Post Specification

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| Post Title: | Research Assistant - Chief II Pharmacist  |
| Post Status: | Fixed-term Contract (24 months) full time |
| Research Group /Department/School: | Clinical Research Facility St. James’s HospitalSchool of MedicineTrinity College Dublin, the University of Dublin |
| Location: | Clinical Research Facility, St. James’s Hospital, Dublin 8. |
| Reports to: | Associate Director |
| Salary: | Appointment will be made on the HSE pay scales for Chief II Pharmacist at a point in line with Government pay policy |
| Closing Date and Time: | 12 noon on Friday 6th March 2020 |

**Please note: The successful candidate will be expected to take up appointment May 2020**

**Please note that Police 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 Chief 2 Research Pharmacist/ Senior Research Pharmacist within the CRF .

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 1,300M2 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 Michael Gill, Professor of Psychiatry in Trinity’s School of Medicine.

Pharmacy services are essential to the safe conduct of clinical trials involving Advanced Therapeutic and Investigational Medicinal Products (ATIMPs). The CRF Research Pharmacy at St. James’s Hospital dispenses clinical trial and other investigational medications in accordance with strict legislative requirements. It is dedicated to providing a high quality and safety service.

Key pharmacy services that are provided by the CRF include:

* Dispensing study medications to patients.
* Compounding and dispensing novel therapeutics.
* Management of ATIMP/IMP supplies: accountability, storage, dispensing, record keeping, destruction etc.
* Handling patient ATIMP/IMP returns and monitoring for compliance.
* Preparation of prescription templates, treatment protocols and other documents.

**Key leadership functions of this post**

* The CRF presently has an ATIMP room and fully operational Gene therapy infusion suite which is being used for ongoing studies. We anticipate growth and expansion in this innovative work and it is expected the successful applicant will take the lead role in developing strategy, processes and business planning in relation to this.
* In addition, the CRF is awaiting final completion of a state of the art aseptic suite for the safe compounding of innovative study medications. We anticipate delivery of two state of the art isolators and that this room will become fully operational in Q3 of 2020. It is expected that the successful applicant will take a lead on commissioning the unit and its isolators and developing a business plan and strategy for its use.

Standard duties and Responsibilities of the Post

The Research Pharmacist will be responsible for the pharmacy support of all clinical trials and research studies conducted in the Clinical Research Facility. The Research Pharmacist will be responsible for routine pharmacy activities within the CRF in compliance with PSI regulations as applicable. The Research Pharmacist will be responsible for ensuring the Pharmacy activities of the CRF meet standards of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and Good Clinical Trial Practice (GCP).

Working closely with the Chief pharmacist of St James’s Hospital the Chief 2 Research Pharmacist will:

* Participate in the setting up of Clinical Trials ATIMP trials and Research Studies for the CRF.
* Adhere to procedures to ensure the safe recording, handling, storage, prescribing, dispensing, administration, dispatch and destruction of investigational medicinal products (ATIMPS/ IMPs) including investigation and rectification of discrepancies.
* Participate in the dispensing & release of IMPs.
* Ensure that all pharmacy trial documentation complies with the EU clinical trials regulations, adhering to the principles of GCP and CRF Quality Assurance (QA) policies and procedures.
* Provide advice to investigators on formulation, prescribing, medication interactions and administration.
* Ensure that amendments to the clinical trial, that involve the IMP and/or other medicines are reflected in the pharmacy documentation, by updating procedures and the file to include the latest protocols and documents.
* Liaise with the HPRA, the EPA and other such regulatory authorities and groups as may be required.
* Prepare pharmacy documentation for HPRA GCP inspections and the follow up and action of GCP inspection findings.
* Assist the QA manager in implementing procedures and maintaining documentation relating to the procurement, preparation and importation of IMPs, where applicable.
* Participate in policy and SOP development and implementation within the CRF Research Pharmacy and the CRF.
* Highlight any discrepancies, incidents or inadequacies in services to the Chief II Research Pharmacist, Quality and Regulatory Affairs Manager (QRAM) or CRF Management team as appropriate.
* Be responsible for regularly updating own knowledge on clinical trials regulations and GCP and disseminate information to researchers and pharmacy staff involved in clinical trials both within & outside of the CRF.
* Support the concept of ‘zero-harm’ practice in the Clinical Research Facility.
* Contribute to the clinical pharmacy service and provide medicines information for the CRF.
* Contribute to the SJH Pharmacy Department service if deemed necessary.
* Participate, where appropriate, in the training of intern and undergraduate pharmacy students, pharmaceutical technicians, and pharmacy assistants.
* Support, where appropriate, staff undertaking postgraduate courses or supervise students from the School of Pharmacy.
* Represent and attend CRF subcommittee meetings on behalf of the CRF Research Pharmacy team, keep one’s self informed and maintain CPD, and communicate information.
* Comply with all Hospital and TCD policies and procedures, work safely and efficiently.
* Assist in the training and supervision of other grades of CRF staff.
* Contribute to cover so that holidays and time off of staff can be coordinated.
* Undertake other duties appropriate to the post on request of the Chief II Research Pharmacist.
* Contribute to service review, performance monitoring, professional and clinical audit, and research and development.

The Senior Research Pharmacist will also be involved in the start-up and operation of the CRF’s Aseptic Compounding Unit. Previous experience in aseptic compounding is desirable for application purposes.

The above Role Profile is not intended to be a comprehensive list of all duties involved and consequently the post holder may be required to perform other duties as appropriate to the post which may be assigned to him/her from time to time and to contribute to the development of the post while in office.

The post is advertised as a full time position

Funding Information

The funding for this post is via the Health Research Board

Person Specification

Qualifications

Essential:

* Be registered (or will be eligible for registration) as a member of the Pharmaceutical Society of Ireland.
* Hold a higher degree (in Clinical or Hospital Pharmacy)

**Desirable:**

* Post graduate qualification in clinical research would be an advantage.

Knowledge & Experience

Essential:

* At least 4-5 years’ experience in a hospital healthcare or pharmaceutical area
* Clinical research experience relevant to this position.
* Experience in commissioning and managing an aseptic compounding unit and demonstrable interest in the delivery of advanced therapeutics.
* Experience is managing staff and building relationships across institutions and groups internally and externally.

 Experience in commercial clinical trials of medicinal products or medical devices.

 Experience in Project/Study Management.

 Experience in a Pharmacy Aseptic Compounding Unit.

 Other postgraduate qualifications in clinical or life science related subjects.

 Good Clinical Practice (GCP) training.

Skills & Competencies

Essential:

* IT Skills including Word, Excel and Powerpoint.
* Good written and verbal skills.
* Familiarity with clinical trial management software and pharmacovigilance systems or the ability to upskill quickly.
* Good quantitative analysis/statistics skills.
* Experience of Aseptic Compounding.
* Experience of working with regulatory bodies (e.g. IMB, EMA, FDA, MHRA).

**Personal attributes**

Highly motivated and self-driven, good communicator

 Ability to multi-task and work under pressure

Willingness to engage in innovative projects and adopt a solution focused approach to delivering safety for new projects as they are approved

 Capacity to balance risk mitigation with desire to lead and enable innovative clinical and first in man studies.

Further Information for Candidates:

Informal Enquiries to: Mr. Jeremy Towns Jeremy.Towns@tcd.ie or

 Ms. Derval Reidy Reidyde@tcd.ie

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| URL Link to School | [www.tcd.ie](http://www.tcd.ie) |
| URL Link to Research Group | 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: Candidates 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 a candidate is not successful in obtaining the post for whatever reason, this information will be destroyed.  If a candidate, therefore, subsequently comes under consideration for another position, they will be required to supply this information again.

While candidates 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 a candidate 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.  Candidates 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 candidate left the relevant country. Candidates 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 candidate.  Only original version documents will be accepted.

Candidates 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 candidate to seek security clearances in a timely fashion as they can take some time.  No candidate 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](http://www.disclosurescotland.co.uk)

[www.psni.police.uk](http://www.psni.police.uk)

[www.afp.gov.au](http://www.afp.gov.au)

This website provides information on obtaining a national police clearance certificate for Australia

[www.courts.govt.nz](http://www.courts.govt.nz)

This website provides information on obtaining police clearance in New Zealand.

For other countries not listed above candidates 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 candidate by post.  Any cost incurred in this process will be borne by the Candidate

**Trinity College Dublin, the University of Dublin**

Founded in 1592, Trinity is at the nexus of tradition and innovation, offering undergraduate and postgraduate programmes across 24 schools and three faculties: arts, humanities, and social sciences; engineering, maths and science; and health sciences. Spread across 47 acres in Dublin’s city centre, Trinity’s 17,000-strong student body comes from all 32 counties of Ireland, and 16% of students come from outside the country. Of those, 40% are from outside the European Union, making Trinity’s campus cosmopolitan and bustling, with a focus on diversity.

As Ireland’s leading university, the pursuit of academic excellence through research and scholarship is at the heart of the Trinity education. Trinity is known for intellectual rigour, excellence, interdisciplinarity, and research-led teaching. Home to Nobel prize-winners such as scientist Ernest Walton and writer Samuel Beckett, Trinity draws visitors from across the world to its historic campus each year, including to the Book of Kells and Science Gallery which capture the university’s connection to both old and new.

Trinity accounts for one-fifth of all spin-out companies from Irish higher education institutions, helping to turn Ireland into an innovation-intensive, high-productivity economy. That culture of innovation and entrepreneurship is a defining characteristic of our campus as we help shape the next generation of job creators.

Trinity has developed significant strength in a broad range of research areas, including the 19 broadly based multi-disciplinary thematic research areas.



Ireland’s first purpose-built nanoscience research institute, CRANN, houses 150 scientists, technicians and graduate students in specialised laboratory facilities. Meanwhile, the state-of-the-art Biomedical Sciences Institute is carrying out breakthrough research in areas such as immunology, cancer and medical devices.

The Old Library, which houses the Long Room, in Trinity is the largest research library in Ireland, with a collection of six million printed items, 500,000 maps, 80,000 electronic journals, and 350,000 electronic books. Some of the world’s most famous scholars are graduates of Trinity, including writer Jonathan Swift, dramatist Oscar Wilde, philosopher George Berkeley, and political philosopher, and political theorist Edmund Burke. Three Trinity graduates have become Presidents of Ireland - Douglas Hyde, Mary Robinson and Mary McAleese.

Trinity is the highest ranked university in Ireland, and among the world’s leading higher education institutions.

**Trinity College Dublin World University Rankings**

**Overall**

* Trinity is Ireland’s No.1 University in the QS World University Ranking, THE World University Ranking and the Academic Ranking of World Universities (Shanghai).
* Trinity is ranked 71st in the World and 21st in Europe in the 2013/2014 QS World University Ranking across all indicators.

**Internationalisation**

* Trinity is ranked 44th in the World in the Times Higher Education Top 100 Most International Universities.
* Trinity is 46th in the World in the QS World University Ranking 2013/2014 in terms of International Faculty.

**Research Performance**

* Trinity is ranked in the top 70 universities in the world in the Times Higher Education Ranking of World Universities in terms of overall research and in the top 75 universities in the world in terms of citations (research impact).
* Trinity ranks in the top 1% of research institutions in the world in the following 17 Essential Science Indicators fields (an increase of over 150% from 2004): Physics, Chemistry, Engineering, Social Sciences (General), Immunology, Neurosciences, Nanosciences, Materials Science, Pharmacy and Toxicology, Molecular Biology and Genetics, Biology and Biochemistry, Microbiology, Plant and Animal Science, Clinical Medicine, Agriculture, Psychiatry/Psychology, Environment/Ecology.

**In the QS Faculty Rankings 2015\*:**

* Trinity is ranked 63rd in the world in Arts and Humanities.
* Trinity is ranked 69th in the world in Life Sciences and Medicine.
* Trinity is ranked 89th in the in Social Sciences and Management.

**In the QS Subject Rankings 2015\*\*:**

Trinity College Dublin features in the world's elite (Top 200) institutions in 25 of the 28 subjects in which it was evaluated by the QS World University Rankings by Subject 2015. Of these, Trinity ranks in the top 100 in the world in 14 subjects and in the top 5 in the world in 5 subjects.

**Top 50**

* Trinity is ranked 32nd in the world in English Language and Literature.
* Trinity is ranked 33rd in the world in Politics and International Studies.
* Trinity is ranked 39th in the world in History.
* Trinity is ranked 48th in the world in Biological Sciences.
* Trinity is ranked 49th in the world in Modern Languages.

**Top 100**

* Trinity is in the top 100 in the world in Chemistry.
* Trinity is in the top 100 in the world in Computer Science and Information Systems.
* Trinity is in the top 100 in the world in Education.
* Trinity is in the top 100 in the world in Geography.
* Trinity is in the top 100 in the world in Law.
* Trinity is in the top 100 in the world in Medicine.
* Trinity is in the top 100 in the world in Pharmacy and Pharmacology.
* Trinity is in the top 100 in the world in Philosophy.
* Trinity is in the top 100 in the world in Psychology.

**Trinity subjects ranked in the world top 101-200 (QS Subject Ranking 2015)**

Subject Trinity Rank

Accounting and Finance 101-150

Business and Management Studies 101-150

Economics and Econometrics 101-150

Linguistics 101-150

Physics and Astronomy 101-150

Sociology 101-150

Engineering - Civil and Structural 151-200

Engineering – Electrical 151-200

Engineering – Mechanical 151-200

Environmental Sciences 151-200

Mathematics 151-200

\* QS ‘Faculty’ Rankings 2015: [www.topuniversities.com/faculty-rankings](http://www.topuniversities.com/faculty-rankings)

\*\* QS Subject Rankings 2015: [www.topuniversities.com/subject-rankings](http://www.topuniversities.com/subject-rankings)

**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.

### Employment Permit Eligibility Criteria

Applications from non-EEA citizens are welcomed. However, eligibility is determined under the relevant regulations of the Department of Jobs, Enterprise and Innovation. Trinity, as an accredited research organisation, can form Hosting Agreements with third country nationals (Non-EEA nationals) for the purposes of conducting research in the University. 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 a Hosting Agreement or Employment Permit as appropriate. See <https://www.djei.ie/en/What-We-Do/Research-Innovation/Hosting-Agreement-Scheme/>

### Equal Opportunities Policy

Trinity College 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 College’s Diversity Statement can be viewed in full at

<https://www.tcd.ie/diversity-inclusion/diversity-statement>

**Application Procedure**

Candidates should submit a cover letter together with a full curriculum vitae to include the names and contact details of 3 referees (email addresses if possible) to:

Name: Ms. Geraldine Quinn

Title: Senior Executive Officer

Email Address: gquinn@tcd.ie

Contact Telephone Number: 00353 (0)1 8962241

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