The University of North Carolina at Chapel Hill

JOB ANNOUNCEMENT - Clinical Trial Quality Assurance Manager

The University of North Carolina in Vietnam is a research organization of the University of North Carlina at Chapel Hill, USA. Our missions are conducting clinical research on new treatment methods for HIV prevention, TB treatment, mental health focusing on both treatment and behavior changes for people living with HIV, TB patients, men who have sex with men and people who inject drug. Our partners are Hanoi Medical University, National Lung Hospital, Provincial CDCs nationwide. We are conducting clinical trials of the HIV/AIDS Prevention Trial Network (HPTN) and Advancing Clinical Therapeutics Globally (ACTG). To ensure all clinical trial activities are complied with Good Clinical Practice (GCP) regulations, current legal requirements, and protocols, we are seeking a talent individual to fulfill the position of Clinical Trial Quality Assurance (QA) Manager.

Position: **Clinical Trial Quality Assurance (QA) Manager**

Full-time, based in Hanoi.

Report to: In-Country Director

Position Summary:

The Clinical Trial Quality Assurance (QA) Manager is responsible for implementation and oversight of quality management activities for all clinical trials conducted at UNC Clinical Research Sites in Vietnam, ensuring compliance with regulatory requirements, protocol, and sponsor guidelines.

Main Duties & Responsibilities:

1. **Develop and Maintain the Clinical Quality Management Plan (CQMP)**
    - Establish and implement standard operating procedures (SOPs) for Quality Management System
    - Manage, update, and control the documentation of SOPs related to all phases of clinical trials from start to completion.
    - Develop and manage the quality-controlled documentation system, including forms, work instructions, and related records.
    - Ensure SOPs are disseminated, trained on, and adhered to by all relevant parties.

2. **Auditing**
    - Plan and conduct regular internal audits at research site to assess compliance with protocols, regulatory requirements, and Good Clinical Practice (GCP) standards.
    - Perform audits of vendors management.
    - Review study documentation and records before each regular monitoring audit and sponsor audit.
    - Review and prepare responses and actions to audit findings
    - Update and prepare explanations/clarifications for quality issues identified by the sponsors/monitors on the study network website.
    - Monitor and verify the implementation of Corrective and Preventive Action (CAPA) to ensure issues are fully resolved.
    - Prepare reports to IRB and relevant authorities per protocol requirement
3. **Quality Assurance (QA)**
    - Review key study documents, such as IRB submission, CAPA reports, and other materials before presenting them to In-Country Director to ensure accuracy and completeness.
    - Collaborate with other functional teams (e.g., Clinical Operations, Data Management, Laboratory, Pharmacy) to identify and address potential quality issues.
    - Conduct periodic reviews to ensure compliance with regulations related to study data and records.
    - Coordinate with the quality assurance staff at UNC Chapel Hill to develop forms and templates for quality management as required by the sponsors.
    - Propose and implement quality improvement plans for the clinical trials.
4. **Risk Management and Training**
    - Identify, assess, and manage quality-related risks during the clinical trial process.
    - Design and implement GCP training programs for internal staff and research site personnel to enhance awareness and compliance.
    - Stay updated on new legal regulations and health authority guidelines (e.g., Department of Drug Administration, Ministry of Health, National Institute of Health) to ensure the system remains compliant.
    - Develop and maintain plan for risk management and training
5. **Regulatory Inspections**
    - Support the In-country Director in preparing for and supporting inspections from regulatory bodies.
    - Support the In-country Director in representing clinical activities during inspections to present and defend records and procedures.
    - Support the In-country Director in coordinating the handling of inspection findings and developing site responses.

Required qualifications and skills:

- Master's degree in clinical research, Biomedical Science, Health Science, Public Health, Pharmacy or related field
- At least 3-5 years of experience in clinical research or quality assurance (QA) within the pharmaceutical or biotechnology industry.
- Experience in conducting clinical trial audits according to GCP standards is a significant advantage.
- Strong analytical, problem-solving, and independent decision-making skills.
- Excellent communication, negotiation, and presentation skills.
- Ability to work independently and as part of a team effectively.
- Proficiency in English (listening, speaking, reading, writing) to work with international documents and partners.

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 Manager _ 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.