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 POST-REGISTRATION EVALUATIONS x2

Salary: R692 830.00 – R837 326.00 p/a (All-inclusive)

Ref No.: SAHPRA 003/2023

CENTRE: Pretoria

REQUIREMENTS: ● Appropriate 4-year Bachelor of Pharmacy Degree from a recognised university or tertiary institution. ● Registration as a Pharmacist with the South African Pharmacy Council (SAPC) is a requirement (Proof of registration [Current Designation Letter] must accompany the application).

Experience: ● A minimum of at least 1 year experience within a pharmaceutical regulatory or Production environment would be an added advantage (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 and Guidelines. * Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. * Knowledge of technical aspects for evaluation of quality and efficacy (bioequivalence) of medicines. * Evaluation guidelines as prescribed by the relevant regulatory authorities. * Technical and scientific aspects of medicine regulation. * Self-motivated and able to work independently. * Competent in problem solving and team building. * Information evaluation. * Computer literacy and sound working knowledge of computer software packages. * Planning and organisational skills. * Leadership skills. * Coordination skills. * Written and verbal communication skills. * Diversity management. * Time management. * Good telephone etiquette. * Supervisory skills. * Must be willing to travel and work irregular hours when so required. *A valid driver's licence.

DUTIES: ● Evaluation of generic applications and peer-reviewing of generic applications. * Evaluation of Type I and II quality variation applications. * Prepare an evaluation report. * Peer-review reports done by other reviewers. * Prepare second evaluation report. * Prepare query or approval or rejection letter to the applicant.
● Technical screen and evaluate the quality and efficacy (Bioequivalence) aspects of the quality variation applications for the registered medicines. * Generate screening/evaluation report for each application. * Send report to second evaluator for peer review.

● **Evaluate applicant responses and variations for the registered medicines:** * Evaluate the quality and efficacy (Bioequivalence) aspects of responses and variations for the registered medicines. * Prepare report for the internal peer review and where necessary present at advisory committee.
● **Form part of technical working groups or special projects and also provide support to the Advisory Committees:** * Participate in special projects and Pre and Post registration group. * Lead and manage assessments peer review and discussion working group where relevant. * Compile discussion documents and reports. * Take comprehensive notes of discussions of relevant discussions.
● **Risk Management and Audit:** * SOP and Guidelines must be adhered to. * Create and maintain data bases. * Respond to relevant queries timeously. * Respond to applicants' questions pertaining to recommendations and any other related concerns. * Provide and attend relevant training as may be necessary.

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 February 2023 at 16H00.