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.

Re- Advertisement of Ref no:. SAHPRA 052-2023. Candidates who previously applied are encouraged to reapply.

GOOD MANUFACTURING PRACTICE (GMP) INSPECTOR
SALARY: R 657 376.00 – R834 199.00 per annum. (TOTAL COST TO COMPANY)
(Grade 1 – Grade 2) Market related salary will be determined by the years of experience obtained post qualification and community service.
Ref No.: SAHPRA 065/2023

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 pharmaceutical regulatory or GMP environment. Extensive knowledge of GMP regulations and industry practice, as well as substantial experience of undertaking GMP inspections within a 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 pharmaceutical regulatory or GMP environment. Extensive knowledge of GMP regulations and industry practice, as well as substantial experience of undertaking GMP inspections within a 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 pharmaceutical regulatory or GMP environment. Extensive knowledge of GMP regulations and industry practice, as well as substantial experience of undertaking GMP inspections within a regulatory environment.

CORE COMPETENCIES, TECHNICAL PROFICIENCIES, AND VALUES: *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). *Resilience. *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. *Valid Driver's License. *Ethical behaviour and adherence to the SAHPRA Code of Conduct. *At SAHPRA we adhere to our core values: *Ubuntu *Responsiveness *Integrity *Transparency *Efficiency *Excellence

DUTIES: Inspect pharmaceutical manufacturing sites for compliance with Good Manufacturing Practices as accepted by SAHPRA. Assess and evaluate GMP inspection reports of other regulatory authorities on international pharmaceutical manufacturing sites where medicines for exportation to South Africa are manufactured. Perform Pre- and Post-Registration inspections on information submitted in a medicine application dossier. Perform Once-Off evaluation on information submitted by HCR (Applicants). 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 GMP/GWP 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 [and medicines quality issues. 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. Manage the associated risks and audit queries through a clear governance process, ensuring that the correct procedure is followed, care taken, and ethical behaviour demonstrated when managing inspection-related resources and that all relevant records and evidence is sufficiently maintained for audit purposes.

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.
- 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: The closing date has been extended to the 12 January 2024 at 16H00. SAHPRA apologies for any inconvenience caused.