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.

Re- Advertisement of Ref no:. SAHPRA 050-2023. Candidates who previously applied are encouraged to reapply.

MEDICINES REGISTRATION OFFICER:
PHARMACEUTICAL EVALUATION MANAGEMENT: PRE-REGISTRATION X5
SALARY: R 657 376.00 – 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.
Ref No.: SAHPRA 076/2023

CENTRE: Pretoria

Requirements: Matric certificate and appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA. A relevant Master's qualification will be an added advantage.

Grade 1 – 4-year Bachelor of Pharmacy Degree NQF or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of five (5) of experience in pharmaceutical regulatory environment or related medicine production quality assurance sector.

Grade 2 - 4-year Bachelor of Pharmacy Degree NQF level 8 as recognised by SAQA and registration as a Pharmacist with South African Pharmacy Council (SAPC) and minimum of three (3) years of experience in pharmaceutical regulatory environment or related medicine production quality assurance sector or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of ten (10) years of experience in pharmaceutical regulatory environment or related medicine production quality assurance sector

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: 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

(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: 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. * 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.

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.

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.

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.

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 MRO’s and external evaluators. * Take comprehensive notes of discussions of relevant discussions. * Prepare documents for SAHPRA management/ RC meeting.

SOP’s 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: 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.
- 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: The closing date has been extended to the 12 January 2024 at 16H00. SAHPRA apologies for any inconvenience caused.