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 REGISTRATION OFFICER:
PHARMACEUTICAL EVALUATION MANAGEMENT (PRE & POST) x 3
(FIXED TERM CONTRACT POSITIONS – ENDING MARCH 2025)
Salary: Salary: Level 11 (R788 910.00 – R837 326.00) TOTAL COST TO COMPANY
Ref No.: SAHPRA 040/2023

CENTRE: Pretoria

REQUIREMENTS: ● Appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) - proof of current registration as a Pharmacist to accompany the application) **OR** 4-year Science Degree in a health science related field from a recognised university or tertiary institution. ● A relevant NQF 9 qualification in the health sciences will be an added advantage.
Experience: ● Minimum 3 years' experience, one being regulatory experience (post community service).

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: * Knowledge and application of the Medicines and Related Substances Act (101 of 1965), as amended, and its related Regulations, with respect to the regulation of medicines in terms of quality, safety, and efficacy. * Knowledge of technical aspects for evaluation of quality and efficacy of bioequivalence of medicines. * Comprehensive knowledge and understanding of relevant legislation, guidelines, protocols, standard operating procedures, and work instructions as outlined by regulatory authorities. * Good planning, organizational and interpersonal skills. * Self-motivated and able to work independently. * Good communication skills (written, verbal, negotiation, conflict management, presentation). * Innovative thinking, initiative, assertive and leadership qualities. * Dedication and accurate work. * Ethical behaviour. * Must be willing to travel and work irregular hours. *Customer service.

DUTIES: ● Evaluation of new applications and peer-reviewing of new applications / variations: * Generate evaluation reports for each new application and submit for peer review in compliance with required template and adopted regulatory /scientific standards (depend on the type of application, i.e., Full/partial reviews Q-BE and Reliance. * Evaluation of Type I and II clinical/quality variation applications. * Following peer review process, amend the report accordingly to generate a list of queries to the applicant using the correct templates (Full/partial reviews Q-BE and reliance). * Peer review other evaluators reports according to the required template and adopted regulatory /scientific standards (Full/partial reviews Q-BE and reliance). * Evaluation of PI/PIL applications (new applications and responses). * Prepare query or approval or rejection letter to the applicant. ● **Evaluate applicant responses for registration/approval of medicines:** * Generate second (and subsequent) evaluation report

(s) for each response application review. * Following peer review process, amend the report accordingly to generate a list of queries to the applicant, if necessary. * Peer review other evaluators response reports, according to the required template and adopted regulatory/scientific standards. ● **Develop and update guidelines, SOPs, and templates:** * Review existing guidelines, SOPs and templates and update when necessary, and provide and attend trainings on guidelines, SOPs and template to new MROs and external evaluators. * Create new guidelines, SOPs, and templates where relevant. * Provide regular work-plans and output to the unit manager (qualitative and quantities report). * Perform any other related duty as requested by manager/senior manager. ● **Form part of technical working groups or special projects and provide support to the unit as well as to the Advisory Committees:** * Prepare report for the internal working groups and/or advisory committee and where necessary, present at advisory committee for complex scientific matters and ensure adherence to SOPs and Guidelines. * Provide quality assurance of reports and facilitate resolutions on technical matters. * Align with ICH, WHO, IPRP, international standards, SAHPRA QMS requirements and use the most current SAHPRA templates and guidelines. * Timeous execution of recommendations from the advisory committee. ● **Provide technical advice and information to all stakeholders (internally and externally): *** Attend to queries from various stakeholders. * Provide technical advice and information to all stakeholders. * Attend to queries from the Manager, Senior Manager, other Programmes, the legal unit and the Chief Regulatory Officer's office. ● **Technical screening of applications for the registration of medicines: *** Generate technical screening evaluation report(s) for each application and submit for peer review. * Following peer review process, amend the technical screening report (s) accordingly to generate a list of queries to the applicant using the correct templates. * Peer-review technical screening report (s) done by other reviewers. * Prepare screening query / screening rejection letter to the applicant. * Provide quality assurance of reports and facilitate resolutions on technical matters.

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: 17 August 2023 at 16H00.