Post Specification (034387)

<table>
<thead>
<tr>
<th>Post Title:</th>
<th>Research Assistant - Chief II Pharmacist</th>
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<tbody>
<tr>
<td>Research Group /</td>
<td>Clinical Research Facility St. James’s Hospital</td>
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<tr>
<td>Department / School:</td>
<td>School of Medicine, Trinity College Dublin, the University of Dublin</td>
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<tr>
<td>Location:</td>
<td>Clinical Research Facility, St. James’s Hospital, Dublin 8</td>
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<td>Reports to:</td>
<td>Associate Director</td>
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<tr>
<td>Salary:</td>
<td>Appointment will be made on the HSE pay scales for Chief II Pharmacist at a point in line with Government pay policy</td>
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<tr>
<td>Closing Date:</td>
<td>12 Noon (Irish Standard Time), Friday 6th March 2020</td>
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Please note: The successful candidate will be expected to take up appointment May 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 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 & Desirable)**

**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.

**Application Procedure**

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

**Further Information for Applicants**

**Informal Enquiries to:**

Mr. Jeremy Towns Jeremy.Towns@tcd.ie or
Ms. Derval Reidy Reidyde@tcd.ie

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<thead>
<tr>
<th>URL Link to School</th>
<th><a href="http://www.tcd.ie">www.tcd.ie</a></th>
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<tr>
<td>URL Link to Research Group</td>
<td><a href="http://www.sjhcrf.ie">http://www.sjhcrf.ie</a></td>
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<tr>
<td>URL Link to Human Resources</td>
<td><a href="https://www.tcd.ie/hr/">https://www.tcd.ie/hr/</a></td>
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<tr>
<td>URL Link to Area</td>
<td><a href="http://www.tcd.ie">www.tcd.ie</a></td>
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<tr>
<td>URL Link to Human Resources</td>
<td><a href="https://www.tcd.ie/hr/">https://www.tcd.ie/hr/</a></td>
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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 premier university, with a proud tradition of excellence stretching back to its foundation in 1592. The oldest university in Ireland, and one of the oldest in Europe, today Trinity sits at the intersection of the past and the future, and is ideally positioned as a major university in the European Union. Our 47-acre campus is located in the heart of Dublin city centre and is home to historic buildings dating from the University’s establishment, as well as some of the most cutting-edge teaching and research facilities in Ireland. Students at Trinity benefit from a unique educational experience across a range of disciplines in our three faculties – Arts, Humanities, and Social Sciences; Engineering, Mathematics and Science; and Health Sciences. 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 18 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. These internationally recognised themes include such diverse areas as Cancer, Immunology, Telecoms, Identities in Transformation, Nanoscience, Neuroscience, and Making Ireland. Researchers from across the University work together in innovative ways to develop new and exciting approaches to their research and explore the frontiers of knowledge in the 21st century. In creating these dedicated research themes, Trinity’s researchers are able to become a more powerful force on the global stage, successfully competing for large-scale grants and attracting top students and faculty to the University. Trinity is home to Ireland’s first purpose-built Nanoscience research institute, CRANN, which opened in January 2008. This state-of-the-art facility houses 150 scientists, technicians, and graduate students in specialised laboratories, fostering creative innovations that have seen Trinity’s researchers make significant breakthroughs.

The Trinity Long Room Hub for Arts and Humanities Research Institute is the University’s flagship institute for research in the Arts and Humanities, providing a world-class environment for cross-disciplinary collaborative projects. The Long Room Hub provides a central location through which the University’s internationally respected Arts and Humanities research can become more visible, demonstrating its relevance for contemporary and future societies.
Researchers from across the University regularly participate in debates on topical issues facing the world today. As well as operating an International Visiting Research Fellowship programme, the Long Room Hub also hosts major EU-funded Digital Humanities projects.

One of the most instantly recognised parts of Trinity’s campus is the famous Old Library, home to the historic Book of Kells as well as other internationally significant holdings in manuscripts, maps, and early printed material. Trinity’s Library is the largest research library in Ireland and is an invaluable resource to Trinity’s students and research community. Built up over the four centuries of the University’s existence, the Library’s collections have benefitted from its status as a Legal Deposit library for the past 200 years, granting Trinity the right to claim a copy of every book published in Ireland and the UK. At present, the Library’s holdings span approximately 4.25 million books, 22,000 printed periodical titles, and access to 60,000 e-journals and 250,000 e-books.

Trinity attracts top students from Ireland and abroad and prides itself on the consistently high standard of student admitted to the University every year. These students are drawn to Trinity for the excellence of our research-led teaching and for the quality and prestige a degree from this University confers. Trinity has also pioneered accessibility to education in Ireland, becoming the first university in the country to reserve 15% of its undergraduate places for students from non-traditional learning groups. Trinity is the top-ranked European university for student entrepreneurship and Europe’s only representative in the world’s top-50 universities.

Our alumni have gone on to shape the history of Ireland and of Western Europe in a wide range of fields. These include such notable figures as Jonathan Swift, Oscar Wilde, William Rowan Hamilton, Edmund Burke, William Stokes, Denis Burkitt, Louise Richardson, Lenny Abrahamson, and Anne Enright. Three of Trinity’s graduates have been awarded Nobel prizes: Ernest Walton for Physics in 1951; Samuel Beckett for Literature in 1968; and William Campbell for Physiology / Medicine in 2015. Trinity also counts the first female President of Ireland among its alumni in Mary Robinson, as well as other notable former Presidents Douglas Hyde and Mary McAleese. At Trinity we are justifiably proud of our tradition, and we strive to uphold this excellence as we face the demands of the 21st century.
Ranking Facts
Trinity is the top ranked university in Ireland. Using the QS methodology, the University is ranked 108th in the world and using the Times Higher Education World University Rankings methodology Trinity is 164th in the world.

Overall
- Trinity is Ireland’s No.1 University in the QS World University Ranking 2019 Academic Ranking of World Universities (Shanghai), 2019

Internationalisation
- Trinity is ranked 16th Most International University in the World.
- Times Higher Education World University Ranking, 2020. Trinity is also the highest ranked university in Ireland.

Employability
- Of Trinity is ranked 1st in Ireland for employer reputation and alumni outcomes.
- QS World University Rankings for Graduate Employability 2020.

Innovation and Entrepreneurship
- Ireland’s most innovative university (Reuters Most Innovative European Universities 2018)
- Trinity is 1st in Europe for producing entrepreneurs for the 5th year in a row (Pitchbook Universities Report 2019)

In the QS World University Subject Rankings:
- Trinity is ranked 13th in Classics and Ancient History.
- Trinity is ranked 28th in English Language and Literature.
- Trinity is ranked 39th in Mineral and Mining Engineering.
- Trinity is ranked 41st in Nursing.
- Trinity is ranked 42nd in Performing Arts
- Trinity is ranked 50th in Pharmacy and Pharmacology.
Trinity ranks in the top 100 in 20 subjects, including those in the 51-100 bracket:

- Computer Science and Information Systems
- Modern Languages
- Theology, Divinity and Religious Studies
- History
- Biological Sciences
- Medicine
- Chemistry
- Geography
- Materials Science
- Education
- Law
- Politics and International Studies
- Social Policy and Administration / Sports Related Subjects

About Trinity College Dublin, the University of Dublin

- Trinity College Dublin, the University of Dublin was founded in 1592
- Trinity has three faculties - Arts, Humanities and Social Sciences, Engineering, Mathematics and Science and Health Sciences
- The city centre campus occupies some 51 acres (including the Trinity Technology and Enterprise Campus)
- There is in excess of 220,000 m2 of buildings, including beautiful historic architecture and state-of-the-art modern facilities
- Students can avail of over 170 societies and sports clubs
Research Themes - [https://www.tcd.ie/research/themes/](https://www.tcd.ie/research/themes/)

- Ageing
- Biomedical Engineering
- Cancer
- Creative Arts Practice
- Creative Technologies
- Digital Engagement
- Digital Humanities
- Genes & Society
- Identities in Transformation
- Immunology, Inflammation & Infection
- Inclusive Society
- International Development
- International Integration
- Making Ireland
- Manuscript Book & Print Cultures
- Nanoscience
- Neuroscience
- Smart Sustainable Planet
- Telecommunications
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 Jobs, Enterprise and Innovation and further information on the Highly Skills Eligible Occupations List is set out in Schedule 3 of the Regulations https://www.djei.ie/en/What-We-Do/Jobs-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://www.djei.ie/en/What-We-Do/Jobs-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

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