Quality and Regulatory Affairs Officer

The National Children's Research Centre (NCRC) is the primary paediatric research institute in Ireland. Based at Our Lady's Children's Hospital, Crumlin, the NCRC funds and provides infrastructure to conduct research into childhood disease and has a national and international reputation for high quality research.

The NCRC is funded by the CMRF Crumlin.

Clinical research is essential to provide an evidence base for improved medicines and treatment of sick children. The Children's Clinical Research Unit (CCRU) was established in 2010 by the NCRC to provide infrastructure to support clinical teams in the conduct of clinical research at OLCHC and other paediatric centres in Ireland. The CCRU is made up of a team of research staff with the specialist expertise required to conduct clinical trials in children and young adults. We aim to ensure that children are offered the opportunity to participate in, and benefit from, research within the hospital and wider community.

As part of ongoing capacity building and strengthening of our paediatric research infrastructure, we are currently inviting applications to the position of Quality and Regulatory Affairs Officer. This is a new role in the Children's Clinical Research Unit and is an exciting and challenging opportunity for a highly motivated individual to join our team and work in a rewarding and developing area.

Job Description:

Title:	Quality and Regulatory Affairs Officer
Location:	Children's Clinical Research Unit, National Children's Research Centre, Our Lady's Children's Hospital Crumlin
Duration:	Full-time two-year fixed term
Hours:	35 hours per week
Reporting to:	Quality and Regulatory Affairs Manager

The Quality and Regulatory Affairs Officer will work closely with the Quality and Regulatory Affairs Manager in the day-to-day running of the Quality Assurance & Regulatory Affairs function and the ongoing development, implementation, and maintenance of the CCRU Quality Management System (QMS). They will have a key role in supporting clinical research teams to ensure that all research studies are conducted in accordance with ICH GCP guidelines and applicable legislative and regulatory requirements.

Key Duties and Responsibilities:

Quality

- Work closely with the Quality and Regulatory Affairs Manager (QRAM) to meet the objectives, goals and targets of the CCRU Quality Assurance & Regulatory Affairs function.
- Develop, implement, and maintain the CCRU quality management system in accordance with the principles of quality management, legislative and regulatory requirements, and international best practice.

- Promote a culture of quality and continuous improvement during engagement with Principal Investigators, clinical research teams, and all other stakeholders. In addition, communicate the requirements, activities and services offered under the CCRU QMS.
- Provide support to teams in developing and defining quality system processes. Receive and process requests for document control and provide ongoing follow-up and support.
- Identify any non-conformances to the requirements of the quality management system or compliance with legislative and regulatory requirements and record appropriately in the QMS.
- Provide support to clinical research teams in carrying out root cause investigations, risk assessments, and drafting and implementing corrective and preventative action plans.
- Provide support to members of the CCRU Management Team with development and implementation of the QMS in each functional area.
- Maintain systems for recording and follow up on training on controlled documents.
- Participate in the CCRU internal audit programme. Prepare for, conduct, and follow-up on internal audits and CAPA plans.
- Support the delivery of the Paediatric Good Clinical Practice Training Programme.
- Support the clinical teams to ensure ongoing conformance with the quality management system and compliance with legislative and regulatory requirements.
- Support the QRAM on horizon scanning activities in relation to new and amended legislative and regulatory requirements. Support the development and implementation of regulatory roadmaps, as applicable.
- Identify and participate in CCRU quality improvement projects and initiatives. Participate in CCRU cross-functional working groups, as required.
- Provide input into the preparation of materials for internal and external communications, including the NCRC annual report and website.
- Provide support to the QRAM on national working groups and clinical research network initiatives.
- Attend and represent the CCRU / NCRC at national and international meetings and events, as required.
- Support the maintenance of the CCRU annual training plan.
- Complete all assigned training and take ownership for ongoing personal development and learning.

Regulatory Affairs

- Support Principal Investigators and clinical research teams during the planning, conduct, and follow up phases for clinical trials and/or clinical investigations. Liaise closely with the QRAM.
- Advise the PI and clinical research team on regulatory requirements and the collection of essential study documents during set-up and throughout study conduct.
- Submit new applications and amendments for the conduct of clinical studies to the Regulatory Authority and Ethics Committees, working closely with the PI and Quality and Regulatory Affairs Manager.
- Provide support to the PI and clinical research team with any queries received from the Regulatory Authority and Ethics Committees.
- Ensure that internal trackers for ethics and regulatory submissions and decisions are maintained.

- Provide support to the PI and clinical research team during Pre-study visits, Site Initiation Visits, and other Sponsor meetings, as required
- Provide support to the PI and clinical research team in relation to Sponsor Audit and Monitoring
- Perform a check of Development Safety Update Reports received from Sponsors, Annual Progress Reports, End of Trial declarations prior to submission to the Regulatory Authority and Ethics Committee.
- Support Principal Investigators and the QRAM during preparations for regulatory inspections, gathering and collating requests for information, as required.
- Support the clinical teams to ensure ongoing compliance with ICH Good Clinical Practice (GCP) for study related activities
- Adhere to CCRU and all relevant hospital or institution policies, SOPs or guidelines at all times.

All duties will be carried out in accordance with ICH-GCP guidelines and all applicable laws and regulations for the conduct of clinical research.

Requirements:

Essential:

- Degree in science, quality, or a similar related discipline
- Minimum of three years' experience in quality assurance and/or regulatory affairs in the biomedical, pharmaceutical, medical device industry, or regulatory environment
- Understanding of current Irish medical, academic and health services research environment and knowledge of the legislative and regulatory requirements relating to the conduct of clinical research
- Experience in quality assurance / quality control and/or quality management systems, in a healthcare or regulatory environment
- Knowledge of the requirements for the preparation, or assessment, of applications to competent authorities and ethics committees
- Excellent communication and team working skills, as well as excellent interpersonal skills
- An individual with initiative, capable of problem solving and working independently
- An individual with the ability to manage multiple competing priorities, who can prioritise effectively, and work to meet regulatory deadlines
- Proven planning, organisation and/or project management skills
- Readiness and the ability to adapt and learn new skills as required by the position
- Excellent attention to detail
- Knowledge of medical/scientific terminology
- Knowledge and understanding of the requirements of Good Clinical Practice (GCP)

Desirable:

- Knowledge of legislative and regulatory requirements for medical devices
- Internal audit and monitoring experience

Applicants must have the right to work in Ireland.

The closing date is 24th March 2019.

Applications to: https://cmrf.bamboohr.co.uk/jobs/view.php?id=42