The South African Health Products Regulatory Authority (SAHPRA), is the National Medicines Regulatory Authority established in terms of the ***Medicines and Related Substances Act, 1965, (Act No. 101 of 1965) as amended*****,** *to* provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, and related matters in the public interest.

MANAGER: CLINICAL TRIALS
Ref No.: SAHPRA 001/2021

CENTRE: Pretoria

REQUIREMENTS: • B. Pharm degree PLUS a relevant NQF 9 level post-graduate qualification in the health sciences OR an NQF 9 level post-graduate qualification in Pharmacology OR an MBBCH degree. • Registration with the relevant professional councils (SAPC/HPCSA). • A qualification in general or project management will be an added advantage. • A sound and in-depth knowledge of local and international requirements for the regulation of medicines.

Experience: A minimum of 8 years relevant experience, 3 years in supervisory or middle management.

COMPETENCIES, KNOWLEDGE AND SKILLS: * A solid understanding of clinical trials regulation procedures. * Comprehensive knowledge and understanding of international medicines regulation. * Planning and organisational and skills. * Performance measurement skills. * Computer skills and knowledge of MS Office. * Drive and self-management skills. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Resilience * Assertiveness. * Ethical behaviour. *A valid driver's licence.

DUTIES: • Plan, organise, co-ordinate and control the activities of the Clinical Trials Unit: * Supervise the development and implementation of Standard Operating Procedures (SOPs) and regulatory guidelines for the assessment of new clinical trial protocols and amendments for sound scientific methodology, ethics and protection of participants. ***** Monitor, evaluate, and manage the implementation of operational processes within the Clinical Trials Unit. ***** Supervise the Clinical Trials Unit personnel and performance, implement performance agreements and conduct quarterly performance assessments. ***** Manage risk and audit queries. ***** Submit weekly work-plans and outputs to the Senior Manager: Clinical Evaluations and Management (quantitative and qualitative reports). ***** Prepare annual budget estimates, quarterly performance reports and monthly financial reports for the Unit. ***** Where required, prepare reports for consideration by the SAHPRA Board and Executive, CEO and the Director-General: Health and Minister of Health. Prepare technical reports for SAHPRA and relevant expert advisory committees. ***** Perform any other relevant/related functions delegated by the Senior Manager.

• **Develop and maintain relations with local and international stakeholders: *** Communicate with the pharmaceutical research industry, the public, health professional bodies and other internal and external stakeholders on matters related to the regulation of clinical trials. ***** Communicate with counterparts in other regulatory authorities on matters of common regulatory interest. ***** Timeously investigate and resolve industry / applicants' queries related to the regulation of clinical trials. ***** Monitor and evaluate the preparation of advisory expert reports; attend and actively participate in technical scientific expert committee peer review meetings. ***** Supervise the recording of expert recommendations and ensure compliance with the relevant regulatory guidelines and requirements before finalising them for SAHPRA to make the final regulatory decision to either approve or reject clinical trial protocol applications or amendments.

INSTRUCTIONS TO APPLICANTS: All applications must:

- Be submitted with a covering letter clearly reflecting the **name of the position and post reference number**, be signed, accompanied by a comprehensive CV, the names of 3 referees and recently certified copies of ID and qualification/s.
- Applications without the afore mentioned will not be considered. Should you be in possession of a foreign qualification, it must be accompanied by an evaluation certificate from the South African Qualification Authority (SAQA).
- A separate application must be completed for each post. SAHPRA will not be liable where applicants use incorrect or no reference number on their applications.
- Applications must be submitted by email to **recruitment@sahpra.org.za,** including the required certified documentation as indicated. **DO NOT MAKE ENQUIRIES TO THIS ADDRESS.**
- No late applications will be accepted. CVs will not be returned. Applications, which are received after the closing date, will not be considered.
- Further communication will be limited to shortlisted candidates. If you have not received a response from SAHPRA within 3 months of the closing date, please consider your application as unsuccessful.
- It will be expected of candidates to be available for selection interviews on a date, time and place as determined by SAHPRA.

Applicants must note that further checks will be conducted once they are shortlisted and that their appointment is subject to positive outcomes on these checks, which include security clearance, qualification verification, criminal records, credit records, citizenship status and previous employment.
SAHPRA is guided by the principles of Employment Equity. Candidates with disabilities are encouraged to apply and an indication in this regard will be appreciated. SAHPRA reserves the right to fill or not to fill the vacant post/s.

Enquiries: Ms S. Molepo, Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 05 February 2021 at 16H00.