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.

This procurement will be managed by Supporting Health Initiatives (SHI), a Division of Wits Health Consortium Pty Ltd (WHC) for and on behalf of SAHPRA. SHI is dedicated to promoting and enabling public health activities that lead to new, significant advancements in healthcare and related fields and does this by providing resources, collaborative opportunities and project management support to partners and funders. SHI has developed a strong track record of delivering on assignments in Africa. SHI's operations and business teams have demonstrated capacity to quickly align with partners, distribute funds, and oversee implementation.

SPECIALIST - GOOD MANUFACTURING PRACTICES (GMP) X2

Two (2) year contract period subject to renewal to five (5) years

Salary Package: Grade D2 all-inclusive remuneration per annum (total cost to company)

Ref No.: SAHPRA 001/2024

CENTRE: Pretoria

REQUIREMENTS: Matric certificate and B. Pharm with Master's degree in Pharmacy (NQF level 09). Registration as a Pharmacist with South African Pharmacy Council (SAPC). Participation in local, regional or international associations or advisory bodies. Experience in development of policies and guidelines in the respective field. Demonstration of scientific or technical leadership in the respective field. A minimum of 10 years' experience in manufacturing/QMS in the Health Sector, including experience of conducting and participating in GMP inspections. A relevant PhD will be an added advantage.

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). Works largely on own initiative and

effectively evaluates the most complex assessments. Resilience.. Can handle challenges that are complex, requiring the application of research and newly assimilated knowledge. Acts as a peer reviewer and mentor for the work of others. Writes and critically evaluates written assessment reports and presentations. 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. Knowledge of SAHPRA policies and guidelines.

DUTIES: Inspect local and international pharmaceutical manufacturing sites for compliance with Good Manufacturing Practices as accepted by SAHPRA and prepare reports following inspections. 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. Play an advisory role on SAHPRA regulations, Policies, Standard Operating Procedures (SOPs) and guidelines of Inspectorate for compliance with GMP 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.

Conduct peer review of inspection reports for SAHPRA. Liaise with inspectors from international regulatory authorities. Liaise with members from the industry to discuss SAHPRA 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. 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. Training, development and capacity building on Good Manufacturing Practice regulatory inspection and related matters.

INSTRUCTIONS TO APPLICANTS (HOW TO APPLY): Interested applicants who meet the above requirements should forward their applications accompanied by signed covering letter attached to the comprehensive CV with the names and email addresses of three (3) referees clearly reflecting the **name of the position and post reference number**, 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.

Interested persons who meet the above-stated qualifications should forward their applications which should consist of a cover letter, detailed Curriculum Vitae, certified copies of qualification(s) and Identity Document (certified within the past 3 months).

SAHPRA comply with the provisions of Protection of Personal Information Act (POPIA); Act No. 4 of 2013. We will use your personal information provided to us for the purpose of recruitment only and more specifically for the purpose of the position/vacancy you have applied for. In the event your application was unsuccessful, SAHPRA will retain your personal information for internal audit purposes as required by policies.

Enquiries: Ms S. Molepo, Email: setlola.molepo@sahpra.org.za **(APPLICATIONS SENT TO THIS EMAIL ADDRESS WILL NOT BE CONSIDERED FOR THE RECRUITMENT PROCESS). The closing date is the 26th of April 2024 at 16H00.**

Applications must be sent to: tmotswasejane@witshealth.co.za