Candidate Information

Position:	Quality Assurance and Regulations Officer
School/Department:	School of Medicine, Dentistry and Biomedical Sciences
Reference:	26/113385
Closing Date:	Monday 22 June 2026
Salary:	£51,016 - £62,695 per annum
Anticipated Interview Date:	Monday 6 July 2026
Duration:	Permanent

JOB PURPOSE:

The post holder will have overall responsibility for the quality assurance and regulatory compliance function within the Northern Ireland Clinical Research Facility (NICRF). They will lead and be accountable for the development, implementation and continuous improvement of quality assurance and regulatory systems, ensuring that all standards, policies and processes are robust, compliant and aligned to best practice.

The Quality Assurance and Regulations Officer will play a key strategic role, providing expert leadership on regulatory compliance, quality systems and governance. The post holder will influence practice across NICRF and partner organisations, ensuring alignment with University, Trust and national regulatory requirements. The role will also influence research governance, quality standards and regulatory compliance across the School and partner organisations.

They will act as the lead representative and primary point of contact for regulatory inspections (e.g. MHRA), with authority for organisational readiness and response.

The role will be responsible for developing and implementing a quality assurance strategy, leading audit and inspection readiness, and embedding a culture of continuous improvement. The post holder will work with senior stakeholders to ensure high standards of data integrity, patient safety and research governance, contributing to the reputation and performance of NICRF and Queen's University Belfast.

The post will initially be based in the NICRF but will be relocated to NICRF within the iREACH Health Building at the Belfast City Hospital site, which is due to be operational early 2027 and will provide the platform to create a patient-centred, pro-innovation and digitally enabled clinical research environment.

MAJOR DUTIES:

1. Lead the development and maintenance of quality assurance systems relevant to CRF research delivery, including:
   - the development, implementation and evaluation of NICRF specific Standard Operating Procedures (SOPs) and processes for the safe and effective delivery of research activity;
   - the development, implementation and evaluation of appropriate risk assessment and management processes for research delivery in the NICRF; and
   - the development and implementation of processes which ensure staff are appropriately trained in regard to SOPs, Good Clinical Practice (GCP) and other applicable regulations and guidelines.
2. Maintain up to date knowledge of clinical trials methodology and current legislation regarding Clinical Research delivery including GCP, Research Governance Frameworks and Data Protection laws, including the General Data Protection Regulation (GDPR). Utilise this knowledge to ensure that NICRF staff are working according to the highest standard according to ICH GCP principles.
3. To work collaboratively with a wide range of internal and external, local and national stakeholders and key partners (such as Queens University Belfast and commercial study sponsors) to develop research activity at the NICRF.

4. To lead and manage quality assurance processes and systems relating to the co-ordination, set up and delivery of research studies within the NICRF, in addition to maintaining awareness of key issues surrounding data confidentiality, ethical and research governance, research processes and Patient and Public Involvement.
5. Provide expert advice, reports and recommendations on quality assurance processes at senior level as requested.
6. Lead quality assurance practices, within the Clinical Research Facility (CRF), facilitating improvement and ensuring compliance with research governance requirements.
7. Develop a strategy for, and carry out reviews including a programme of regular system and documentation audits within the NICRF to monitor adherence to Quality Processes and Procedures and regulations, provide formal written feedback to the senior management team as appropriate, as well as other relevant staff, and ensure execution of any necessary corrective action.
8. In the event of any statutory Good Clinical Practice Inspection (MHRA) or external audit, advise all relevant staff to ensure that all necessary preparation is carried out beforehand, leading in the conduct of the Inspection, and coordinate preparation of response.
9. Advise and influence senior managers, on corrective and preventative action plans to address issues highlighted from external audits and regulatory inspections ensuring that any follow up action is carried out within the specified timelines.
10. On occasion, other duties which are not included above, but which will be consistent with the role and the overall functions of the Department and the Directorate.

ESSENTIAL CRITERIA:

1. Degree in Clinical or life science.
2. Relevant experience to include:
   • Experience and/or certification in Quality Assurance or Quality Management.
   • Reviewing, enhancing and implementing administrative procedures and practices relating to quality assurance.
   • Experience of audit and implementation of quality initiatives.
   • Experience of successful project management.
3. Advanced IT skills including experience of Microsoft Office software applications.
4. Knowledge and understanding of the policy and practices relevant to the role, including Good Clinical Practice, Medicines for Human Use (Clinical Trials) Regulations and Research Governance, together with the ability to disseminate the knowledge and information.
5. Ability to communicate effectively with internal and external stakeholders (oral, written & presentation).
6. Ability to prioritise, plan, and manage own workload, and that of others, producing work to exceptional levels of accuracy within the required timeframes.
7. Responsive to change and adaptable to new challenges, demonstrating strong problem solving skills.
8. Willing to work flexibly to meet the requirements of the post.

DESIRABLE CRITERIA:

1. Undertaking, co-ordinating or managing clinical research and clinical trials.
2. Post graduate qualification in clinical research or health science.
3. Excellent working knowledge of the major regulatory issues governing clinical trials.
4. Experience in validation of computer systems and software.
5. Experience of developing Quality Processes and Procedures.
6. Experience in delivering training.