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 CONTROL OFFICER: REGULATORY COMPLIANCE
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 027/2024
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. A relevant Master's qualification 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) at NQF level 8 as recognised by SAQA plus a minimum of three (3) years' experience as a practicing pharmacist post Community Service, of which two (2) should be in pharmaceutical regulatory environment.

Grade 2: 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 plus a minimum of five (5) years' experience as a practicing pharmacist post Community Service, of which three (3) should be in pharmaceutical regulatory environment.

COMPETENCIES, KNOWLEDGE, AND SKILLS: A solid understanding of application procedures. Medicines Act as Amended and its Regulations. Consolidated Schedules. Planning and organisational skills. Interpersonal skills. Investigation skills. Computer skills and knowledge of MS Office. Drive and self-management skills. Communication skills. Report writing. Resilience. Assertiveness. Ethical behaviour. Ability to work under pressure and irregular hours. Professionalism. Ethical conduct and adherence to the SAHPRA Code of Conduct. Integrity.

DUTIES: **Investigation of compliance / non-compliance and reporting:** Investigate matters related to the contravention of the Medicines Act (Medical device establishments, Pharmacies, Complementary medicine establishments, Ports of entries, Illegal establishments etc. Investigate complaints relating to advertising of medicines (Control of promotional, marketing, and advertising activities). Allocated Post marketing surveillance of advertising cases. Issuing of authorizations for samples, reference standards etc relating to import, export. Processing of applications for donations. Processing of applications for Section 36. Coordinate, review applications for destruction of scheduled medicines/substances, medical devices and IVDs. Cooperation and collaborations with stakeholders locally and abroad. Review applications and compile possession permits for manufacturing and research. Detention/ Seizure of non-compliant products. Coordinate and schedule allocated investigations with team inspector as per allocation. Investigate and attend to industry /Applicant queries. Conduct joint inspection/s with law enforcement agencies (e.g. BMA, SARS, HPCSA, SAVC, SAPS & SAPC). Perform all activities according to relevant SOPs.

Responsible for overall Product Quality defects/ Complaints activities requiring Alerts and Recalls actions (Substandard /Falsified medical products): Identify activities relating Product Quality defects for a specifically requiring alerts. Apply the SOP for Alerts/Recalls timely. Ensure that management is updated. Ensure that appropriate communication is prepared for approval. Ensure that draft information for internal and external stakeholders is available for review and approval. Ensure that Applicants comply with conditions of alerts/recalls. Update the website notifications. Prepare monthly report for manager. Write an annual report for Alerts/Recalls. Provide feedback to relevant SAHPRA unit/s where applicable.

Inspection and reporting: Inspect allocated sites (e.g. Cannabis sites, pharmacies, wholesalers – site can be based on the complaint received). Reports to be completed within 30 working days from the inspection date. Help review the Investigations SOP and conduct inspections in accordance with SOP. Participate in Risk and Audit enquiries (internal and external audits). Compile reports and resolutions for the licensing unit or referral unit applicable. Ensure the reports comply with QMS approved formats.

Lodge criminal cases with the authorities and appear in court when subpoenaed: Where criminal offenses are identified, open criminal cases with SAPS, and write affidavits/statements. Attend to court as per subpoena. Assist SAPS/NPA with writing affidavits for crimes that relate to contravention of the Medicines Act.

Strengthen Cooperation with stakeholders (training, information sharing): Participate in BMA, SARS, SAPS HPCSA & SAPC as aligned with MOUs. Attend meetings, conferences and briefings with stakeholders including workshops and training overseas. Support the initiatives of stakeholders which are relating to contravention of the Medicines Act. Support the Communication department's queries relating to media. Training of stakeholders. Consult with internal core business and support units whenever applicable (Manager, Senior Manager, Executive Management, Advisory Committees, CAMS, Medical Device Unit, Section 21, Names and Scheduling, Veterinary, Biological). Foster cooperation and collaboration with relevant SAHPRA units to enhance appropriate regulatory outcomes on matters. Foster cooperation and collaboration with statutory bodies, industry associations, activist organizations and media. Attend operations quarterly with law enforcement agencies.

Reporting: Participate in risk and audit queries relating to your focal area. Submit and present performance reports on your focal area monthly. Comply with QMS requirements for a clean audit. Review SOP and Guidelines for Alerts, Recalls and Withdrawals as required.

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.**