VACANCY	
Job title:	Regulatory Manager
Type:	Permanent ☒ Fixed Term ☐ Temporary ☐
Main purpose of the job:	To monitor and ensure compliance with regulatory and Good Clinical Practice (GCP) requirements within research studies at the Wits RHI Ward 21 Clinical Research Site.
Location:	22 Esselen and Klein Street, Hillbrow, Johannesburg.
Closing date:	13 September 2023
Submit detailed CV to:	Vacancy23@wrhi.ac.za
Advert reference number:	NQM024-2023
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

Strengthen and maintain regulatory systems per SAHPRA, WHREC, WHREC BEC, the sponsor and Dept of Health, ICH and SA GCP requirements.
Ensure compliance with local and international regulatory bodies and frameworks.
Detailed knowledge of regulatory application, submission and approval processes.
Submit regulatory applications in a timeous and accurate manner.
Manage and submit all safety updates, critical events and protocol deviations per ICH, SA GCP, Ethics Committees and Regulatory Authorities, sponsor and protocol requirements.
Maintain Investigator site files (ISF), electronic Investigator Site Files (eISFs) and all required study essential documents.
Maintain any other required essential documents, e.g., study insurance, participant materials etc.
Maintain tracking logs and systems for continued trial/study monitoring and compliance.
Maintain all research staff documents (e.g. CVs, SA GCP, HSP, HPCSA, SANC, SAPC, IATA, GCLP etc)
Ensure all required essential study documents per ICH and SA GCP are audit-ready and compliant.
Support study start-up processes: all regulatory activities to enable site activation.
Support study close-out through to archiving; including e-archiving.
Review systems continuously and recommend improvements to streamline the creation and maintenance of trial documentation; Assist in troubleshooting and rectifying process flow problems in the regulatory process.
Participate and drive SOP management (draft, review and maintain CRS SOPs).
Participate and drive CRS quality management: support internal monitoring: regulatory file/ISF reviews per the Clinical Quality Management Plan (CQMP).
Actively participate in site monitoring/audit/inspection preparations and visits.
Support Training/corrective action for site staff based on QC/QA, internal and external findings.
Review and improve systems to monitor compliance with GCP, to ensure standardisation of quality control and quality assurances systems.
Provide training to research staff and new staff/interns etc as required
Effective and efficient staff management

Required minimum education and training

Degree in health-related field or similar (preferable post-graduate).

Must have excellent knowledge and understanding of the Local Ethics and Regulatory requirements, as well that of the FDA, NIH/DAIDS, OHRP and EMA.

Required minimum work experience

Minimum 5 years' experience in a clinical trial environment with solid evidence of essential document management and maintenance and/or quality control and quality assurance environment.
Experience with DAIDS/Network trials
Proficiency and good knowledge with regards to all local and sponsor websites and resources e.g., DAIDS websites, HANC or networks, Wits HREC, WHREC BEC, SAHPRA, DoH, NHRD, PACTR, SANCTR etc.

Desirable additional education, work experience and personal abilities

Master's Degree in a health related field
Organised and methodical with extreme attention to detail
Good written and verbal communication skills
Fluent in English
Effective self-management, conscientious and precise delivery of work, even when under pressure

Should you be interested in applying for this vacancy, please send an email to Vacancy23@wrhi.ac.za. The subject heading of the email must read **NQM024 - 2023** and 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