The University of North Carolina at Chapel Hill

JOB ANNOUNCEMENT – Clinical Trial Quality Assurance (QA) Officer

The University of North Carolina in Vietnam is a research organization of the University of North Carlina at Chapel Hill, USA. We are conducting studies on new therapies for HIV and TB treatment and prevention as well as mental health interventions targeting key populations, including people living with HIV, TB patients, men who have sex with men, transgender woman and people who inject drugs. We are in partnership with clinical trial networks of the US National Institute of Health (NIH) such as the HIV/AIDS Prevention Trial Network (HPTN) and Advancing Clinical Therapeutic Globally (ACTG). In order to expand our operations, we are now seeking a talented and dedicated individual to join our team as QA Officer.

Position: **Clinical Trial Quality Assurance (QA) Officer**
Full-time, based in Hanoi

Report to: QA Manager /and/or In-country Director

Position Summary:

The Clinical Trial Quality Assurance (QA) Officer is responsible for supporting the implementation and monitoring of quality assurance activities for clinical trials conducted at UNC Clinical Research Sites.

The position supports the line manager in ensuring that clinical trial activities are conducted in compliance with applicable regulatory requirements, Good Clinical Practice (GCP), approved protocols, SOPs, and sponsor requirements. The QA Officer also assists in identifying quality issues, maintaining quality assurance documentation, conducting quality reviews, and following up on CAPA activities.

Duties & Responsibilities:
Quality Management System and Documentation:

- Support the implementation and maintenance of the Clinical Quality Management Plan (CQMP).
- Support the development, review, update, and control of QA-related SOPs, work instructions, forms, and records.
- Maintain the QA document filing system and ensure documents are properly version-controlled and archived.
- Monitor the dissemination and implementation of applicable SOPs and quality requirements.
- Support the preparation of quality-related reports and tracking logs.

Quality Review and Monitoring:

- Conduct routine quality reviews of clinical trial documentation and processes according to approved plans and procedures.
- Review essential documents, study records, and quality-related documentation for completeness, consistency, and compliance.
- Identify potential quality issues, protocol deviations, missing documentation, and non-compliance.
- Escalate significant findings to the QA Manager and relevant functional teams.

Audit Support:

- Support the planning and preparation of QA audits and inspections.
- Participate in internal audits, site audits, vendor audits, and other quality assessments as assigned.
- Prepare audit-related documents, checklists, working papers, and reports.
- Record and track audit findings and observations.
- Follow up on CAPA implementation and supporting evidence."

CAPA and Quality Issue Management:

- Support the identification, documentation, and tracking of quality issues, protocol deviations, observations, and CAPA activities.
- Review CAPA documentation for completeness and consistency under the supervision of the QA Manager.
- Monitor CAPA due dates and follow up with responsible teams.
- Maintain CAPA and quality issue tracking logs.
- Escalate overdue or significant CAPA items to the QA Manager."

Compliance and Regulatory Support:

- Update relevant changes in GCP, clinical trial regulations, and applicable health authority requirements.
- Support the QA Manager in assessing the impact of new or updated requirements on clinical trial activities.
- Assist in preparing regulatory inspection-related documents and records.
- Support responses to inspection findings and follow-up activities as assigned.

Training and Quality Awareness:

- Support the organization and delivery quality-related training for staff and research site personnel.
- Maintain training records and training matrices.
- Monitor completion of required QA and compliance training.
- Support the preparation and updating of QA training materials.

Cross-functional Collaboration:

- Work closely with Clinical Operations, Data Management, Laboratory, Pharmacy, and other relevant teams to identify and resolve quality issues.
- Provide QA support and guidance within the scope of assigned responsibilities.

- Participate in quality meetings and study-related meetings when required.
- Communicating quality concerns promptly and appropriately.

Quality Reporting and Continuous Improvement:

- Support the preparation of periodic QA reports, quality metrics, and management reports.
- Assist in identifying recurring quality issues and potential areas for improvement.
- Provide data and observations to support quality trend analysis and continuous improvement activities.

May perform other job-related duties as requested or required.

Required qualifications and skills:

- Bachelor's degree or above in Clinical Research, Biomedical Science, Health Science, Public Health, Pharmacy, Life Sciences, or a related field.
- At least 1–3 years of experience in clinical research, clinical trials, quality assurance, quality control, pharmaceutical, biotechnology, healthcare, or a related field.
- Experience in clinical trial documentation, GCP, QA/QC, or audit activities is an advantage.
- Experience in supporting clinical trial audits or quality assessments is preferred.
- Basic data analysis and quality metrics
- Risk management principles
- Clinical trial documentation systems
- QA/QC activities and documentation
- Audit and inspection support
- CAPA tracking and follow-up
- Fluent in both spoken and written English.
- Excellent adaptability, interpersonal and organizational skills.
- Attention to detail.

Salaries and Benefits: Competitive salary

How to Apply:

Interested candidates are invited to email a cover letter and CV with contacts of three references to Ms. Hien Vu at hienvu@unc.edu and Ms. Thuy Ha at thuyha@email.unc.edu (Please quote the position title in the subject line: "**Application for QA Officer _ full name**").
The application deadline is August 30, 2026, or until the position is filled, whichever occurs first.

We regret to inform that only short-listed candidates will be contacted for interview.