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: PRE-REGISTRATION X 3
(PHARMACEUTICAL EVALUATION MANAGEMENT)
Salary: R692 830.00 – R837 326.00 p/a (All-inclusive)
Ref No.: SAHPRA 007/2023

CENTRE: Pretoria

REQUIREMENTS: ● 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) - (Proof of registration [Current Designation Letter] must accompany the application) **OR** 4-year Science Degree in a health science related field from a recognised university or tertiary institution.
Experience: ● 2 years' work experience within a pharmaceutical regulatory environment.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: * Knowledge and application of the Medicines and Related Substances Act (101 of 1965), as amended, and its related Regulations and Guidelines. * Knowledge of technical aspects for evaluation of quality and efficacy of bioequivalence of medicines as outlined by: * Comprehensive knowledge and understanding of relevant legislation, guidelines, protocols, standard operating procedures, and work instructions as outlined by regulatory authorities. *Self-motivated and able to work independently. *Ability to manage a variety of cross-functional team members. *Decision making informed by technical expertise. Communication skills (written, verbal, negotiation, conflict management, presentation). *Assertiveness. * Ethical behaviour. * Customer service. *Planning and organising skills.

DUTIES: ● Evaluation of new applications and peer-reviewing of new applications: *Generate evaluation report (s) for each new applications (NCE and Generics) in compliance with required template and adopted regulatory/scientific standards and submit for peer review. * Following peer review process, amend the report (s) accordingly to generate a list of queries to the applicant using the correct templates. *Primary report (s) are initially generated by new or junior members of the team, with peer-reviews carried out by more senior or more experienced members of the team. *Prepare report (s) for the internal working groups and where necessary present at advisory committee for complex scientific matters. * Prepare query letter to the applicant. *Prepare a basis of approval or rejection. * Provide quality assurance of reports and facilitate resolutions on technical matters.
● **Evaluate applicant responses for registration/approval of medicines:** *Generate second (and subsequent) evaluation report (s) for each response application and submit for peer review in compliance with required template and adopted regulatory/scientific standards and submit for peer 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. *Prepare report for the internal working groups and where necessary present at advisory committee for complex scientific matters. *Prepare query letter to the applicant. *Prepare a basis of approval or rejection. *Provide quality assurance of reports and facilitate resolutions on technical matters.

● **Technical screening for the quality and efficacy (bioequivalence) aspects of new 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 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.

● **Develop and update guidelines, SOPs, and templates:** * Review existing guidelines, SOPs and templates and update when necessary. *Provide training on guidelines, SOPs, and templates. *Create new guidelines, SOP's, and templates where SOPs aren't in place. *Provide regular work-plans and output to the unit manger (qualitative and quantities report). *Perform any other relate 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:** *Participate in special projects and registration group. *Lead and manage assessments peer review and discussion working group where relevant. *Compile discussion documents and reports. *Provide regular trainings to new MRO's and external evaluators. *Take comprehensive notes of relevant discussions. * Prepare documents for SAHPRA management/RC meeting.

● **Risk Management and Audit:** *SOP's and Guidelines must be adhered to. *Create and maintain data bases. *Use the most current templates and guidelines. *Provide and attend the relevant training as may be necessary. *Align with QMS requirements. *Align with ICH, WHO, IPRP and international standards.

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: 23 February 2023 at 16H00.