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.

GOOD CLINICAL PRACTICE (GCP) INSPECTOR
SALARY: R 657 376.00 – R834 199.00 per annum. (TOTAL COST TO COMPANY)
FIXED-TERM CONTRACT (ENDS IN MARCH 2025)
(Grade 1 – Grade 2) Market related salary will be determined by the years of experience obtained post qualification and community service.
Ref No.: SAHPRA 066/2023

CENTRE: Pretoria

REQUIREMENTS: Matric certificate and appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA. A relevant Master's qualification will be an added advantage.

Grade 1 – 4-year Bachelor of Pharmacy Degree NQF or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of five (5) of experience in experience in clinical trials and bio-equivalence studies. Extensive knowledge of GxP regulations and industry practices, as well as substantial experience of undertaking GxP inspections within the regulatory environment.

Grade 2 - 4-year Bachelor of Pharmacy Degree NQF level 8 as recognised by SAQA and registration as a Pharmacist with South African Pharmacy Council (SAPC) and minimum of three (3) years of experience in clinical trials and bio-equivalence studies. Extensive knowledge of GxP regulations and industry practices, as well as substantial experience of undertaking GxP inspections within the regulatory environment or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of ten (10) years of experience in clinical trials and bio-equivalence studies. Extensive knowledge of GxP regulations and industry practices, as well as substantial experience of undertaking GxP inspections within the regulatory environment.

CORE COMPETENCIES, TECHNICAL PROFICIENCIES, AND VALUES: * Comprehensive and Sound knowledge of all relevant legislation, regulations and guidelines pertaining to the Medicines and Related Substances Act 101 of 1965. *Good verbal and numerical reasoning skills to allow analysis and interpretation of written and numerical data. Good communication skills (verbal, written, conflict management and resolution). Delivery of service objectives with professional excellence and efficiency. *Ability to make effective decisions by using evidence and knowledge to support accurate, expect decisions and advice while carefully considering the implications of such a decision. Ability to work unsupervised for long periods of time. *Ability to work within a team environment. *Good planning and organisational skills. *Ability to meet tight deadlines and manage multiple, often competing priorities. *Knowledge of MS Office. *Valid driver's license. *Ethical behaviour and adherence to the SAHPRA Code of Conduct

DUTIES: • Inspect clinical trial vendors, laboratories, and other identified sites for compliance with Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) as accepted by SAHPRA. • Assess and evaluate GCP inspection reports of other regulatory authorities on international bioequivalent trials to verify clinical data to support registration of medicines in South Africa. • Work closely across inspection teams, SAHPRA departments and external regulators to ensure inspection activities are planned and communicated effectively • Evaluate Standard Operating Procedure (SOPs) of Inspectorate for compliance with GCP Guidelines as adopted by SAHPRA.• To contribute to the inspectorate's compliance management process by ensuring that instances of suspected or known non-compliance are handled in the appropriate manner. • To prepare reports for SAHPRA and relevant advisory committees and the Finance department. • Liaise with inspectors from international regulatory authorities. • Assist in minuting the recommendations of relevant advisory committees of SAHPRA applicable to the activities of the inspectorate.• Interview members from the industry to discuss requirements of the Medicine and Related Substances Act, No. 101 of 1965. • To provide advisory support to key stakeholders, including participation in regulatory meetings and conferences, external presentation all while demonstrating sound industry and technical knowledge. • Record statistics of generated and peer-reviewed reports.

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 and email addresses of 3 referees and recently certified copies of ID, required qualification/s (matric included) and driver's licence where applicable.
- Applications without the aforementioned documents/information 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: 18 December 2023 at 16H00.