POSTGRADUATE DIPLOMA IN PHARMACEUTICAL REGULATORY SCIENCES

Overview

NFQ Level 9, Major Award

The Postgraduate Diploma in Pharmaceutical Regulatory Sciences is a full time programme delivered in a blended format, running over a minimum of 9 months from the date of first registration for the programme.

Students must satisfactorily complete taught modules to the value of **60** credits.

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:		
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
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 Postgraduate Diploma 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.