VACANCY	
Job title:	Regulatory and Compliance Officer
Type:	Permanent ☒ Fixed Term ☐ Temporary ☐
Main purpose of the job:	To monitor and ensure compliance with regulatory and good clinical research practice requirements within research studies.
Location:	Wits Vaccines & Infectious Diseases Analytics (VDA) Research Unit, Nkanyezi (Rahima Moosa Mother and Child Hospital)
Closing date:	29 April 2024
Submit detailed CV to:	vacancies28@witshealth.co.za
Advert reference number:	RCO
In accordance with our Employment Equity goals and plan, preference will be given to suitable applicants from designated groups as defined in the Employment Equity Act 55 of 1998 and subsequent amendments thereto.	

Key performance areas

1. Regulatory Management

- Create, establish, and maintain regulatory systems for all studies per regulatory authorities' requirements.
- Monitor regular and annual submission cycles and ensure updated submissions and recertifications, track and report on all regulatory department functions.
- Provide guidance on the requirements of local and international regulatory bodies and frameworks and support all relevant departments and study teams to comply with those requirements.
- Review systems and recommend improvements to streamline the creation and maintenance of trial documentation.
- Oversee regulatory submissions to IRBs, SAHPRA, other required bodies and sponsors or Clinical Research Organizations as needed. This includes identifying, compile, proof-checking and submitting applications and maintenance submissions as necessary.
- Coordinate regulatory and compliance administration and filing.
- Review and ensure all regulatory essential documentation are present, maintained and updated for studies.
- Maintain Investigator site files (ISF and electronic ISF) and trial master files (in the case of sponsored studies), research staff files and all required study essential documents according to site or sponsor Table of Contents, SOPs, SA GCP, and ICH.
- Compile relevant progress reports as well as unit-wide project management of regulatory submissions and maintenance.
- Provide safety updates and reporting as required to applicable bodies.
- Support unit research teams to update, maintain and control all Informed Consent forms and versions.
- Develop, maintain, and implement Regulatory SOP and maintain records and updates on all unit SOPs.
- Oversee capture and update all relevant study information on relevant websites/registries.
- Advise and assist with Investigator Driven / Grant Funded protocols and submissions as required.
- Contribute to budgeting requirements for regulatory department.
- Provide feedback and tracking of departmental expenditure in liaison with finance.
- Liaise with sponsors, CROs and applicable partners regarding regulatory matters.

2. Quality control/Quality Assurance

- Review and improve systems to monitor compliance with GCP, to ensure standardisation of quality control and quality assurances systems and recommend interventions to identify, evaluate and rectify problems.
- Review and advise on improvements and standardisation of quality control and assurance systems with respect to improved compliance with regulatory frameworks.
- Collaborate with QC and administration teams to conduct internal monitoring regulatory file reviews regularly / every quarter and conduct participant file reviews per the Clinical Quality Management Plan (CQMP)
- Actively participate and ensure site is well prepared for internal and external regulatory, laboratory, pharmacy, clinical, community etc site monitoring visits/audits/inspections, sponsor visits, site activations etc through preparation, follow-up, and close-out of findings – this includes quality assurance pre-checks.
- Assist sponsors/ monitors before, during and after reviews.
- Contribute to and maintain Clinical and Laboratory Quality Management Plan in conjunction with clinic and laboratory management.
- Contribute to unit Quality Assurance and Quality Control management (establish a committee)
- Prepare quality management reports in liaison with lab, clinic, and applicable study quality teams.
- Respond to monitoring and quality queries as required.

3. Staff Management

- Attend to all staffing requirements and administration.
- Supervise and manage the duties of permanent and fixed-term or ad hoc team members to ensure optimal staff.
- Consistent application of sound labour relations
- Perform and facilitate performance development and assessments.
- Identify substandard performance by team members and take necessary corrective action.
- Coach and train subordinates and team members to ensure the acquisition of knowledge and skills required by the organisation.
- Promote harmony, teamwork and sharing of information.

4. Effective Self-Management

- Take ownership and accountability for tasks and demonstrates effective self-management.
- Follow through to ensure that quality and productivity standards of own work are consistently and accurately maintained.
- Maintain a positive attitude and respond openly to feedback.
- Take ownership for driving own career development by participating in ongoing training and development activities such as conferences, workshops etc.

Required minimum education and training.

3 years diploma or degree in a health-related field.

Required minimum work experience.
Minimum 3 years relevant work experience in a research environment with demonstrable regulatory coordination experience.

Desirable additional education, work experience and personal abilities

- Understanding of the research language, detailed knowledge and understanding of the relevant studies and SOPs, knowledge of clinical research documentation.
- Detailed knowledge of regulatory applications and approval processes.
- Computer literate with ability to create or work with databases. Good written and verbal communication skills.
- Strategic thinking and problem-solving skills.
- Conscientious and precise delivery of work even when under pressure.
- Effective self-management, resourcefulness, and initiative to solve problems.
- Excellent communication and presentation skills including ability to independently drive priorities, reporting and deadlines.

Should you be interested in applying for this vacancy, please send an email to vacancies28@witshealth.co.za. The subject heading of the email must include the job title of position applying for. Please include the following documentation:

- A cover letter (maximum one page) that clearly states which vacancy you are applying for.
- A detailed CV