

Job Description

Reference ID: CF-2024-2367-I

Job Title: Quality Controller

School/Department: School of Computer Science and Statistics

Principal Investigator: Prof Vincent Wade

Duration: 12 months, starting Sept 2024 (can be flexible)

Salary Salary starts at €46,569 -€54,956 depending on

experience. Annual increments apply on SFI Pay Scale.

The Wider Research Project

The Quality Controller is required to contribute to a new overall project led by Prof. Vinny Wade focused on the development of an AI Voice Technology companion to help care for the elderly. The Quality Controller is responsible for ensuring that the software meets regulatory standards and functions safely and effectively in a medical context. They will support bridging the gap between the clinical expertise and the technical development to ensure that the software meets the standards of healthcare providers and patients

AmethystCare is the voice technology companion that helps care for people with mobility-related illnesses and dementia at home, allowing them to live independently for longer. AmethystCare will offer an Al-driven voice assistant that is delivered through Amazon Alexa devices (or similar) to B2B care and health organisations that seek to enable patients to stay at home as long as possible. The assistant will monitor patient loneliness, and cognitive decline, assist with medicine adherence, and detect falls or other emergencies. The data will be tracked through our analytics hub. This will be tracked over time to allow medical professionals and carers to have a detailed view of the patient's progress and ability to live at home. This service both reduces the cost of care and enables organisations to provide a better service but also improves patients' lives and gives more data to improve patient outcomes.

A suitable candidate will have a Primary Degree and 6 years of research/ industrial experience. They will be responsible for medical device certification and will work closely with the regulatory consultant and project team to ensure that AmethystCare develops a GenAi approach and quality management system that will comply with medical certification requirements.

The overall team in this project will consist of the commercial lead, two developers, clinical lead and one AI researcher. The position is fully in-person and requires the person to be based in Dublin, Ireland.

Context

The position will be based in the ADAPT SFI Research Centre, hosted in the School of Computer Science & Statistics, Trinity College Dublin. ADAPT is the world-leading SFI Research Centre for Al-Driven Digital Content Technology, and brings leading academics, researchers and industry partners together to deliver excellent science, engage the public, develop novel solutions for business across all sectors and enhance Ireland's international reputation. The ADAPT Centre is hosted and coordinated in the School of Computer Science and Statistics, TCD.

The School of Computer Science and Statistics is ranked #1 in Ireland (QS Rankings) and is a proud recipient of a Bronze Athena Swan award, attained in 2021. As part of the School's on-going actions in relation to equality, diversity and inclusion it welcomes all applications that meet the criteria below and particularly those from under-represented groups. The School offers a collegiate and supportive environment to all its staff and works to ensure that all its staff and students can perform at their best while putting in those steps that facilitate a healthy work/life balance

Main Responsibilities

Quality Controller

As part of the overall project, the Quality Controller will work on the following tasks:

- Rolling out a Quality Management System (QMS)
- Preparing and maintaining documentation for regulatory submissions and audits
- Provide insights and expertise to guide the design and development of software.
- Ensure the software aligns with clinical workflows and standards.
- Ensuring the software complies with relevant regulatory standards, such as FDA regulations (21 CFR Part 820 for medical devices), ISO 13485, IEC 62304 (for software lifecycle processes), and GDPR for data protection.
- Report regularly to the PI and Commercial Lead of the project, and interact regularly with other team members to maintain momentum in the project.

Additionally, they will support other team members with the following tasks:

- Collaborate with software developers, designers, and the clinical lead to create user-friendly and clinically relevant software.
- Ensure that the software complies with healthcare regulations and standards by working with the clinical lead in rolling out a QMS system and becoming a Class 2 medical device in the EU. Along with HIPAA compliance and FDA approvals in the United States.

As a Quality Controller in Adapt, the person will occasionally be required to engage in administrative tasks in support of the PI and Commercial Leads overall activity. This may include drafting sections of reports for funding bodies; organising a programme of suitably themed group meetings and seminars; contributing to research funding proposals; drafting of ethics applications; and other such tasks as they arise.

Person Requirements

The Quality Controller will require a range of knowledge, skills and attributes for successful performance in the role. The successful candidate is expected to:

- Have excellent written and oral proficiency in English
- Be skilled at taking research ideas and draw innovative conclusions, or see new solutions
- Have excellent communication and interpersonal skills
- Be willing to work as part of a multidisciplinary team and learn new cross-over skills as well as transfer skills to others
- Be highly organised in their work, with an ability to balance medium term and longer-term objectives in a project.
- Ability to represent the group at appropriate events.

Qualifications

A suitable candidate will have a Primary Degree and 6 years of research/ industrial experience. They will be responsible for medical device certification and will work closely with the regulatory consultant and project team to ensure that AmethystCare develops a GenAi approach and quality management system that will comply with medical certification requirements.

Knowledge & Experience (Essential & Desirable)

Essential:

- A suitable candidate will have a Primary Degree and 6 years of research/industrial experience.
- Experience in developing and implementing quality management systems (QMS) tailored to SaMD

- Performing internal audits to ensure adherence to quality standards and continuous improvement processes.
- Ensuring the software is user-friendly and meets performance criteria under different conditions.
- Evaluating the impact of changes on the overall system and mitigating any potential risks.
- Strong commitment to their own professional development

Desirable

- Providing training to staff on quality standards, regulatory requirements, and best practices for SaMD.
- Keeping the team updated on new regulations and industry standards.
- Contribution to successful funding applications
- Exposure to standard tools for Software as a Medicla Device (SaMD) management

Benefits

- Competitive salary
- High-end computer and peripherals
- Dedicated desk in shared office space, with generous social spaces
- A creative and enabling environment with impactful research
- Pension and social insurance (PRSI) included
- Trinity Day Nursery
- Travel Pass Scheme
- Bike to Work Scheme
- Employee Assistance Programme
- Sports Facilities
- 22 days of Annual Leave
- Paid Sick Leave
- Training & Development
- Staff Discounts locally

Application Procedure

Applicants should provide the following information when applying:

- 1. A motivation statement outlining their interest and suitability for the position.
- 2. A comprehensive curriculum vitae, including a full list of publications.

3. The names and contact details (e-mail) of three referees.

Deadline for applications is 31st Oct 2024.

Note:

Candidates who do not address the application requirements above will not be considered for interview.

Further Information

Informal enquiries about this post should be made to Conor McNally (conor.mcnally@tcd.ie).

Snapshot of the Faculty

The Faculty of Science, Technology, Engineering and Mathematics is located at the east end of the Trinity campus. It brings together eight schools that deliver discipline-specific research and training (Biochemistry & Immunology, Chemistry, Computer Science and Statistics, Engineering, Genetics & Microbiology, Mathematics, Natural Sciences, Physics). Each School produces graduates that are leaders, innovators and doers in STEM education and research, in Ireland and beyond.

As well as these eight schools, the Faculty is made up of three Trinity College Research Institutes, five National Research Centres and three Units. Together these represent approximately 30% of the staff in the College.

Researchers in the Faculty address challenges that are complex and multi-faceted. They do this by continuously asking the fundamental questions of how? and why? They seek out answers to current and future challenges in climate change, food and water security, sustainable urbanisation, personal privacy, healthy ageing and eradicating infectious diseases. They lead innovations at the frontiers of science and technology often in high-level multi-disciplinary teams based within the Schools, Research Institutes and Centres.

The three Trinity Research Institutes are:

- CRANN The Centre for Research on Adaptive Nanostructures and Nanodevices
- TBSI Trinity Biomedical Sciences Institute
- TCIN Trinity College Institute of Neuroscience

The four National Research Centres are:

- ADAPT The SFI Centre for digital content and media innovation
- AMBER The SFI Centre for Advanced Materials and BioEngineering Research
- CONNECT The SFI Centre for digital content and media innovation
- **ENABLE** Connecting communities with smart urban environments through the Internet of Things

The three units that support our teaching and learning mission are:

- **Biology Teaching Centre** responsible for the coordination of all Biology teaching to Junior and Senior Freshman students in Science, as well as providing service teaching to other groups within the College.
- Comparative Medicine Unit aims to advance knowledge and improve the health and wellbeing of humans and animals by servicing, and providing, world-class facilities and infrastructures, to the Trinity research community.
- Science Course Office responsible for facilitating the Junior and Senior Fresh undergraduate Science Programmes.

Trinity College Dublin, the University of Dublin

Trinity College Dublin, the University of Dublin is Ireland's leading university, one of the top ranked universities in Europe and a member of the League of European Research Universities. It is currently ranked 98th in the QS World University Rankings 2023. 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; Science, Technology, Engineering and Mathematics; 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. Our research charter outlines the principles that are central to our research vision:

www.tcd.ie/research/about/charter

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 five leading flagship research institutes:

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

Trinity is the top-ranked European university for producing entrepreneurs for the past seven successive years and Europe's only representative in the world's top-50 universities (Pitchbook Universities Report 2021).

Trinity has been incorporating sustainability right across the university. Commitments to sustainability have been made in the Strategic Plan (2020 – 2025) and via Trinity's environmental sustainability practices under nine goals in areas that range from biodiversity to sustainable transport and green procurement.

For more on these sustainability commitments, please visit **www.tcd.ie/provost/sustainability/initiatives**

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 7 million printed items, 500,000 e-books and 150,000 e-journals.

With over 130,000 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 98th in the world (QS World University Rankings 2023). Trinity ranks in the top 50 in the world on 4 subjects and in the top 100 in 17 subjects (QS World University Rankings by Subject 2021).

Full details are available at: www.tcd.ie/research/about/rankings