

Research Centre

ICNT - International Centre for Neurotherapeutics

Post title

Quality Assurance Specialist (QA) Full-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.

Overview of the role:

The QA Specialist is responsible for the preparation, in consultation with the QP, of everything needed for application to the Health Products Regulatory Authority (HPRA) for accreditation of a GMP facility and licence to manufacture an Investigational Medicinal Product (IMP).

Principal responsibilities:

Ensure that the Qualified Person is appraised on all quality matters relating to the GMP and Good Laboratory Practice.

- Responsibility for the management of documentation control related to the Quality Management System for compliance with GMP.
- Preparation and approval of standard operating procedures (SOPs).
- Preparation for and participation in regulatory inspections, including post inspection follow up.
- Preparation of Annual Product Quality Reviews.

- Management of Change Control processes and procedures.
- Process Deviation Report Management including implementation of effective corrective actions.
- Monitoring of supplier performance and evaluation/auditing of suppliers and potential suppliers.
- Review of IMP batches prior to release by the QP.
- Archiving of batch documentation and reference samples.
- Induction GMP training and training plan preparation.

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:

- A primary degree in Life Sciences or another related field.
- A postgraduate qualification which allows the candidate to act as a competent QA Supervisor.
- A minimum of 5 years working in a similar role in the BioPharma Industry.
- High attention to detail.
- A good understanding of regulatory requirements.
- Excellent oral and written communication skills.
- Experience in implementation of continuous improvement initiatives.

Aptitudes and Abilities:

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

Capable of working without supervision and co-operatively/flexibly as part of a team to achieve milestones and meet deadlines.

Salary: Up to €65,000 p.a. subject to qualifications and experience

Closing date: 7th 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 ; 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 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 #271: Quality Assurance Specialist (QA) Full-time Post

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