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 006-2023. Candidates who previously applied are encouraged to reapply.

MEDICINES REGISTRATION OFFICER
PHARMACEUTICAL EVALUATION MANAGEMENT
PRE AND POST- REGISTRATION EVALUATION MANAGEMENT X3
(FIXED TERM CONTRACT POSITIONS – ENDING MARCH 2025)
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 074/2023
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: *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. *Diversity management. *Time management. *Good telephone etiquette. *Supervisory skills. *Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. *Performance measurement skills. *Self-motivated and able to work independently. *Ability to manage a variety of cross-functional team members. *Competent in problem solving and team building. *Information evaluation. *Decision making. *Objectivity. *Resilience. *Communication skills (verbal, written, negotiation, conflict management, presentation). *Interpersonal skills. *Assertiveness. *Ethical behaviour. *Customer service. *Planning and organising skills. *Team management.

DUTIES: Evaluation of quality variations for small molecule product applications and peer reviewing of these applications. Write reports and draft query and approval/rejection letters after evaluation: • Evaluation of Type I and II quality variation applications in accordance with EMA variation guidelines, ICH requirements and minimal international standards. • Prepare a detailed scientific evaluation report in accordance with the Good Review Practice guide and competency assessment rubric. • Peer-review reports done by other reviewers in accordance with the Good Review Practice guide and competency assessment rubric. • Do a QA check or technical discussion on evaluation reports, in cases where this is needed. • Prepare report for the internal peer review or technical discussion meetings and where necessary present at advisory committee. • Prepare draft query, approval, or rejection letter to the applicant, whichever is relevant. Check letters for correctness for technical requirements and for spelling, grammar and sentence construction.

Technical screen and evaluate the quality and efficacy (Bio-equivalence) aspects of the quality variation applications for the registered medicines: • Complete technical screening of all new variations received in accordance with technical screening SOP and record on the tracker. • Generate screening/evaluation query letter for relevant technical queries. • Complete technical screening check on the validation template and draft templates for evaluators. Save these on the shared drive in the application specific folder. • Complete admin screening and verify fees, by calculating required fees. Record the fees paid as per the POP in the dossier, in the tracker and communicate shortfalls via unit email. • Create POP folder on the shared drive for each new sequence and save POPs. • Update the tracker with the above information and the payments which were made in response to queries sent to the applicant.

Evaluate applicant responses and variations for the registered medicines: • Evaluate the quality and efficacy (Bio-equivalence) aspects of responses to queries on the variations to registered products, in line with Good Review Practice guide, ICH guidelines, EMA guidelines and other relevant international standards. • Generate detailed scientific evaluation reports in line with the Good Review Practice guide, ICH guidelines, EMA guidelines and other relevant international standards. • Prepare report for the internal peer review and where necessary present at advisory committee. • Prepare approval/query/rejection letter as applicable.

Form part of technical working groups or special projects and provide support to the Advisory Committees: • Participate in special projects and Pre and Post registration working groups as required and engage in technical scientific discussions on ongoing applications under review. • Lead and manage (including organising) assessments peer review and discussion working groups, where relevant, and do research if necessary to contribute to the discussions. • Compile discussion documents, including agendas, minutes and actions items, and reports. Update these regularly as necessary. Record meetings and save in the unit shared drive. •

Take comprehensive notes of discussions of relevant discussions in meetings and update documents regularly. Implement any scientific decisions in future assessments. • Participate in international scientific regulatory forums and discussion groups including ICH, IPRP and WHO, as relevant and when nominated. • Review existing SOPs and update when necessary. • Provide comments and corrections to SOPs which are currently under review. • Create new SOPs where relevant or as instructed by the manager. • 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.

Risk Management and Audit: • SOPs and SAHPRA, ICH, EMA and other relevant guidelines must be adhered to. • Create and maintain data bases as needed. • Respond to relevant queries timeously. • Respond to applicants' questions pertaining to recommendations and any other related concerns. • Attend relevant training as may be necessary and give feedback to the unit after attendance. • Provide training and mentorship for other staff members if relevant. This includes technical scientific trainings as well as practical administrative trainings. • Keep updated on regulatory updates and latest scientific discussions and alerts with regards to medicines quality, safety and efficacy

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.