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 X3
(Pharmaceutical Evaluations Management: Pre-registration)
Salary (DPSA Equivalent Level SR 10 (Non-OSD TCE) – R653 613.00 p/a)
Ref No.: SAHPRA 030/2022

CENTRE: Pretoria

REQUIREMENTS: ● 4-year BPharm degree from a recognised university or tertiary institution (Registration with the South African Pharmacy Council (SAPC) is a requirement with a BPharm degree - proof of active registration as a Pharmacist to accompany the application). **Experience:** ● Experience within a pharmaceutical regulatory or clinical 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. * Knowledge of technical aspects for evaluation of quality and efficacy of bioequivalence of medicines. * 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 (verbal, written, 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 reports for each new application and submit for peer review in compliance with required template and adopted regulatory /scientific standards (depend on the type of application, i.e., Full/partial reviews Q-BE and Reliance. * Following peer review process amend the report accordingly to generate a list of queries to the applicant using the correct templates (Full/partial reviews Q-BE and reliance) – typically 2 per month depending on the reports generated. * Peer review other evaluators reports according to the required template and adopted regulatory /scientific standards (Full/partial reviews Q-BE and reliance) – typically completed within 8 hours for full review quality. ● **Evaluate applicant responses for registration/approval of medicines:** * Generate second (and subsequent) evaluation report (s) for each response application within 8 hours and submit for peer review (target of 2 per month). * 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 within 3 hours. ● **Develop and update guidelines, SOPs, and templates:** * Review existing guidelines,

SOPs and templates and update when necessary and provide and attend trainings on guidelines, SOPs and template to new MROs and external evaluators (typically 1 per quarter and 2 training sessions per annum). * Create new guidelines, SOPs, and templates where relevant (typically 1 per quarter). ● **Form part of technical working groups or special projects and provide support to the unit as well as to the Advisory Committees:** * Prepare report for the internal working groups and where necessary present at advisory committee for complex scientific matters and ensure adherence to SOPs and Guidelines (typically 2 reports per annum). * Provide quality assurance of reports and facilitate resolutions on technical matters. * Align with ICH, WHO, IPRP, international standards, SAHPRA QMS requirements and use the most current SAHPRA templates and guidelines

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: 27 May 2022 at 16H00.