

**Research Centre**

**ICNT - International Centre for  
Neurotherapeutics**

**Post title**

**Qualified Person (QP) Part-time Post**

**Reports to:**

**Director of ICNT or GMP nominee**

**Post duration**

**One year in the first instance (there  
may be an opportunity for longer  
contracts, subject to DCU recruitment  
& selection procedures)**

**Background:**

ICNT is a multi-disciplinary, internationally-competitive and well-funded Centre <http://www.dcu.ie/icnt/> whose research focuses on developing novel, long-acting biotherapeutics for chronic pain. Recent advances include generation of potent and selective SNARE-proteases that inhibit neuro-exocytosis and give prolonged relief of neuropathic pain in rodents. These unique and promising recombinant anti-nociceptives are to be produced in a new 'state-of-the-art' Good Manufacturing Practice (GMP) facility for evaluation in man.

**Principal responsibilities**

- Full range of QP activities including proactive driving of quality improvements, quality performance reporting, stability/compliant and other investigations/project support.
- Work with requisite team members to develop a Quality Management System, Validation Master Plan and Site Master File acceptable to the Health Products Regulatory Authority (HPRA).
- Preparation of an application to the HPRA, acting as liaison with the HPRA as nominated QP, for accreditation of our GMP facility and licence to manufacture an Investigational Medicinal Product (IMP).
- Certify the release of IMP batches and maintain a register of these, abiding by the principles and guidelines of GMP as stated in Directive 2003/94/EC for medicinal products and IMP for human use, as interpreted in the EU Guide to GMP.
- Carry out audits of relevant suppliers and of the GMP facility, promote GMP through training and guidance and perform all routine duties as detailed in EU Guide to GMP.

- Ensure validation of manufacturing and testing processes, including Quality Control.
- Review of batch records as part of QP certification
- Maintain in-depth knowledge and experience up-to-date in light of technical/scientific progress and changes in quality management relevant to any IMP you are required to certify.

**Note:** This job description does not form part of the employee's contract of employment but is provided for guidance. Precise duties and responsibilities could change over time. Job holders will be consulted over any proposed changes before implementation.

**Qualifications:**

- Must meet the minimum requirements for education and experience, as outlined in Directive 2001/83/EC relating to medicinal products for human use.
- M.Sc. in Industrial Pharmaceutical Technology or similar qualification to practice as a QP.
- Adequate QP experience in the BioPharma Industry to competently perform the prescribed roles.

**Aptitudes and Abilities:**

Maintaining good, open communication and working relations with colleagues and agencies involved.

Capable of working independently and co-operatively/flexibly as part of a team to achieve milestones and meet deadlines.

**Salary:**

Up to €90,000 p.a. pro-rated for time worked and subject to qualifications and experience,

**Closing date:** 7<sup>th</sup> March 2016.

**Informal initial enquiries:** Prof. J. Oliver Dolly, Director of ICNT; Tel: +353 (0)1 700 7757 or E-mail: [oliver.dolly@dcu.ie](mailto:oliver.dolly@dcu.ie) ; and include C.V. plus names of 3 referees.

## **Application Procedure**

Application forms are available from the DCU Current Vacancies (open Competitions) website at <http://dcu.ie/hr/vacancies/current.shtml> and also from the Human Resources Department, Dublin City University, Dublin 9. Tel: +353 (0) 1 700 5149. Applications should be submitted by email to [hr.applications@dcu.ie](mailto:hr.applications@dcu.ie) or by Fax: +353 (0)1 700 5500 or by post to the Human Resources Department, Dublin City University, Dublin 9

***Please clearly state the role you are applying for in your application and email subject line: Job Ref #270: Qualified Person (QP) Part-Time Post***

***Dublin City University is an equal opportunities employer***

