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: PHARMACEUTICAL POST-REGISTRATION EVALUATIONS

(PHARMACEUTICAL EVALUATION MANAGEMENT)

SALARY: R657 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 in line with governing frameworks.

Ref No.: SAHPRA 028/2024
CENTRE: PRETORIA

REQUIREMENTS: Matric certificate and appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) at NQF level 8 as recognised by SAQA **OR** Honours Degree in related health Sciences at NQF level 8 as recognised by SAQA. Those with Honours Degree in related health Sciences and Post graduate related qualification in Pharmaceutics/Chemistry/Pharmacology, at NQF level 9 as recognised by SAQA, will be an added advantage. Valid driver's license.

EXPERIENCE:

Grade 1: 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) plus a minimum of three (3) years' experience (post community service) in a Regulatory, Quality Assurance or Production environment; **OR** Honours Degree in related health Sciences at NQF level 8 as recognised by SAQA plus a minimum of five (5) years' experience in a Regulatory, Quality Assurance or Production environment.

Grade 2: 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) plus a minimum of five (5) years' experience (post community service) in a Regulatory, Quality Assurance or Production environment; **OR** Honours Degree in related health Sciences at NQF level 8 as recognised by SAQA plus a minimum of eight (8) years' experience in a Regulatory, Quality Assurance or Production environment.

COMPETENCIES, KNOWLEDGE, AND 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, and 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 also 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.
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.
Develop and update guidelines, SOPs and templates: 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.

INSTRUCTIONS TO APPLICANTS (HOW TO APPLY): Interested applicants who meet the above requirements should forward their applications accompanied by signed covering letter attached to the comprehensive CV with the names and email addresses of three (3) referees clearly reflecting the **name of the position and post reference number**, 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. **All shortlisted candidates will be subjected to a technical exercise that intends to test relevant knowledge, skill and technical elements of the job.**
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.

Interested persons who meet the above-stated qualifications should forward their applications which should consist of a cover letter, detailed Curriculum Vitae, copies of qualification(s) and Identity Document. ONLY shortlisted candidates will be required to submit certified copies of

qualifications and other related documents on or before the day of the interview following communication from Human Resources.

SAHPRA comply with the provisions of Protection of Personal Information Act (POPIA); Act No. 4 of 2013. We will use your personal information provided to us for the purpose of recruitment only and more specifically for the purpose of the position/vacancy you have applied for. In the event your application was unsuccessful, SAHPRA will retain your personal information for internal audit purposes as required by policies.

Applications should be submitted through the SAHPRA Website Online Portal: **SAHPRA website (**https://www.sahpra.org.za**) – About Us – Vacancies**.

Enquiries: Ms S. Molepo, Email: setlola.molepo@sahpra.org.za **(APPLICATIONS SENT TO THIS EMAIL ADDRESS WILL NOT BE CONSIDERED FOR THE RECRUITMENT PROCESS). The closing date is 08 October 2024 at 16H00.**