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.

MEDICINE CONTROL OFFICER: INSPECTOR GCP X2
(FIXED TERM CONTRACT POSITIONS: 24 MONTHS)
Salary: As per DPSA OSD Framework
Ref No.: SAHPRA 048/2022

CENTRE: Pretoria

REQUIREMENTS: • 4-year bachelor's degree in pharmacy, pharmaceutical sciences, chemistry, medicine, veterinary, biological sciences and biomedical science (Proof of current registration as a Pharmacist must accompany your application if you have a B-Pharm degree).
Experience: • Minimum of 8 years' experience in a GxP Inspector role, preferably GCP (post community service).
The post-holder must have: • Extensive knowledge of GxP regulations and industry practice, as well as substantial experience of undertaking GxP inspections within a regulatory environment. • Sound knowledge of the Medicines and Related Substances Act 101 of 1965 as amended and all regulations pertaining to the Act.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: * Comprehensive and sound knowledge of all relevant legislation, protocols, 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, expert 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. * Ethical behaviour and adherence to the SAHPRA Code of Conduct. * Valid Driver's License.

DUTIES: * Inspect clinical trial vendors, laboratories, and other identified sites for compliance with Good Clinical Practices (GCPs) and Good Laboratory Practices (GLPs) 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. * To work closely across inspection teams, SAHPRA departments and external regulators to ensure inspection activities are planned and communicated effectively. * Evaluate Standard Operating Procedures (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. * 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 SAHPRA Board resolutions and 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 presentations 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: 22 August 2022 at 16H00.