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

Job Description

Comp ID:	**035789**
Job Title:	Quality and Regulatory Affairs Manager/ Administrative Officer 1(to the bar)
School/Department:	Medicine/Clinical Research Facility
Job category & level:	Professional / Administrative

The Purpose of the Role:

The Quality and Regulatory Affairs Manager will be based in the Wellcome-HRB Clinical Research Facility (CRF) at St James's Hospital (CRF) and will be responsible for developing and contributing to the quality management system of the CRF and in ensuring the highest standards are applied to studies taking place including studies and CTs sponsored by Trinity College Dublin. The QRAM will work as part of the broader CRF quality team which includes a senior QRAM, a quality data manager and study monitor and Quality Officer. In addition to implementation of the quality and regulatory affairs system and ensuring inspection readiness the successful postholder will also be responsible for providing clinical and regulatory advice relevant to study approval, protocol development, start up, progress and risk-based monitoring to potential principal investigators from both the Hospital and the University. They will share the workload of pharmacovigilance and monitoring with the rest of the quality team. 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 and investigational medicinal products (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) and regulatory affairs 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.

Trinity College is developing its sponsorship function. The successful postholder will liaise with the sponsorship office as it implements operational procedures and a quality management system for research clinical trial sponsorship services (Investigational Medicinal Products and Medical Device) within the CRF.

The CRF is a collaboration between St James's Hospital (SJH) and Trinity College Dublin (TCD) and has been providing investigator services for clinical research trials since 2013 with many Principal Investigators from both the hospital and academic communities. It is a state of the art facility including a research pharmacy and employs 22 staff, the majority funded by research grants from HRB/IRC/EU with Trinity as the host sponsor for many grant awards that have resulted in increased access by patients to cutting edge medicinal therapies and novel medical devices. The Quality and Regulatory Affairs Manager will form part of the CRF operational team and will report directly to the CRF Director.

The specific purpose of this employment is to manage, develop and contribute to the quality management system of the CRF and ensure the highest standards are applied to all studies taking place, as well as identifying the implications for the CRF operation and initiate necessary changes to practice to ensure CRF is compliant with statutory regulations. . This employment is not offered on an indefinite basis as this project is finite.

This is a specific purpose contract.

Context:

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Main Responsibilities:

Compliance with protocols and pharmacovigilance and reporting to the regulator in respect of serious adverse events where appropriate. The Quality and Regulatory Affairs Manager is responsible for all study regulatory and compliance services in the CRF and will:

- Ensure implementation of the CRF quality management system within study scope, ensuring the performance of the clinical research portfolio including sponsorship assessments, risk management, study documentation, pharmacovigilance and monitoring and internal compliance assessments.
- 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.
- Liaise with the Head of Clinical Sponsorship oversight (HCSO) at Trinity College when this post is filled to develop Trinity's clinical trial sponsorship function to align with key University strategic plans for research.
- Using their expertise and knowledge of the regulatory landscape and legislation governing clinical trials of drugs and medical devices, lead on interpreting complex legislation as it relates to trial sponsorship, approvals and conduct, identifying the implications for the CRF and initiating necessary changes to practice research trials to ensure continued compliance with ICH, GCP, ISO 14155 and all applicable regulations are addressed.
- Oversee and lead ongoing development of standard operating procedures (SOPs) for Clinical Research services and lead by example in terms of implementation of, and compliance with the SOPs.
- Maintain quality management systems (QMS) for Clinical Research ensuring ongoing compliance with International Conference on Harmonisation Good Clinical Practice guidelines (ICH-GCP), Medical Device regulation, Clinical Trial Regulations, ISO 14155 and all applicable legislation and standards.
- Train Clinical Research Associates, sponsorship staff and upskill grant funded researchers to perform their roles as principal investigators and sub-investigators to the required ICH-GCP and regulatory standards. This includes management of investigational medicines and medical devices.
- Fulfil regulatory affairs requirements pertaining to communications with competent authorities i.e. The Health Products Regulatory Agency and the National Research ethics Committee and the chief Data Protection Officer for sponsored programmes.
- Act as a partner with key clinical research stakeholders at all levels within the CRF and extending to the hospital and the University, providing consultancy and professional advice for investigator-led studies, campus companies and spinouts.

- Line manage assigned clinical research staff such as a core team of research assistants, post doc researchers and administrative staff in line with CRF SOPs and Trinity College guidelines.
- Identify opportunities for process improvements and creative solutions in pursuit of service excellent and shares lessors learned.
- Develop Key Performance Indicators (KPIs) and report against these for sponsored research.
- Monitors quality team deliverables against milestones and act promptly to manage deviations.
- Develop, implement and maintain corrective action preventative action (CAPA) plans for protocol deviations in collaboration with colleagues.
- Provide input to study budgets in terms of ensuring clinical research studies are appropriately costed for quality elements at the grant/ award application stage.
- Develop study work and project plans (e.g. monitoring, data management, pharmacovigilance and safety monitoring plans) that align with clinical research team responsibilities.
- Perform vendor and internal audits and selection for sub-contracted sponsorship services as appropriate.

- Perform additional tasks related to clinical Research and sponsorship by mutual agreement on behalf of the CRF director that arise to fulfil the aims of this role.

Person Requirements

The role-holder will require the following knowledge, skills and attributes for successful performance in the role:

Qualifications:
Bachelor's degree or an advanced degree in a clinical or life sciences related discipline.

Knowledge:
- Minimum of 5 years' experience as a Clinical Project Manager or Clinical Trial Lead or Monitor or other relevant role in a clinical research organisation or sponsor environment.
- Experience with quality assurance, regulatory affairs, risk assessments.
- Experience ensuring audit readiness of clinical trial master files and QMS ahead of inspections by competent authorities and/ or audits by the sponsor CRA.
- Deep knowledge of the regulatory landscape and legislation governing clinical trials of drugs and medical devices.
- Experience resourcing and leading cross-functional teams.
- Solution Orientated with operational management experience in a similar environment.
- Self-motivated influencer, showing strong leadership and initiative.
- Experience liaising with competent authorities and research ethics committees.
- Knowledge of sponsor responsibilities as defined by Good Clinical Practice guidelines.
- A clear and confident communicator (oral and written), can easily articulate complex information to a non-specialist.
- Prior experience in conducting site audits or monitoring
- Strong technical writing skills.
- Experience of quality management systems.
- Ability to work independently, interpret complex information and with ambiguity.

- Highly organised, detail oriented with good time management skills.

Desirable

- Familiar with clinical trial management software and Pharmacovigilance systems.
- Prior experience in managing medical device clinical investigations.
- Experience in oversight of third party vendors.
- Experience of financial project management.

Skills:

Excellent written and verbal communication skills.
High standard of accuracy in both written and numerical work.

Personal attributes:

Understands the importance of the Quality and Regulatory Affairs Manager
Pays close attention to quality standards.
Helpful and courteous approach to colleagues, students, academic staff and customers.
Committed to achieving results, putting in additional effort as required.