HR191	**POSITION DESCRIPTION**	UNIVERSITY OF CAPE TOWN IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

NOTES

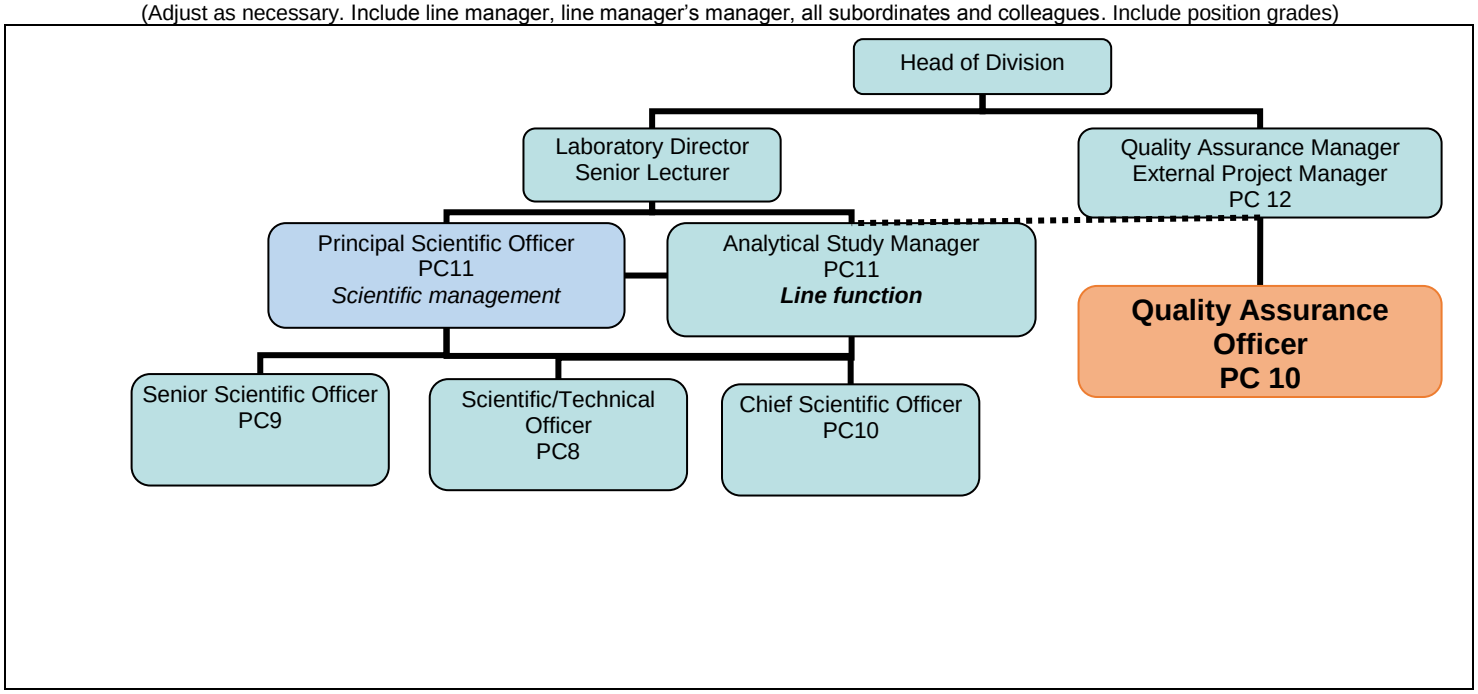
- Forms must be downloaded from the UCT website: http://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Quality Assurance (QA) Officer		
Job title (HR Practitioner to provide)			
Position grade (if known)	PC 10	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	Medicine		
Division / section	Clinical Pharmacology		
Date of compilation	09 Feb 2017		

ORGANOGRAM

(Adjust as necessary. Include line manager, line manager's manager, all subordinates and colleagues. Include position grades)



PURPOSE

The main purpose of this position is to support the QA Manager by providing SOP development and review, regulatory and accreditation oversight, quality planning, and auditing services to the Clinical Pharmacokinetic (PK) and routine Therapeutic drug monitoring (TDM) laboratories within the Division of Clinical Pharmacology.

The Division is accredited for TDM services and 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.

In addition to this, the regulated bioanalytical work supported by the Clinical PK Laboratory requires QA oversight and quality management.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
E.g.	General and office administration	25%	Takes, types up and distributes minutes and agendas for monthly departmental meeting. Greets visitors, enquires as to the nature of their visit and directs them to the appropriate staff member.	All staff members receive an electronic copy of accurate minutes and agendas, in the departmental template/format, a week before the meeting. Visitors are directed to appropriate staff member in a professional and efficient manner.
1	Quality Documentation System	20	• Quality Manual: Update and manage the Quality Manual(s) for each QMS within the laboratory system. • Standard operating procedures: Develop and implement new SOPs for the QA team, review and approve (QA) all SOPs for the laboratories • Assay methods and validations/verifications reports: Review and approve (QA) all final assay method SOPs and analytical validation report (s).	• Document and control system managed • Input provided to SOP's • SOP's managed including ensuring consistent formats and the scheduling of reviews. • Non-conformances initiated and corrective action coordinated in consultation with stakeholders.
2	Quality Planning	10	• Audit plans: Develop an annual internal audit plan covering all of the required aspects of the quality management system over the course of the year. This includes the development of any tools required to facilitate the audit • Verification/Validation plans: Develop or assist with the development of all verification or validation plans within the laboratories. • Quality Objectives: Define measure the quality objectives within the laboratories. • Accreditation: Maintain the accreditation status of the laboratory and plans and execute accreditation extensions as and when required.	• On-site internal monitoring and audits provided • Data is verified and verified with source documents and standard operating procedures • Quality Insurance Manager informed of quality, staff compliance and conduct deviations
3	Internal Quality Assurance	50	• Conduct audits per the audit plan • Produce audit reports with identified areas for corrective and preventive action (CAPA) as necessary. • Follow up on all correction actions to ensure completion.	• On-site internal monitoring and audits provided • Audit reports submitted per agreed deadlines • Non-conformances initiated and corrective action coordinated. • Quality deviations are highlighted and dealt with effectively • Corrective action coordinated

4	External Quality Assurance (EQA)	10	• Design and implement appropriate EQA processes where there are no commercially available/viable EQA programs. • Manage all EQA programs within the laboratories • Facilitate and represent the laboratories during external audits. • Manage the CAPA processes as a result of external audit finding. • Represent the laboratories on all QA related calls i.e. Clinical Pharmacology Quality Assurance (CPQA) and working groups • Manage all submissions of assay methods and validation reports to CPQA, including submissions and follow ups/amendments.	• Review and maintenance of good standard with various EQA programs. • Identification of new or suitable EQA programs for the laboratory • Identification and response co-ordination to trends observed in EQA results
5	Training/Teaching	10	• Provide a teaching service to the department for all appropriate staff and students in laboratory guidances and standards, including regulatory guidances i.e. European Medicines Agency (EMA) / the US Food and Drug Administration (FDA), ISO standards and Good Practices. • Provide training in the internal procedures and policies as appropriate.	• Employees and students coached to increase skills and knowledge. • Employees and students are informed of and understand their responsibilities

MINIMUM REQUIREMENTS

Minimum qualifications	Scientific qualification (Med Tech, BSC in life sciences, chemistry or equivalent) Regulatory training (ISO, FDA, EMA guidances) Internal auditing training			
Minimum experience (type and years)	5 years of quality management experience within the bioanalytical laboratory environment. May consider a pathology laboratory environment			
Skills	Auditing; Bioanalysis; LCMS; Excellent time management; Excellent communication (oral and written) skills;			
Knowledge	Required: ISO standards and accreditation (South African and International) Highly advantageous: Regulatory requirements for bioanalytical laboratories			
Professional registration or license requirements	Recommended: Registration with the Health Professions Council of South Africa (HPCSA) as a medical scientist			
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)	Ability to work under pressure in a team setting Ability to motivate colleagues and junior staff			
Competencies (Refer to UCT Competency Framework)	Competence	Level	Competence	Level
	Quality commitment	2	Results focused	2
	Organizational skills	2	Written and verbal communication skills	2
	Time Management	2	Attention to detail	2
	Teamwork and Cooperation	2	Resilience	2

SCOPE OF RESPONSIBILITY

Functions responsible for	Implementing the Quality Management System within the Divisional Laboratories
Amount and kind of supervision received	QA oversight; Independent work with weekly meetings to discuss progress and planning; All reports require management and QA sign off.
Decisions which can be made	All decisions linked to the job function; implementation of approved plans and procedures
Decisions which must be referred	All decisions not linked to job function; final approval of all plans and procedures.

CONTACTS AND RELATIONSHIPS

Internal to UCT	QA Manager; Laboratory Director; Head of Division; Analytical Study Manager
External to UCT	CPQA; Regulatory working groups; Audit hosting

AGREED BY

	PRINT NAME	SIGNATURE	CONTACT NO.	DATE
Position Holder				
Line Manager				
HOD				