The South African Health Products Regulatory Authority (SAHPRA) is the National Medicines Regulatory Authority established in terms of the *Medicines and Related Substances Act, 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 POST-REGISTRATION
SALARY: R700 105.00 – R888 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 29/2025
CENTRE: PRETORIA

REQUIREMENTS: Matric certificate and an appropriate four-year degree in Pharmacy at NQF Level 8 as recognised by the South African Qualifications Authority (SAQA) and registration with a Professional Body (South African Pharmacy Council) or an MBChB degree and registration as a Medical Officer with the Health Professions Council of South Africa (HPCSA). A relevant Masters degree in Health Sciences will be an added advantage.

EXPERIENCE:
Grade 1 – A minimum of two (2) years of clinical experience post-internship and community service. Regulatory experience of a least one (1) year will be an added advantage.

Grade 2 –A minimum of five (5) years of clinical experience post-internship and community service. Regulatory experience of a least one (1) year will be an added advantage.

COMPETENCIES, KNOWLEDGE, AND SKILLS: Knowledge and application of the Medicines and Related Substances Control Act (101 of 1965), as amended, and its related Regulations, concerning the regulation of medicines in terms of quality, safety, and efficacy. Knowledge and application of good review practices, SAHPRA guidelines, and other relevant international guidelines, e.g., ICH. Knowledge and understanding of the legal and regulatory framework governing the review process, locally and internationally. An understanding of the medicine's discovery process and the pharmaceutical regulatory environment. Technical proficiency in regulatory review practices, pharmacokinetics, pharmacodynamics, bioavailability/bioequivalence, clinical study data analysis, and review for safety, efficacy, and quality.

- Computer literacy (MS Office packages).

- Supervisory skills.
- Good planning, organisational, and interpersonal skills
- Good communication skills (written and verbal).
- Innovative thinking, initiative, and leadership qualities.
- Dedication and accurate work.
- Knowledge of database management will be advantageous.
- Must be willing to travel and work irregular hours.
- A valid driver's license.
- Ability to work well under pressure.
- Collaborative skills.
- Knowledge of quality management systems.
- Organisational awareness.
- Good decision-making and critical analytical skills.

DUTIES: **Reviewing a broad range of applications as a primary-, peer reviewer:** * Assess, analyse, and provide recommendations for minor safety amendments (Type Iain and Type IB) applications, including the applicant's responses to safety concerns raised by either the applicants or the Authority. * Identify key issues and critically evaluate scientific data (i.e., pharmacokinetic, bioavailability, and bioequivalence data, *in vitro* (pre-clinical) and *in vivo* clinical studies of a medicine with different endpoints) from multiple sources. * Provide recommendations for major safety and/or efficacy amendments for simpler and complex molecules. * Conduct a comprehensive review to ensure that the risk profile of each medicinal product is regularly updated to incorporate new information and that risk criteria are modified based on new statistical data on hazards, possible damages to manage their impact on clinical practice and public health. * Review and summarise relevant information from clinical trials for product information documents to ensure that the product information contains accurate claims on product effectiveness, safety and adequate directions for product use. * Consult other experts, act as a mentor, and guide assessments to other reviewers by conducting a critical review of their reports. * Ensure timeous reviews of applications. **Conducts evidence-informed practice: *** Identify the parts of a scientific publication and the general purpose of each part. Search published literature using key terms to find articles on specific subjects related to the application undergoing review. * Summarise the essential message and purpose of published materials, such as scientific publications, reports, or guidelines. * Utilise the full range of reference and resource materials in this area. **Makes or recommends regulatory decisions: ***Generate detailed scientific evaluation reports in line with the good review practice guide, ICH guidelines, SAHPRA guidelines and other relevant international standards for internal peer review and, where necessary, for presentation to the Advisory Clinical Committee. * Prepare evaluation outcome (recommendations/queries/approval/non-approval) to be communicated to the external stakeholders. **Technical Validation / Screening of Variation Applications and Responses: *** Ensure priority medicines and urgent applications/responses are screened and identified as such for rapid processing as per the priority review policy. * Attend to queries from previous and/or current screening cycle. * Ensure that the outcome is captured on the database and that a rejection/approval letter is sent out to the applicant. * Conduct thorough technical screening of variation applications for evaluation, i.e., ensuring references submitted to support the proposed amendments are appropriate and complete. * Assess submissions for compliance with the local regulatory requirements as stipulated in the variation addendum and other clinical guidelines**.** * Direct the implementation of

different regulatory pathways based on reliance, collaboration, and recognition. * Prepare a screening outcome report to be communicated to the external stakeholders. **Evaluation of Responses to Variations: *** Assess submissions for compliance with the Variation addendum and other clinical guidelines. * Primary and peer review of responses with clinical data for simpler molecules. *Prepare a critical clinical response evaluation report after the review of the safety and/or efficacy data from clinical studies, published literature sources, reliance decisions of other regulatory authorities, or review of documented signals. *Prepare evaluation outcome (recommendations/queries/approval/non-approval) and communicate outcome to the applicant. **Audit and Risk Management:** * Ensure an unqualified risk and internal audit opinion for Clinical Post-Registrations by submitting monthly POEs and updating the risk register monthly. * Continuously respond to the needs and expectations of the industry, external evaluators, and Internal queries within one (1) week. * Adherence to SOPs and SAHPRA, ICH, EMA, and other relevant guidelines. * Develop, review, and improve the accuracy of databases to enable revenue recognition by the Finance Unit. * Respond to relevant queries timeously. * Attend relevant training as may be necessary. **Implement internal communication and provide regulatory support through stakeholder management: *** Liaising with management, legal, and communication units for advice to clarify established SAHPRA systems and methodologies. * Provides comments, inputs and advice on international standards and guidance documents, representing the interest of SAHPRA at national, regional, and international levels. * Provides regulatory support and guidance to industry and other stakeholders of the Authority. * Provides support to management in the operation of the department/unit. * Participate in special projects and Pre and Post-registration working groups as required and engage in technical scientific discussions on ongoing applications under review. * Prepare discussion documents, including agendas, minutes and action items, and reports where required. * Preparation of recommendations for pharmacovigilance referral outcome. * Capturing and execution of Advisory Clinical Committee recommendations. *Participate in international scientific regulatory forums and discussion groups, including ICH or WHO, as relevant and when nominated. * Provide regular work plans and output to the manager. * Perform any other related duty as requested by the manager/senior manager.

INSTRUCTIONS TO APPLICANTS (HOW TO APPLY):

- Interested persons who meet the above-stated requirements should submit their application, including a signed cover letter. Clearly state the position name and post reference number, detailed Curriculum Vitae (CV) with the names and email addresses of three (3) referees, copies of required qualifications (including matric) 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.
- Should you have a foreign qualification, your application must be accompanied by an evaluation certificate (report) from SAQA.
- Incomplete applications or applications without the aforementioned documents or information will not be considered.
- No late applications will be accepted. Any submissions received after the specified date and time will not be considered, and CVs will not be returned.

- **Due to the larger number of responses anticipated, communication will be limited to short-listed candidates only. Applicants who have not been contacted within three (3) months after the closing date should consider their application to be unsuccessful.**
- Shortlisted candidates will be expected to attend selection interviews at a date, time, and location as specified by SAHPRA.
- Applicants should note that pre-suitability checks will be conducted after they have been shortlisted. Their appointment is subject to positive outcomes from these checks, which include security clearance, verification of qualifications, criminal records, credit checks, citizenship status, and work experience.
- SAHPRA is committed to being an equal opportunity employer. When filling vacant positions, the entity will consider the principles outlined in Section 195(1)(i) of the Constitution of the Republic of South Africa, Act 101 of 1996, and the Employment Equity Act, 55 of 1998. Applicants with disabilities (indicate their disability status, which will be appreciated) and males are encouraged to apply.
- SAHPRA reserves the right not to make any appointment(s) to the advertised post(s).
- SAHPRA adheres to the provisions of the Protection of Personal Information Act (POPIA), 4 of 2013. CVs will not be returned, as personal information you provide will be used solely for recruitment purposes, specifically for the position or vacancy you have applied for. If your application is unsuccessful, your personal information will be retained for internal audit purposes.
- Applications should be submitted through the SAHPRA Website Online Portal: https://www.sahpra.org.za/vacancies.
- **For enquiries:** Please contact Ms Bafedile Rakgotho, HR Business Partner, via email at bafedile.rakgotho@sahpra.org.za. **NOTE: APPLICATIONS SUBMITTED TO THIS EMAIL ADDRESS WILL NOT BE CONSIDERED AS PART OF THE RECRUITMENT PROCESS.**
- **The closing date is 10 June 2025 at 16:00.**