



# University of Cape Town Lung Institute **ALLERGY AND IMMUNOLOGY UNIT**

## **QUALITY ASSURANCE & QUALITY CONTROL OFFICER**

The **Allergy and Immunology Unit (AIU)**, based at the University of Cape Town Lung Institute ([www.lunginstitute.co.za](http://www.lunginstitute.co.za)), requires applications for a **QUALITY ASSURANCE AND QUALITY CONTROL OFFICER\*** to work on a **Fixed Term Contract**.

The main purpose of this position is to ensure that all essential study- and participant-related documents are present in the participant binders to individually and collectively permit evaluation of the conduct of a study and the quality of the data produced; to ensure that the trial is performed and the data is generated, documented and reported, in compliance with Good Clinical Practice (GCP), the approved study protocol, Standard Operating Procedures (SOPs) and any applicable regulatory requirements.

### **Minimum Requirements:**

- Grade 12 / National Senior Certificate or Equivalent
- Bachelor of Science Degree or Degree in Health Sciences or documentation of adequate Clinical Research Associate training (would be advantageous)
- 3 – 5 Years relevant clinical research experience within Quality Control would be preferred
- experience of and insight into Clinical Quality Management and Study Procedures
- Knowledge of relevant protocols, policies and procedures and GCP
- Strong communication and interpersonal skills
- Detail orientated
- Analytical and effective problem-solving skills
- Computer skills, particularly in the use of Web applications and Microsoft Office applications
- Valid GCP Certificate (advantageous)
- Proactive and ability to work under pressure and in a fast-paced environment
- Excellent organization, co-ordination and administrative skills

### **Responsibilities include (but not limited to):**

- Responsible for ensuring regulatory compliance and quality control for the research data produced in the unit
- Overseeing that the Site's Clinical Quality Management Plan is implemented and ensure efficient quality control and quality assurance by performing regular reviews (using QC/QA tools as per the QA plan).
- Assures compliance to the Protocol and unit SOPs through a thorough understanding of the protocol and being familiar with the unit SOPs.
- Oversee monitoring of source documentation and CRF's (Case Report Forms) and assess source data verification needs per study.
- Responsible for reviewing Informed Consents prior to study procedures being performed.
- Prepare participant source documents and CRF's (Case Report Forms) for audit purposes.
- Assists with any CAPA execution as necessary.
- Assist with the submission of regulatory documents as required
- Responsible for internal monitoring validation of participant source files to ensure completeness and consistency of data
- Raise source or CRF queries with relevant staff and review that these queries are resolved adequately.
- Report on protocol deviation, critical event or quality issues that has been identified
- Attend to any monitoring findings/actions timeously
- Liaise and communicate with relevant stakeholders on issues related to the trial protocols
- Review and resolve quality issues, errors or omissions with relevant study monitors.
- Attend Monitor meetings for studies that they are responsible to QC/QA.
- Provide/assist with training with regard to ongoing error or omission trends if required.

### **Additional Information:**

- Position based in Mowbray
- 12-month Fixed Term Contract
- Working hours: 40 hours per week, Monday to Friday

**To apply**, interested applicants are requested to [click here](#) to complete the online application process with a cover letter and updated CV

**Closing Date:** 06 January 2025

Only shortlisted candidates will be contacted. Should you not receive a response within 30 days of the closing date, please consider your application unsuccessful.

*The University of Cape Town Lung Institute is committed to equity in our employment practices and reserves the right not to appoint. The selection process will be guided by the Employment Equity Plan and Targets of the University of Cape Town Lung Institute (Pty) Ltd.*

**\*Please Note: This Position is not on UCT Conditions of Service.**

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