MSC IN PHARMACEUTICAL REGULATORY SCIENCES

Overview

The MSc in Pharmaceutical Regulatory Sciences is a full-time programme delivered in a blended format, running over a minimum of 12 months from the date of first registration for the programme.

Graduates of the Postgraduate Diploma in Pharmaceutical Regulatory Sciences (https://ucc-ie-public.courseleaf.com/programmes/pdprs/) who obtain a place on the MSc programme may apply for exemptions for modules already completed.

Exit Award

Postgraduate Diploma in Pharmaceutical Regulatory Sciences (NFQ Level 9, Major Award)

Upon successful completion of taught modules to the value of 60 credits, registered MSc in Pharmaceutical Regulatory Sciences students may opt not to proceed with the programme and exit with a Postgraduate Diploma in Pharmaceutical Regulatory Sciences. (https://ucc-ie-public.courseleaf.com/programmes/pdprs/)

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 **90** credits as follows:		
Part I		
Core Modules		
EH6136	Pharmacoepidemiology	5
EH6137	Pharmaceutical Data Management and Pharmacovigilance	5
PF6026	Pharmaceutical Technology and Unit Operations with Regulatory Insights	5
PF6027	Pharmaceutical GxP and Regulatory Science	5
PF6028	Process Control and Validation for Pharmaceutical Processes	5
PF6029	Biotechnology-derived and Advanced Therapy Medicinal Products (ATMPs)	5
PF6032	Bioprocessing Unit Operations	5
PF6038	Skills Development in Pharmaceutical Regulatory Sciences	10
ST6024	Introduction to Probability and Statistics	5
ST6025	Statistical Modelling	5
ST6026	Basics of Machine Learning	5
Part II		
Core Modules		
PF6031	Dissertation in Pharmaceutical Regulatory Sciences	30
Total Credits		**90**

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 MSc in Pharmaceutical Regulatory Sciences (NFQ Level 9, Major Award)

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

- Assess pharmaceutically relevant datasets using appropriate statistical and machine learning methodologies.
- Develop manufacturing processes which apply quality-by-design principles for a range of medicinal products including small molecules, biopharmaceuticals and ATMPs.
- Critically evaluate the regulation of medicinal products and identify opportunities to accelerate the integration of emerging science and technology in medicines' development.
- Appraise the quality, safety and efficacy of a medicine based on the clinical trial outcomes and real-world data.
- Integrate interdisciplinary knowledge to execute a project relating to the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of a drug product.