OLLSCOIL NA GAILLIMHE
UNIVERSITY OF GALWAY

HR EXCELLENCE IN RESEARCH

Research Assistant – QA Co-ordinator -(DTIF) – Immunomodulatory Alpha Neutrophils (IMANs) - Centre for Cell Manufacturing Ireland (CCMI) - College of Medicine, Nursing and Health Sciences

Ref. No. 011688

JOB ADVERTISEMENT

Applications are invited from suitably qualified candidates for a full-time 24 month, fixed term position as a **QA Co-ordinator (Research Assistant)** at the Centre for Cell Manufacturing Ireland (CCMI) - College of Medicine, Nursing and Health Sciences

This position is funded by Disruptive Technologies Innovation Fund (DTIF)
and is available from May 2026 to end date of April 2028 with the possibility of a further one year extension in line with 3 year grant award.

Salary: **Research Assistant:** Salary scale €33,791 - €43,872 per annum, (subject to the project's funding limitations), and pro rata for shorter and/or part-time contracts.
The default position for all new public sector appointments is the 1st point of the salary scale. This may be reviewed, and consideration afforded to appointment at a higher point on the payscale (subject to the project's funding limitations), where evidence of prior years' equivalent experience is accepted in determining placement on the scale above point 1, subject to the maximum of the scale.
(Research Salary Scales - University of Galway)

Closing date for receipt of applications is 17:00 (Irish Time) on 17 April 2026 It will not be possible to consider applications received after the closing date.

Interviews are planned to be held on 27 April 2026

***Please review full job description for further details and essential requirement**

JOB DESCRIPTION

The primary focus of this work centres around the quality systems that will underpin the manufacture and testing of Neutrophil-based Leukocyte Infusion Therapy products in a Good Manufacturing Practices (GMP) environment at the Centre for

Cell Manufacturing (CCMI) – University of Galway and to supply these products into the first human trial of IMAN therapy, targeting treatment-resistant advanced solid tumours at Galway Institute for Clinical Trials.

Duties:

KEY RESPONSIBILITIES

Update and maintain the quality management system as defined in the **Quality Manual** and governed by **EU GMP Volume 4** and GMP for medicinal and investigational medicinal products for human use reference Directive (EU) 2017/1569 and clinical trial directive 536/2014.

Assist in the preparation or regulatory applications as required.

Vendor management, including evaluation, creation, review and update of technical agreements with contract manufacturers and contract testing laboratories.

Preparation and review of certificates of analysis for batch release.

Approval or rejection of material, e.g. raw materials, packing material, intermediates, bulk and finished products, in accordance with specifications.

Creating and updating QA SOPs and Quality Documents
Ensure continuous development and improvement of the Standard Operating Procedures across all functions in CCMI.

Evaluating and trending in-process control test and final product results.
Assist in ensuring that issues and trends are critically evaluated and addressed in cooperation with the Quality Manager.

Issuance, distribution and back-up of quality-controlled documents.

Ensure that all activities conform to the required cGMPs, GLP protocols and SOPs.

Co-ordinate Equipment Qualification and Validation, where required in CCMI across all functions.

Ensure all maintenance documents are kept up to date and filed in the appropriate file.

Co-ordination and updating of AMS logs and documents including but not limited to Change Control Log, Technical Agreement Log.

Track and co-ordinate plans for internal Audits and External Supplier Audits.

Preparation and participation in both internal and external regulatory audits/inspections.

Co-ordination and preparation of the annual Management presentation.

Procurement of services and materials, including tender preparation and review as applicable.

Assist in the preparation of data for IMPD Submission.

Participate in the design, draft and performance of critical process validations and participation in equipment validations as required

Provide support at the Clinical Trial Site

Stock cleanroom suites and support areas with released inventory (based on team Rota)

File and maintain batch records and production related records as required

ADDITIONAL DUTIES:

- Contribute to the research project's dissemination in whatever form - report, papers, chapters, book i.e. with respect to IMANs project and other new projects that may come on stream.

- Engage in appropriate training and professional development opportunities as required by your Principal Investigator, your School or Institute, or the University.
- May contribute to teaching /tutoring/mentoring, specifically in relation to the preparation and delivery of relevant Quality Systems lectures in educational projects delivered via CCMI.
- May contribute to the College/School/Research Unit through, for example, participating in promotion activity such as student Open Days, career days, or contribute to public events such as science week etc.

ELIGIBILITY REQUIREMENTS

Essential Requirements:

- Primary degree in Life Sciences or equivalent
- At least one years experience in a QA working environment
- Proven procedure-document writing skills
- Computer software skills including Microsoft Office

Desirable Requirements:

- Masters degree in Life Sciences
- At least one years' experience in a GMP QA working environment
- Good understanding and exposure to Regulatory affairs in general
- Some exposure to the environment for the manufacture of Advanced Medicinal Therapy Product and/or cellular processing

CONTINUING PROFESSIONAL DEVELOPMENT

Continuing Professional Development/Training:
Researchers at University of Galway are encouraged to avail of a range of training and development opportunities designed to support their personal career development plans. University of Galway provides continuing professional development supports for all researchers seeking to build their own career pathways either within or beyond academia. Researchers are encouraged to engage with our Researcher Development Centre (RDC) upon commencing employment - see HERE for further information.

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FURTHER INFORMATION/LINKS

- **TO APPLY:**
- Search Current University of Galway vacancies. Applications must be submitted online.
    - How to apply guide

- For informal enquiries, please contact Andrew Finnety (andrew.finnerty@universityofgalway.ie)

- University's Strategic Plan

- Working in Research at University of Galway

- Moving to Ireland (Euraxess)

- Applicant Information

- We reserve the right to re-advertise or extend the closing date for this post.

- University of Galway is an equal opportunities employer.

- All positions are recruited in line with Open, Transparent, Merit (OTM) and Competency based recruitment.

Athena Swan Ireland
EQUALITY CHARTER