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

NOTES

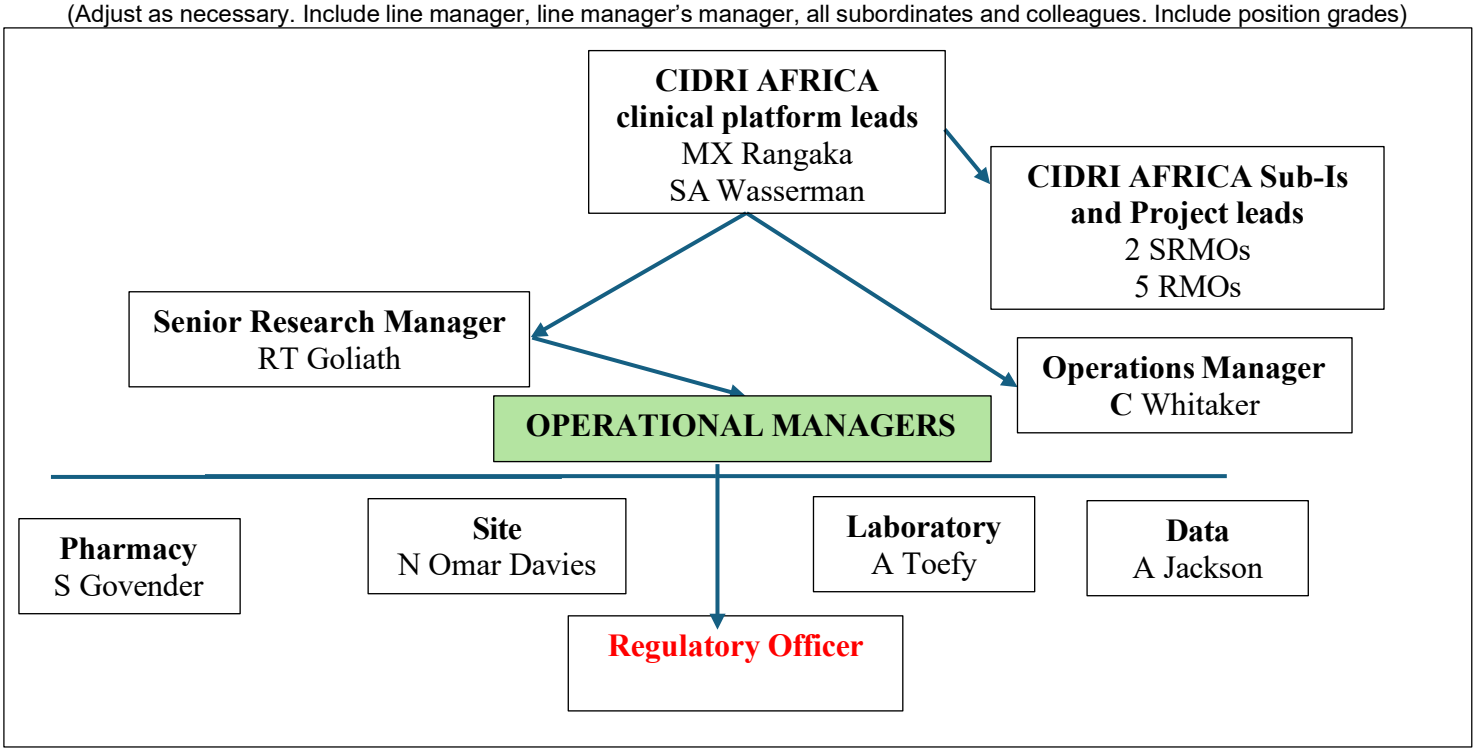
- Forms must be downloaded from the UCT website: https://forms.uct.ac.za/forms.htm
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

POSITION DETAILS

Position title	Regulatory Officer		
Job title (HR Business Partner to provide)			
Position grade (if known)	PC8	Date last graded (if known)	
Academic faculty / PASS department	FHS		
Academic department / PASS unit	CIDRI AFRICA		
Division / section	IDM		
Date of compilation	17 August 2026		

ORGANOGRAM

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



PURPOSE

The purpose of this position is to be responsible for ensuring that clinical trials adhere to regulatory guidelines, which are in place to protect the rights and welfare of study participants. To work closely with researchers, sponsors, institutional review boards, ethics committees and regulatory agencies to ensure that all necessary approvals and documentation are in place before a clinical trial can begin. Responsibility includes support of CRA/CRO during monitoring ongoing trials to ensure compliance with regulatory requirements and for reporting any adverse events or safety concerns to the appropriate regulatory and ethical authorities.

To be responsible for submitting regulatory and ethics documents to the correct bodies and the filing and maintaining said documentation within the regulatory requirements throughout the lifecycle of the studies.

CONTENT

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
1	Regulatory and ethics Submissions, Annual reviews, monitoring of approvals and general admin	40	• Preparing, compiling, and submitting Clinical Trial Applications (CTA) and Investigational New Drug (IND) to health authorities (such as the FDA or SAHPRA and Institutional Review Boards and Ethics Committees) • Submissions will include MTAs and applications for export permits • Review and submit requests to IBC for all studies • Ensuring safety guidelines are upheld throughout and possibly beyond the trial lifecycle • Working alongside PIs and RMO teams to manage, log, and report Serious Adverse Events (SAE) to regulatory bodies and IRBs within mandated timelines.	• On-time submission rates, minimal protocol approval delays, and accurate tracking of amendments and renewals. • Accurate documents to be submitted, inclusive of staff documents • Regulatory binders folders are securely stored and accounted for, both e-binders and hard copies to be up to date and audit ready at all times • Payments of SAHPRA and other regulatory bodies completed timeous
2	Compliance Monitoring and Quality Assurance	20	• Ensuring that all active research adherence matches legal, ethical, and organizational protocols • Reviewing clinical research reports and participant Informed Consent Forms (ICF). Conducting internal audits to identify non-compliance and establishing corrective and preventive actions (CAPA) • Support coordinator with regulatory binders and monitors visits • Create File management SOP	• Number of findings during internal reviews, implementation speed of corrective actions, and full alignment with Good Clinical Practice (GCP) guidelines. • Create systems to ensure that site and all studies are audit ready. • Audits from regulatory bodies and sponsors are done on time • TMF and ISF up to date • SOP in place and reviewed annually
3	Documentation Management and Trial Master File (TMF) Maintenance	15	• Maintaining accurate, audit-ready oversight of all essential study records • Building and updating electronic regulatory study binders. Tracking investigator site files, staff training logs, professional licenses, and CV.	• Document retrieval times, version control compliance, and complete audit readiness for unscheduled health authority inspections.
4	Regulatory Strategy Safety Reporting and Post-Trial Surveillance	10	• Proactively evaluating regulatory landscapes to advise project leadership • Monitoring changes in healthcare and flag updates and amend internal Standard Operating Procedures (SOPs) and advising clinical teams	• Actively updating internal protocols following a legislative change, and accuracy of risk mitigation plans •

5	Stakeholder Liaison and Communication	5	Acting as the primary, connection between the CIDRI Africa and external regulatory bodies	• Working systems in place for liaison with UCT Ethics, SAHPRA, DOH, SANCTR, PACTR • Excellent response times to regulatory inquiries, and successful facilitation of third-party external enquiries.
6	Safety Reporting	5	• Co-ordinate systems to store and transfer study folders; • Execute general data administrative activities as required. • Raise purchase orders for translation of consents and SAHPRA payments	• Strict adherence to emergency reporting windows and accuracy of safety documentation • Ensure all follow-up reports are completed • Sponsor CIOMS documents are completed and submitted
7	Training	5	• Train clinical team to use any new systems • Remain up to date with regulatory landscape and ensure current systems are in place • Complete all personal training required.	• Research Teams are appropriately trained and understand the regulatory processes • All staff are aware of how to complete and update required personal regulatory documents

MINIMUM REQUIREMENTS

Minimum qualifications	Matric; GCP certified
Minimum experience (type and years)	2+ years of working as a regulatory officer Previous experience or knowledge of regulatory support for multi-centered international clinical trials Excellent knowledge of current regulatory requirements governing clinical trials including a practical understanding of GCP Understanding of local and international laws, industry standards, and regulatory compliance frameworks
Skills	Understanding local and international laws, industry standards, and regulatory compliance frameworks. Skill in reviewing internal processes, assessing risks, and preparing operations for official inspections. Capacity to handle multiple submission timelines, prioritize tasks, organize files, track submission and responses and meet strict deadlines.
Knowledge	Knowledge of health data systems and quality control processes. Up to date with UCTHREC and SAHPRA SOP.
Professional registration or license requirements	None
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Ability to handle cash or finances'.)	

Competencies (Refer to UCT Competency Framework)

Competence	Level	Competence	Level
Task-related knowledge and skill	2	Communication	2
Quality commitment/ work standards	2	Planning and organizing / work management	2
Teamwork/ collaboration	2	Adaptability/ flexibility	1
Results focus	1	Analytical thinking / Problem solving	1

SCOPE OF RESPONSIBILITY

Functions responsible for	Preparing, compiling, and submitting Clinical Trial Applications (CTA) and Investigational New Drug (IND) to health authorities (such as the FDA or SAHPRA and Institutional Review Boards and Ethics Committees) Acting as the primary, connection between the CIDRI Africa and external regulatory bodies Proactively evaluating regulatory landscapes to advise project leadership Monitoring changes in healthcare and flag updates Amend internal Standard Operating Procedures (SOPs)when needed and advise clinical teams accordingly Ensuring safety guidelines are upheld throughout and possibly beyond the trial lifecycle Working alongside PIs and RMO teams to manage, log, and report Serious Adverse Events (SAE) and other reportable events to regulatory bodies and ethics committees within mandated timelines. Maintaining accurate, audit-ready oversight of all essential study records Building and updating electronic regulatory study binders. Tracking investigator site files, staff training logs, professional licenses, and CV. Train clinical teams on all new systems
Amount and kind of supervision received	Clinical Research Manager assigns work by broadly defining assignments, objectives, priorities and deadlines. Where problems and deviations are solved with reference to instructions, policies, and accepted practices, and guidance is available. Reviewing documents for technical adequacy and conformance with practice and policy. General assistance in unusual situations that do not have clear objectives.
Amount and kind of supervision exercised	None, but maintain close working relations with SC, Lead Investigators, PI, Ethics personnel, Monitors and SAHPRA contact staff
Decisions which can be made	Process, system decisions. Execute rules according to interpretive decision-making levels. Decides 'how" the rule is to be carried out from established processes, practice, systems, trade knowledge and rules and regulations. Can choose which process to use, deciding 'how', 'where' and 'when'.
Decisions which must be referred	Major amendments submissions

CONTACTS AND RELATIONSHIPS

Internal to UCT	Institutional Review Committee (IRC), UCT HREC, UCT Clinical Research Sites, Principal Investigators (PIs), UCT Procurement office and all CIDRI Africa staff
External to UCT	SAHPRA, CROs and Study sponsors

OPERATIONAL FLEXIBILITY

Work Location (✓ tick appropriate box and provide detail in space below) (Refer to UCT Flexible Work Approach Guideline	✓	Onsite		Hybrid	✓	Remote
	As per UCT policy					
Work Schedule (✓ tick appropriate box and provide detail in space below) (Refer to UCT Flexible Work Approach Guideline	✓	Structured		Semi-Structured		Unstructured
	As per UCT policy					