



## **QUALITY ASSURANCE OFFICER (2-year contract, Payclass 10)**

**Clinical Pharmacology  
Department of Medicine  
Faculty of Health Sciences**

Applications from suitably qualified candidates are invited to apply for this 2-year, fixed-term contract position as soon as possible.

The Division of Clinical Pharmacology, housed within the Department of Medicine at UCT's Faculty of Health Sciences, is accredited for Therapeutic Drug Monitoring (TDM) services. The maintenance of this South African National Accreditation System (SANAS) is critical to the research undertaken by the division as well as other units within and external to the university. Regulated bioanalytical work supported by the division's Clinical Pharmacokinetic (PK) Laboratory requires Quality Assurance (QA) oversight and quality management.

The QA Officer will play a crucial role in supporting the QA Manager by providing SOP development and review, regulatory and accreditation oversight, quality planning and auditing services to the Clinical PK and TDM laboratories. As this post is funded by several externally derived funding bodies; the possibility of contract extension is dependent on whether funding is renewed.

### **Requirements:**

- Scientific qualification (Medical Technology, Bachelor of Sciences (BSC) life sciences, chemistry or equivalent)
- Regulatory training: International Organization for Standardization (ISO), European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) guidances.
- 5 years of quality management experience within the bioanalytical laboratory environment or within a Pathology laboratory environment.
- Knowledge of ISO standards and accreditation; South African and International

### **Key competencies:**

- Excellent communication, interpersonal, and time-management skills
- Quality Commitment coupled with meticulous attention to detail
- Ability to work under pressure in a team setting
- Ability to motivate colleagues and junior staff
- Innovative and proactive problem-solving.
- Auditing, Bioanalysis and Liquid Chromatography Mass Spectrometry (LCMS) skills

### **The following will be advantageous:**

- Registration with the Health Professions Council of South Africa (HPCSA) as a Medical Scientist
- Knowledge of regulatory requirements for bioanalytical laboratories (recommended)

### **Responsibilities:**

- Update and manage the quality manual(s) for each Quality Management System (QMS) within the laboratory system.
- Develop and implement new Standard Operating Procedures (SOPs) for the QA team.
- Review on behalf of QA all laboratory SOPs, final assay method SOPs and analytical validation report(s).
- Develop an annual internal audit plan covering all required aspects of the QMS over the course of the year (this includes the development of any tools required to facilitate the audit).
- Develop or assist with the development of all laboratory verification or validation plans.
- Maintain Laboratory's accreditation status (plan and execute accreditation extensions as and when required).
- Represent the laboratories on all QA related calls i.e. Clinical Pharmacology Quality Assurance (CPQA) and working groups.
- Conduct internal and external audits per the audit plan and produce audit reports with identified areas for corrective and preventive action (CAPA) as necessary.
- Provide a teaching service to the department for all appropriate staff and students in laboratory guidances and standards, including regulatory guidances i.e. EMA / FDA.

The annual cost of employment, is between R259 653 and R494 154, is dependent on qualifications and experience and does not include benefits.

**To apply**, please e-mail the below documents in a **single pdf file** to Lisa Peregrino at [Lisa.Peregrino@uct.ac.za](mailto:Lisa.Peregrino@uct.ac.za)

- UCT Application Form (download at <http://forms.uct.ac.za/hr201.doc>)
- Cover letter, and
- Curriculum Vitae (CV)

Please ensure the title and reference number are indicated in the subject line. An application which does not comply with the above requirements will be regarded as incomplete. Only shortlisted candidates will be contacted and may be required to undergo an assessment.

**Telephone:** 021406 6479

**Website:** [www.medicine.uct.ac.za](http://www.medicine.uct.ac.za)

**Reference number:** E70904

**Closing date:** 15 September 2017

UCT is committed to the pursuit of excellence, diversity and redress in achieving its equity targets. Our Employment Equity Policy is available at <http://www.uct.ac.za/downloads/uct.ac.za/about/policies/eepolicy.pdf>

UCT reserves the right not to appoint.