## POSTGRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATORY SCIENCES

## **Programme Learning Outcomes**

Programme Learning Outcomes for Postgraduate Certificate in Pharmaceutical Regulatory Sciences (NFQ Level 9, Minor Award)

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

- Develop manufacturing processes which apply quality-by-design principles for a range of medicines including small molecules, biopharmaceuticals and ATMPs.
- · Critically evaluate the regulation of medicinal products.
- Identify opportunities to accelerate the integration of emerging science and technology in medicines' development.
- Evaluate major process parameters and critical quality attributes for different manufacturing processes, including conventional medicines, biologics and advanced therapy medicinal products
- Interpret the regulatory requirements for approval, licensing and manufacture of medicinal products in the EU, with reference to the relevant EU legislative frameworks