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 x5

Ref No.: SAHPRA 050/2023

SALARY LEVEL: 11(R788 910 to R837 326 per annum Total Cost To Company)

CENTRE: Pretoria

REQUIREMENTS:

- Appropriate 4-year Bachelor of Pharmacy Degree or 4-year Science degree in related health Sciences.
- A minimum of 3 years' work experience within pharmaceutical regulatory environment or related medicine production quality assurance sector.
- A relevant master's qualification in the health sciences will be an added advantage.

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 of 3 referees and recently certified copies of ID and qualification/s.

- Applications without the afore mentioned 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 or faxed applications will be accepted. CV's 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: Email: setlola.molepo@sahpra.org.za **(DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 23 October 2023 at 16H00.