

# MSC (PHARMACEUTICAL TECHNOLOGY AND QUALITY SYSTEMS) (2 YEAR PATHWAY)

## Overview

### NFQ Level 9, Major Award

The MSc in Pharmaceutical Technology and Quality Systems is a part-time distance learning programme running over a minimum of 24 months from the date of first registration for the programme. This taught MSc is recognised by the Health Products Regulatory Authority (HPRA) as fulfilling the educational requirements for Qualified Person (QP) status required by EC Directive 2001/83/EC and so forms a good starting point for suitably experienced graduates to apply to the HPRA for registration as a QP.

In Part I students take taught modules to the value of **60** credits, run over a minimum of 18 months. The taught modules will incorporate a combination of self-instructional printed materials (i.e. printed module workbooks), teleconferences, web-based seminars and online assessments. Students must also attend the two 3-day workshops on campus per year, involving lectures, practical sessions, tutorials and industrial site visits.

In Part II students complete a research project module to the value of **30** credits. The conditions of employment of graduates wishing to pursue the programme should be such that they may carry out their research project in their place of employment.

**Note:** The Programme Management Committee may permit students to undertake the MSc (Pharmaceutical Technology and Quality Systems) (1 year pathway) (<https://ucc-ie-public.courseleaf.com/programmes/mscpqs/>) only if they hold a Postgraduate Diploma (equivalent to NFQ Level 9) in Pharmaceutical Technology and Quality Systems or a similar award from an accredited School of Pharmacy, which has been completed within the previous five years.

## Exit Award: Postgraduate Diploma in Pharmaceutical Technology and Quality Systems

A candidate who passes all taught modules in Part I (60 credits) may opt to exit the programme and be conferred with a Postgraduate Diploma in Pharmaceutical Technology and Quality Systems (<https://ucc-ie-public.courseleaf.com/programmes/pdptq/>).

## Programme Requirements

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

## Programme Requirements

### Pathway 1

Code	Title	Credits
Students take <b>90</b> credits as follows - taught modules ( <b>60</b> credits) in Part I and a dissertation ( <b>30</b> credits) in Part II:		
<b>Part I - Taught Modules</b> <sup>1</sup>		
Students take <b>60</b> credits as follows:		
<i>Core Modules</i>		
PF6200	Pharmaceutical Chemistry	10

PF6201	Pharmaceutical Dosage Form Design	5
PF6202	Pharmaceutical Manufacturing - API to Finished Product	5
PF6203	Pharmaceutical Microbiology and Sterile Manufacturing	5
PF6204	Pharmaceutical Development of Investigational Medicinal Products	5
PF6205	Pharmaceutical Biotechnology	5
PF6206	Pharmaceutical Statistics and Process Control	5
PF6207	Pharmaceutical Plant and Process: From Design through to Validation	5
PF6208	Quality Management Systems and Regulatory Affairs	5
PF6209	Role and Professional Duties of the Qualified Person	5
PT6401	Pharmacology	5
<b>Part II - Dissertation</b> <sup>2</sup>		
Students take <b>30</b> credits as follows:		
<i>Core Modules</i>		
PF6210	Dissertation in Pharmaceutical Technology and Quality Systems	30
<b>Total Credits</b>		<b>90</b>

<sup>1</sup> Taught modules will be offered on a cyclical basis over alternative years.

<sup>2</sup> The research project will be centred in an industrial pharmaceutical setting. Consideration will be taken of the candidate's chosen project area, but all project titles must be approved in advance by the programme committee and supervised by a member of academic staff at UCC.

## 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 Technology and Quality Systems (NFQ Level 9, Major Award)

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

- Identify and evaluate the role of Quality Systems and Good Manufacturing practices (GMP) in the pharmaceutical industry, and to be aware of the latest trends in good clinical, manufacturing, laboratory, validation and distribution practices;
- Define the legal basis and professional duties of the Qualified Person as defined by EC Directive 2001/83/EC and apply a risk based approach to the evaluation of quality, safety and efficacy of pharmaceutical products;
- Derive and apply a science based approach to solving quality based problems in the manufacture of pharmaceuticals;
- Demonstrate a comprehensive knowledge of pharmaceutical sciences, which includes a sound basis in pharmaceutical chemistry and analysis, pharmacology, pharmaceuticals, microbiology and biochemistry;
- Apply the principles of pharmaceutical dosage-form design and the technologies involved in industrial manufacture of medicinal

products (both sterile and non-sterile) to the production of pharmaceutical products;

- Outline the stages of industrial drug development, from drug discovery, development, testing and clinical trials, registration and post marketing activities;
- Recognise the role and influence of regulatory bodies which controls the development, registration, manufacture and distribution of pharmaceutical products;
- Prepare and review written protocols/reports that provide a clear description of an investigation or study, associated experiments and actions taken, and provide an appropriate conclusion;
- Work effectively as an individual, in teams and in multi-disciplinary settings.