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: CLINICAL TRIALS
SALARY: (R 700 105.00 – R 888 422.00) per annum (TOTAL COST TO COMPANY)
(Grade 1 – Grade 2) Market related salary will be determined by the years of experience obtained post qualification, Internship and Community Service in line with governing frameworks.

Ref No.: SAHPRA 02/2025
CENTRE: PRETORIA

REQUIREMENTS: Matric certificate and appropriate 4-year Degree in Pharmacy at NQF level 8 as recognised by SAQA and registration with a Professional Body (SAPC). A relevant Master's Degree will be an added advantage. A valid driver's license.

EXPERIENCE:
Grade 1 – A minimum of two (2) years of clinical experience post Internship and Community Service. Regulatory experience will be an added advantage.

Grade 2 – A minimum of five (5) years of clinical experience post Internship and Community Service of which two (2) years should be within regulatory experience.

COMPETENCIES, KNOWLEDGE, AND SKILLS: Knowledge and application of the Medicines and Related Substances Control Act (101 of 1965), as amended, and its related Regulations, with respect to the regulation of medicines in terms of quality, safety, and efficacy. Good knowledge of the conduct of clinical trials. Comprehensive knowledge and understanding of relevant legislation, guidelines, protocols, standard operating procedures, and work instructions as outlined by regulatory authorities. Good planning, organizational and interpersonal skills. *Self-motivated and able to work independently. Good communication skills (written, verbal, negotiation, conflict management, presentation). Innovative thinking, initiative, assertive and leadership qualities. Dedication and accurate work. Ethical behavior. Must be willing to travel and work irregular hours. Customer service. Planning and organizing skills.

DUTIES: Technical review of clinical trial applications and provide recommendations for approval/rejection of clinical trial applications: Technical screening and review of new clinical trial applications to ensure adherence to SAHPRA requirements. Review applicant responses and recommend for approval or rejection of clinical trial applications. Communicate the recommendations queries, approval or non-approval to the Applicants. Manage submission of clinical trial application cycles. **Technical Review of applications to conduct Bioequivalence studies and provide recommendations for approval/rejection of Bioequivalence studies**. Technical screening and review of new Bioequivalence studies to ensure adherence to SAHPRA requirements. Provide recommendations on applications to Authority (Clinical Trials Expert Committee, if required). Review applicant responses and recommend for approval or rejection of Bioequivalence studies. Communicate the

recommendations, approval or non-approval to the Applicants. **Provide technical support to appropriate Expert Committee/s and SAHPRA in general:** Co-ordinate clinical trials applications and monitor progress of review. Liaise advisory committee members and external reviewers. Prepare agenda and documentation to serve at the Clinical Trials Expert Committee. Support the proceeding of the Clinical Trial Committee meetings, including the expert consultation meetings. Prepare comprehensive minutes and recommendations following the meeting of the Clinical trials expert committee. **Review safety information, progress reports and any other clinical trials correspondence:** Review Serious Adverse Events (SAE) reports, progress reports and other safety reports during the Conduct of Clinical Trials and Bioequivalence studies. Validate the SAE reports on the system after review. Present the SAE Reports to Clinical Trials Safety Monitoring Committee / Clinical Trial Committee on critical findings. Set up systems to implement the process of SAE reporting. Advise on improvement of system or any other processes in the Unit. Liaise with advisory committee members Clinical Trials Safety Monitoring Committee. Prepare agenda and documentation to serve at the Clinical Trials Safety Monitoring Committee. Support the proceeding of the Clinical Trial Committee meetings. Prepare minutes and recommendations following the meeting of the Clinical Trials Safety Monitoring Committee. Communicate the recommendations to the external stakeholder. **Review applications for protocol amendments for clinical trials applications and Bioequivalence studies:** Screening and technical review of applications for protocol amendments in line with set timelines in annual operations plan. Advise on improvement of system or any other processes in the Unit. Check the status of all applications received to monitor timeline in line with Annual performance plan or annual operations plan. Respond and attend to queries and complaints timely related to applications from external stakeholder. Provide statistics on applications reviewed and outstanding in preparation for monthly reporting. **Review applications for additional investigators and sites for clinical trials applications and Bioequivalence studies:** Review investigators, change in investigators/Principal investigators or additional sites in line with the set timelines. Check the status of all applications received to monitor timeline in line with Annual performance plan or annual operations plan. Respond and attend to queries and complaints timely related to applications from external stakeholder. Provide statistics on applications reviewed and outstanding in preparation for monthly reporting. **Develop policies, guidelines as well as standard operating procedures for conducting clinical trial:** Drafting of policies, review policies and Preparation of Policy document. Develop SOPs, review SOP and ensure availability of SOPs at area of work. Ensures the business unit complies with the approved Standard Operating Procedure. **Manage and perform performance assessment of administrative staff and attend to queries addressed to the Clinical Trials Unit:** Manage and advise Admin staff to ensure compliance with timelines and attend to queries. Perform Performance assessment of admin staff. **Advise and attend to pharmaceutical industry / applicant's queries or other members of the Public:** Investigate and advise to pharmaceutical industry / applicant's queries or other members of the Public. Represent SAHPRA in the local, regional and/or global sphere. Participate in Industry Task Group working groups and external stakeholder meetings. **Manage the associated risks and audit queries:** Attend and support the internal and external Audit, including resolution of queries. *Align with QMS requirements.

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 might 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 B. Rakgotho, Email: bafedile.rakgotho@sahpra.org.za
(**APPLICATIONS SENT TO THESE EMAIL ADDRESSES WILL NOT BE CONSIDERED FOR THE RECRUITMENT PROCESS). The closing date is 10 February 2025 at 16H00**