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.

MEDICINES REGISTRATION OFFICER: PRE REGISTRATION
(PHARMACEUTICAL EVALUATION MANAGEMENT)
SALARY: R657 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 in line with governing frameworks.

Ref No.: SAHPRA 026/2024
CENTRE: PRETORIA

REQUIREMENTS: Matric certificate and appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) at NQF level 8 as recognised by SAQA **OR** Honours Degree in related health Sciences at NQF level 8 as recognised by SAQA. A relevant Master's qualification at NQF level 9 as recognised by SAQA will be an added advantage. Valid driver's license.

EXPERIENCE:

Grade 1: 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) at NQF level 8 as recognised by SAQA plus a minimum of three (3) years regulatory experience (post community service) in pharmaceutical or related medicines regulatory or medicine production quality assurance. **OR** Honours Degree in related health Sciences at NQF level 8 as recognised by SAQA plus a minimum of five (5) years regulatory experience in pharmaceutical or related medicines regulatory or medicine production quality assurance.

Grade 2: 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) at NQF level 8 as recognised by SAQA plus a minimum of five (5) years regulatory experience (post community service) in pharmaceutical or related medicines regulatory or medicine production quality assurance **OR** Honours Degree in related health Sciences at NQF level 8 as recognised by SAQA plus a minimum of eight (8) years regulatory experience in pharmaceutical or related medicines regulatory or medicine production quality assurance.

COMPETENCIES, KNOWLEDGE, AND SKILLS: 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 (bioequivalence) of medicines. Computer literacy and sound working knowledge of computer software packages. Technical and scientific aspects of medicine regulation. Evaluation guidelines as prescribed by the relevant regulatory authorities. Planning and organisational skills. Leadership skills. Coordination skills. Written and verbal communication skills. Diversity management. Time management. Good telephone etiquette. Supervisory skills.

DUTIES: **Evaluation of new applications and peer-reviewing of new applications:** Generate evaluation report(s) for each new application (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. Peer-review primary report(s) done by other reviewers. 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.

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 (bio-equivalence) 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 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, 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 also 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 internal MROs and external evaluators. Take comprehensive notes of discussions of relevant discussions. Prepare documents for SAHPRA management/ RC meeting.

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

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. **All shortlisted candidates will be subjected to a technical exercise that intends to test relevant knowledge, skill and technical elements of the job.**
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, copies of qualification(s) and Identity Document. ONLY shortlisted candidates will be required to submit certified copies of qualifications and other related documents on or before the day of the interview following communication from Human Resources.

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.

Applications should be submitted through the SAHPRA Website Online Portal: **SAHPRA website (**https://www.sahpra.org.za**) – About Us – Vacancies**.

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 27 September 2024 at 16H00.**