UNIVERSITY OF LIMERICK
OLLSCOIL LUIMNIGH

Flexible Learning Centre
Science and Engineering

Professional Diploma in Regulatory Affairs in (Bio) Pharmaceuticals

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.

Participants will learn to:

- Gain a solid understanding of what Regulatory Affairs is and its importance in the drug development process.
- Appreciate the impact a regulatory professional has on the development of innovative medicines.
- Learn about how medicines are regulated to ensure their safety and efficacy.
- Learn from experts, who are currently working in the field, about strategies to improve performance thus speeding up the regulatory approval time.
- Hear from speakers from Regulatory Authorities about how to improve the dossier to maximize the chance of success.
- Develop confidence and interview techniques, as well as CV development and career opportunities.

1 year part-time
(Online/Blended)

Programme Content

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

Springboard funded students can avail of the following optional modules:

Learning How to Learn
Career Development
Industry Case Study Project

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 per semester, (these will be on a Saturday).

Further Qualifications

This level 9 Professional Diploma counts as 30 credits toward a Masters in Engineering Practice

Entry Requirements

Programme participants should hold a NFQ level-8, primary honours degree or an equivalent qualification 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 UL RPL (prior learning) policy and may be interviewed to ascertain their suitability for the programme.

Funding

Springboard and BioPharmaChem Skillnet funding is available for candidates (subject to eligibility criteria and availability of places).

Careers

This programme is aimed at:

- Graduates with a background in quality, manufacturing, clinical, non-clinical, pharmaceutical, biopharmaceutical or the chemical industry.
- For those with an interest in pharmaceutical development.
- Those who wish to discover how medicines are licensed to get on the market.
- Those who are interested in learning how to safeguard patients by ensuring safety, quality and efficacy of medicines on the market i.e. how medicines are regulated in Europe.
- Those who would like to like to learn about the EU regulatory requirements as well as the main features of the US regulatory system, an important other jurisdiction for Irish based RA professionals.

How to Apply

Applicants are encouraged to apply online for this programme.

Visit: www.ul.ie/gps/regulatory-affairs-biopharmaceuticals-professional-diploma

Programme Contact
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