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 – BIOLOGICAL MEDICINE (VACCINE) QUALITY ASSESSOR X3

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 003/2024

CENTRE: Pretoria

REQUIREMENTS: Matric certificate and B. Pharm Degree with master's degree in pharmacology (NQF level 09) and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / PhD in Biomedical sciences or equivalent related qualification at NQF level 10 as recognised by SAQA. Post graduate qualifications in biotherapeutic/vaccine development, pharmaceutics, or regulation of biotherapeutics/vaccines. Good project management skills is an added advantage. Have expert knowledge and experience in quality aspects including chemistry, manufacturing and control of vaccines and or other biologicals. A minimum of 10 years' experience in compilation and/or review of quality aspects of biotherapeutic/vaccine CTD dossiers. Knowledge and experience of international guidelines and regulatory standards on biological medicine dossier compilation, Quality (CMC) aspects of biological dossier review (independent/expert). Effective training/mentorship skills. Sound knowledge of the Medicines and Related Substances Act 101 of 1965 as amended and all regulations pertaining to the Act. Knowledge of quality, safety, and efficacy aspects of medicines

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. Knowledge of technical aspects for evaluation of quality aspects of Biological medicines. Technical and scientific aspects of medicine regulation. Evaluation guidelines as prescribed by the relevant regulatory authorities. Knowledge of international regulatory guidelines as prescribed by the relevant regulatory authorities. Works largely on own initiative and effectively evaluates the most complex assessments. Holds either a more broadly defined or a specialist role within the SAHPRA. Acts as a peer reviewer and mentor for the work of others. Writes and critically evaluates written assessment reports and presentations.

Ethical behaviour and adherence to the SAHPRA Code of Conduct. Resolve issues requiring creative and innovative thinking based on the breadth and depth of knowledge and experience. Computer literacy and sound working knowledge of computer software packages. Performance measurement skills. Self-motivated and able to work independently. Ability to manage a variety of cross-functional team members. Competent in problem solving and team building. Information evaluation. Decision making. Objectivity. Resilience. Interpersonal skills. Assertiveness. Customer service. Team management. Can handle challenges that are complex, requiring the application of research and newly assimilated knowledge. Planning and organisational skills. Leadership skills. Coordination skills. Written and verbal communication skills. Diversity management. Time management. Good telephone etiquette. Supervisory skills. Knowledge of SAHPRA policies and guidelines.

DUTIES: The job exists for the incumbent to provide: Strategic technical leadership considering local and international reports, interventions, and strategies from other NRAs and WHO. Play an advisory role on SAHPRA regulations, Policies, Standard Operating Procedures (SOPs) and Biological medicines guidelines as adopted by SAHPRA. 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] Advisory support to key stakeholders, including participation in Regulatory meetings and conferences, external presentations all while demonstrating sound industry and technical knowledge. Technical support in assessment or evaluation of applications for registration of Biological medicines (Biotherapeutics, Biosimilars and Vaccines) to ensure that they are compliant with the Medicines and related substances Act (101 of 1965) as amended and the subscribed

guidelines. These assessments specifically pertain to quality (chemistry, manufacturing and controls-CMC) aspects of new and variation applications and aligned with ICH and SAHPRA guideline requirements. Critical and analytical feedback as peer reviewer and quality assurer of quality (CMC) sections of Biological submissions. Training/mentorship on assessment of the Quality (CMC) sections of Biological medicine (Vaccines)

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 .