Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Post Specification (034737)

Post Title:	Quality and Regulatory Affairs Research Fellow in Clinical Research Facility, St. James' Hospital, Dublin 8
Post Status:	Specific Purpose Contract, Approximately 1 year, Fulltime
Research Group / Department / School:	Clinical Research Facility – School of Medicine
Location:	Clinical Research Facility, St. James' Hospital, James' Street, Dublin 8.
Reports to:	Clinical Director
Salary:	Appointment will be made on the IUA Research Fellow Scale at a point in line with Government Pay Policy.
Hours of Work:	8 am – 4pm Monday to Friday; Some flexibility will be required should particular studies/trials deem necessary.
Closing Date:	12 Noon (Irish Time) Friday 11th December 2020

Please note that Garda vetting will be sought in respect of individuals who come under consideration for a post.

Post Summary

The Wellcome Trust – HRB Clinical Research Facility (CRF) invites applicants for the post of Quality and Regulatory Affairs Manager.

The CRF is a partnership between the Trinity College Dublin (TCD) School of Medicine and St. James's Hospital funded by Wellcome and the HRB. The €10 million 1,300M^2 facility was opened by An Taoiseach, Enda Kenny, on the 30th May 2013 and is located in the heart of St. James's Hospital, under the Directorship of Professor Martina Hennessy in Trinity's School of Medicine.

Standard Duties and Responsibilities of the Post

The QRAM will maintain systems to assure the quality of clinical research undertaken within the CRF, in accordance with the International Conference on Harmonisation Good Clinical Practice Guidelines (ICH-GCP), National and European legislation and any relevant quality standards. The CRF supports a broad range of clinical research studies including advanced therapy medicinal products (ATMPS), investigational medicinal products (IMPs), medical devices, biobanking and observational research. The QRAM will support regulatory compliance of the CRF and associated research projects and will assist investigators with application submissions to research ethics committees, competent authorities and HRCDC.

The QRAM will lead on Quality Assurance (QA) initiatives to ensure that the studies run through the CRF meet required standards. The QRAM will coordinate CRF preparation for external audit and regulatory inspection by the Health Products Regulatory Authority (HPRA) or other competent authority.

The QRAM is responsible for interpreting complex legislation relating to clinical research, identifying the implications for CRF operation and acting to initiate necessary changes to practice in order to ensure that the CRF remains compliant with statutory regulations.

The QRAM will:

- Maintain systems to ensure that clinical trials and clinical investigations carried out within the CRF are conducted in accordance with ICH GCP guidelines, National and European legislation and any other applicable guidelines.
- Maintain systems to ensure compliance of CRF pharmacy services and clean room with regulatory requirements.
- Maintain compliance of the CRF and associated clinical research with data protection legislation, including the Data Protection Acts and Health research Regulations.
- Develop regulatory strategies that feed into project timelines and will assist in the development of submission documentation (i.e. protocol, patient information sheet and consent).
- Liaise with the competent authorities such as the HPRA in relation to specific clinical trials.
- Provide leadership in quality and regulatory decisions impacting the CRF functions.

- Develop an annual audit programme and conduct regular audits to ensure that staff, facilities, services and ongoing research comply with ICH-GCP, National and European legislation, SOPs and any other applicable guidelines.
- Provide ICH-GCP and Regulatory training to CRF and external personnel as needed.
- Lead the preparation for mandatory inspection of the CRF by the HPRA or other competent authority, developing and maintaining an inspection readiness plan, and accommodating and preparing for any sponsor audits as required.
- Act as the primary contact person for regulatory agencies during mandatory inspections of the CRF, accompanying the inspectors, responding promptly to requests for information and ensuring that designated staff are available for interview as required.
- Review any inspection and/or audit findings, taking responsibility for coordinating remedial action, ensuring completion of tasks and attainment of requisite regulatory standards.
- Coordinate the management of CRF policies and Standard Operating Procedures (SOPs), ensuring that new documentation is created in collaboration with colleagues in St. James's Hospital.
- Assess the education and training needs of research personnel in order to identify knowledge deficits and ensure personnel are trained appropriately.
- Provide professional advice relating to the regulation, management and conduct of clinical research.
- Liaise with ethics committees to ensure that studies meet ethical standards.
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- Develop linkages with colleagues in similar posts in other CRF's.
- Other duties and responsibilities may be specified from time to time at the discretion of the management.

Funding Information

Health Research Board

Person Specification

Qualifications

1. Bachelor's degree in a life science discipline
2. A minimum of 5 years' experience in quality assurance, risk management, audit and/or regulatory inspection of clinical trials
3. Post graduate qualification in clinical research or research nursing or commitment to undertake a relevant course within an agreed timeframe.

Knowledge & Experience (Essential & Desirable)

Technical/Clinical Competencies

Essential:

- Basic IT Skills including Word, Excel and Powerpoint
- Good written skills
- Knowledge of ICH GCP and of relevant national and international clinical trial regulations
- Experience in ICH GCP training
- Experience within a commercial/academic clinical research environment
- Clinical trial monitoring and/or auditing experience
- Proven project management and organisational skills
- Experience in developing quality strategies
- Excellent communication skills (oral, written & presentation) with proven ability to work effectively as part of a team.
- Strong leadership and communication skills
- Self-motivated and able to work independently, showing initiative and good judgment.

Desirable:

- Familiarity with HPRA and sponsor audits
- Experience of quality management systems
- Experience of working with regulatory bodies (e.g. HPRA, EMA, FDA, MHRA)

Application Procedure

Applicants should submit a full Curriculum Vitae to include the names and contact details of 2 referees (including email addresses), to:-

Ms. Geraldine Quinn

Email: gquinn@tcd.ie

Further Information for Applicants

URL Link to Area	http://www.sjhcrf.ie/
URL Link to Human Resources	https://www.tcd.ie/hr/

GARDA CLEARANCE: Police vetting will be sought in respect of individuals who come under consideration for a post.

PLEASE NOTE: Applicants will be required to complete and return a Garda vetting form should they come under consideration for appointment. In some cases they may be requested to complete the form on the day of interview. This form will be forwarded to An Garda Síochána (Irish Police) for security checks on all Irish addresses at which they have resided. An Garda Síochána will make enquiries with the Police Service of Northern Ireland with respect to addresses in Northern Ireland. If an applicant is not successful in obtaining the post for whatever reason, this information will be destroyed. If an applicant, therefore, subsequently comes under consideration for another position, they will be required to supply this information again.

While applicants must complete information in relation to all addresses at which they have resided, the vetting is only done on addresses on the island of Ireland.

If an applicant has resided / studied in countries outside of Ireland for a period of 6 months or more, it is mandatory for them to furnish a Police Criminal Records Check/ Police Certificate from those countries stating that they have no convictions recorded against them while residing there. Applicants will need to provide a separate Police Criminal Records Check/ Police Certificate for each country in which they have resided. The Police Criminal Records Check/ Police Certificate must be dated after the date the applicant left the relevant country. Applicants should provide documentation in the English and/or Irish language. Translations must be provided by a registered translation company/institute in the Republic of Ireland; all costs will be borne by the applicant. Only original version documents will be accepted.

Applicants should be aware that any information obtained in the Garda Vetting process can be made available to the employing area.

It is the responsibility of the applicant to seek security clearances in a timely fashion as they can take some time. No applicant will be appointed without this information being provided and being in order.

The following websites may be of assistance in this regard:

www.disclosurescotland.co.uk
www.psni.police.uk

This website provides information on obtaining a national police clearance certificate for Australia
www.afp.gov.au

This website provides information on obtaining police clearance in New Zealand.
www.courts.govt.nz

For other countries not listed above applicants may find it helpful to contact the relevant embassies who could provide information on seeking Police Clearance. Original Police Clearance documentation should be forwarded to Human Resources where it will be copied and the original returned to the applicant by post. **Any cost incurred in this process will be borne by the Applicant.**

Trinity College Dublin, the University of Dublin

Trinity is Ireland's leading university and is ranked 108th in the world (QS World University Rankings 2020). Founded in 1592, the University is steeped in history with a reputation for excellence in education, research and innovation.

Located on an iconic campus in the heart of Dublin's city centre, Trinity has 18,000 undergraduate and postgraduate students across our three faculties – Arts, Humanities, and Social Sciences; Engineering, Mathematics and Science; and Health Sciences.

Trinity is ranked as the 17th most international university in the world (Times Higher Education Rankings 2020) and has students and staff from over 120 countries.

The pursuit of excellence through research and scholarship is at the heart of a Trinity education, and our researchers have an outstanding publication record and strong record of grant success. Trinity has developed 19 broad-based multidisciplinary research themes that cut across disciplines and facilitate world-leading research and collaboration within the University and with colleagues around the world. Trinity is also home to 5 leading flagship research institutes:

- Trinity Biomedical Sciences Institute (TBSI)
- Trinity College Institute of Neuroscience (TCIN)
- Trinity Translational Medical Institute (TTMI)
- Trinity Long Room Hub Arts and Humanities Research Institute (TLRH)
- Centre for Research on Adaptive Nanostructures and Nanodevices (CRANN)

Trinity is the top-ranked European university for producing entrepreneurs for the past five successive years and Europe's only representative in the world's top-50 universities (Pitchbook Universities Report).

Trinity is home to the famous Old Library and to the historic Book of Kells as well as other internationally significant holdings in manuscripts, maps and early printed material. The Trinity Library is a legal deposit library, granting the University the right to claim a copy of

every book published in Ireland and the UK. At present, the Library's holdings span approximately 6.5 million printed items, 400,000 e-books and 150,000 e-journals.

With over 120,000 alumni, Trinity's tradition of independent intellectual inquiry has produced some of the world's finest, most original minds including the writers Oscar Wilde and Samuel Beckett (Nobel laureates), the mathematician William Rowan Hamilton and the physicist Ernest Walton (Nobel laureate), the political thinker Edmund Burke, and the former President of Ireland Mary Robinson. This tradition finds expression today in a campus culture of scholarship, innovation, creativity, entrepreneurship and dedication to societal reform.

Rankings

Trinity is the top ranked university in Ireland and ranked 108th in the world (QS World University Rankings 2020). Trinity ranks in the top 50 in the world on 6 subjects and in the top 100 in 20 subjects (QS World University Rankings by Subject 2019). Full details are available at: www.tcd.ie/research/about/rankings.

The Selection Process in Trinity

The Selection Committee (Interview Panel) may include members of the Academic and Administrative community together with External Assessor(s) who are expert in the area. Applications will be acknowledged by email. If you do not receive confirmation of receipt within 1 day of submitting your application online, please contact the named Recruitment Partner on the job specification immediately and prior to the closing date/time.

Given the degree of co-ordination and planning to have a Selection Committee available on the specified date, the University regrets that it may not be in a position to offer alternate selection dates. Where candidates are unavailable, reserves may be drawn from a shortlist. Outcomes of interviews are notified in writing to candidates and are issued no later than 5 working days following the selection day.

In some instances the Selection Committee may avail of telephone or video conferencing. The University's selection methods may consist of any or all of the following: Interviews, Presentations, Psychometric Testing, References and Situational Exercises.

It is the policy of the University to conduct pre-employment medical screening/full pre-employment medicals. Information supplied by candidates in their application (Cover Letter and CV) will be used to shortlist for interview.

Applications from non-EEA citizens are welcomed. However, eligibility is determined by the Department of Business, Enterprise and Innovation and further information on the Highly Skills Eligible Occupations List is set out in Schedule 3 of the Regulations https://dbei.gov.ie/en/What-We-Do/Workplace-and-Skills/Employment-Permits/Employment-Permit-Eligibility/Highly-Skilled-Eligible-Occupations-List/ and the Ineligible Categories of Employment are set out in Schedule 4 of the Regulations https://dbei.gov.ie/en/What-We-Do/Workplace-and-Skills/Employment-Permits/Employment-Permit-Eligibility/Ineligible-Categories-of-Employment/ . Non-EEA candidates should note that the onus is on them to secure a visa to travel to Ireland prior to interview. Non-EEA candidates should also be aware that even if successful at interview, an appointment to the post is contingent on the securing of an employment permit.

Equal Opportunities Policy

Trinity is an equal opportunities employer and is committed to employment policies, procedures and practices which do not discriminate on grounds such as gender, civil status, family status, age, disability, race, religious belief, sexual orientation or membership of the travelling community. On that basis we encourage and welcome talented people from all backgrounds to join our staff community. Trinity's Diversity Statement can be viewed in full at https://www.tcd.ie/diversity-inclusion/diversity-statement.

Pension Entitlements

This is a pensionable position and the provisions of the Public Service Superannuation (Miscellaneous Provisions) Act 2004 will apply in relation to retirement age for pension purposes. Details of the relevant Pension Scheme will be provided to the successful applicant.

Applicants should note that they will be required to complete a Pre-Employment Declaration to confirm whether or not they have previously availed of an Irish Public Service Scheme of incentivised early retirement or enhanced redundancy payment. Applicants will also be required to declare any entitlements to a Public Service pension benefit (in payment or preserved) from any other Irish Public Service employment.

Applicants formerly employed by the Irish Public Service that may previously have availed of an Irish Public Service Scheme of Incentivised early retirement or enhanced redundancy payment should ensure that they are not precluded from re-engagement in the Irish Public Service under the terms of such Schemes. Such queries should be directed to an applicant's former Irish Public Service Employer in the first instance.

Application Procedure

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Applicants should submit a full Curriculum Vitae to include the names and contact details of 2 referees (including email addresses), to:-

Name Geraldine Quinn

Email gquinn@tcd.ie