in a blended format, running over one academic year.

On successful completion of the Postgraduate Certificate in Pharmaceutical Regulatory Sciences students may apply for the MSc in Pharmaceutical Regulatory Sciences (<https://ucc-ie-public.courseleaf.com/programmes/mscpr/>) programme and may be eligible for exemptions for modules already completed.

Programme Requirements

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

Programme Requirements

| Code | Title | Credits |
|------|-------|---------|
|------|-------|---------|

Core Modules

Students take **30** credits as follows:

| | | |
|--------|--|---|
| PF6026 | Pharmaceutical Technology and Unit Operations with Regulatory Insights | 5 |
|--------|--|---|

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|--------|---|----|
| PF6027 | Pharmaceutical GxP and Regulatory Science | 5 |
| PF6029 | Biotechnology-derived and Advanced Therapy Medicinal Products (ATMPs) | 5 |
| PF6032 | Bioprocessing Unit Operations | 5 |
| PF6038 | Skills Development in Pharmaceutical Regulatory Sciences | 10 |

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|----------------------|-----------|
| Total Credits | 30 |
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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 Postgraduate Certificate in Pharmaceutical Regulatory Sciences (NFQ Level 9, Minor Award)

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

- Develop manufacturing processes which apply quality-by-design principles for a range of medicines including small molecules, biopharmaceuticals and ATMPs.
- Critically evaluate the regulation of medicinal products.
- Identify opportunities to accelerate the integration of emerging science and technology in medicines' development.
- Evaluate major process parameters and critical quality attributes for different manufacturing processes, including conventional medicines, biologics and advanced therapy medicinal products
- Interpret the regulatory requirements for approval, licensing and manufacture of medicinal products in the EU, with reference to the relevant EU legislative frameworks