UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

Science and Engineering
Flexible Learning Centre

Professional Diploma in Regulatory Affairs in (Bio) Pharmaceuticals

1 year part-time
(Online/Blended)

Programme Overview

There is a strong demand in recent years for Regulatory Affairs (RA) professionals in Ireland, working either at manufacturing or distribution sites or marketing headquarters within the pharmaceutical, biological, biopharmaceutical and chemical sectors.

This programme, offered by the Chemical Sciences Department, is unique in that it is designed and delivered by Regulatory professionals and provides a solid understanding of Regulatory Affairs in the drug development process.

Why do this programme:

- Learn about how medicines are regulated to ensure their safety and efficacy.
- Learn from industry experts, about strategies to improve performance and regulatory approval time.
- Hear from speakers from Regulatory Authorities on how to improve the dossier to maximize the chance of success.
- Appreciate the impact a regulatory professional has on the development of innovative medicines.

Programme Content

The programme consists of six taught modules over two semesters. There is a strong focus on the integration of the concepts, tools and techniques learned during the course of the programme by use of case studies and group working, which really benefits student networking opportunities.

Delivery will combine traditional distance education with online learning. There may be some on-campus tutorials (on Saturday) once per semester.

Semester 1 - Spring	Semester 2 - Autumn
• Drug Regulation and the Agencies • Regulatory Affairs Interactions in Drug Development and Product Marketing • Key Regulatory Considerations for Clinical Development and Operations	• Regulatory Requirements for New Active Substances • Regulatory Strategy and Requirements for Established Active Substances • Employment Enhancement (no credits)

In the Employment Enhancement module students will develop confidence and interview techniques, as well as CV development and career opportunities specific to the RA sector.

Further Qualifications

This level 9 Professional Diploma counts as 30 credits toward a Masters in Engineering Practice. For more details visit the Masters in Engineering Practice webpage.

Entry Requirements

Programme participants should hold a NFQ level-8, primary honours degree or an equivalent qualification in a relevant science related field and ideally have at least two years of relevant work experience. Candidates who do not meet the minimum entry criteria can be evaluated under the University's Recognition of Prior Learning Policy (RPL) and may be interviewed to ascertain their suitability for the programme.

Further Information

Candidates meeting Springboard+ criteria may qualify for funding subject to places. To learn more about the Professional Diploma Regulatory Affairs in (Bio) Pharmaceuticals and how to apply: scan the QR code.

Contact Us

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