



# Specialist Diploma in Regulatory Affairs

Science & Engineering

## COURSE PROFILE

Award	Specialist Diploma
Qualification	NFQ Level 9, Minor award, 48 Credits
Delivery	Part-Time, Online, Distance Learning, On-Campus Tutorials
Duration	1 year
Start Dates	January
Faculty	Science & Engineering

## OVERVIEW

There is a strong demand in recent years for Regulatory Affairs (RA) professionals at manufacturing or distribution sites within the pharmaceutical, biological, biopharmaceutical and chemical sectors. RA professionals carry out a pivotal role in the maintenance of compliance for the provision of safe and effective medicines. This programme was developed with input from the Health Products Regulatory Authority and Solid State Pharmaceutical Cluster (SPCC).

## FOR WHOM:

- This Specialist Diploma is available to graduates with a background in quality, manufacturing, pharmaceutical, biopharmaceutical or chemical sectors. It is for those with an interest in organisational improvement and development through the use of Regulatory Affairs tools and techniques.
- For graduates who would like to learn about the EU regulatory requirements, as well as the main features of the regulatory system in the US, which is the most important other jurisdiction for RA professionals based in Ireland.

## HOW IT WORKS:

- This flexible programme lets students take five taught modules over two semesters. In addition to the taught modules, there will be a strong focus on the integration of the concepts, tools and techniques during the course of the programme. As well as the taught modules therefore, students will complete a project and a career development module.
- Course delivery combines traditional distance education with online learning and approximately three on-campus days per semester.

## PARTICIPANTS LEARN TO:

- Understand both theory and practical application of RA tools and techniques to improve operational outcomes and efficiency.
- Apply RA methodology to help organisations improve performance and speed up the regulatory approval time.
- Each learner will participate in 'Job Readiness' & 'Support into Employment' workshops, to develop their confidence and interview skills, as well as CV development and career development.

## INDUSTRY LEARNING PROJECT

Industry representatives will engage in a series of presentations on employment opportunities in the region, as well as talks on specific RA topics from an industry perspective. In the second semester there will be the opportunity for course participants to apply for work placement with our industry partners. Students will complete a project focussing on the development of a plan to monitor and manage regulatory affairs compliance within an organisation

## COURSE CONTENT

### SPECIALIST DIPLOMA IN REGULATORY AFFAIRS

#### MODULE TIMETABLE

	Spring
1. Drug Regulation & the Agencies	
2. RA Interactions in Drug Development & Product Marketing	
3. Key Regulatory Considerations for Clinical Development and Operations.	
4. Career Development	

  

	Autumn
1. Regulatory Requirements for New Active Substances	
2. Regulatory Strategy & Requirements for Established Active Substances	
3. Industry Learning Project	

#### CAREER DEVELOPMENT

- Industry Presentations on Current Activity in Ireland and Future Potential in the sector
- Employer Open Days
- Presentation Skills Workshops
- CV Preparation
- Confidence, Motivation & Job Readiness Workshops



\* The number of in-company work placements offered depends on the student's location, topic area and motivation to participate in all elements of the course. A work placement manager will work with participants and companies to find the best fit but the onus is on the learner to play an active role in this process.

## HOW TO APPLY

Applicants are encouraged to register and apply online via the Springboard website. Applicants must ensure that they are eligible to apply for Springboard funding for this course, by clicking on the 'Am I Eligible' tab on the front page of the Springboard website. This site also contains full details on the documents you need to gather before you begin your application. Applications will open in mid November.

Visit [www.springboardcourses.ie](http://www.springboardcourses.ie) for more details.

## ENTRY REQUIREMENTS



Programme participants should hold a NFQ level-8, primary honours degree or an equivalent qualification and have at least five years of relevant work experience. Where an applicant does not meet the entry requirements above, they can be evaluated under the UL RPL (prior learning) policy and may be interviewed to ascertain their suitability for the programme.

### VIEW THE FAQs

Prospective students are encouraged to read our FAQs at [www.springboardcourses.ie](http://www.springboardcourses.ie)

### FOR ADDITIONAL QUERIES

Email [cpe@ul.ie](mailto:cpe@ul.ie) or call +353 61 202530