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
(DPSA Equivalent Level OSD CTC: GR 2 = R702 819; GR 3 = R796 041)
Ref No.: SAHPRA 002/2022

CENTRE: Pretoria

REQUIREMENTS: • A four-year degree in Pharmacy and Registration as a Pharmacist with SAPC. • Sound and in-depth knowledge of the regulatory compliance requirements in South Africa.
Experience: • A minimum of 5 years as a pharmacist (post registration as a community pharmacist) with at least 3 years of pharmaceutical quality assurance experience. • Experience or knowledge of pharmaceutical testing laboratories would be an advantage. • Proof of registration as a Pharmacist must be submitted with your application.

COMPETENCIES, KNOWLEDGE AND SKILLS: * A solid understanding of application procedures. * Knowledge and understanding of the international regulators. * Planning and organisational and skills. *Interpersonal skills*Investigation skills, * Computer skills and knowledge of MS Office. * Drive and self-management skills. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Resilience * Assertiveness.
* Ethical behaviour. * Must possess a valid driver's licence.

DUTIES:

1. **Plan, organise, perform and report on your activities in enforcing and monitoring compliance to the provisions of the Medicines and Related Substances Act and align with applicable Acts:**
    - Develop, review and ensure implementation of approved Standard Operating Procedures (SOPs) for regulatory compliance (law enforcement).
    - Perform activities within approved processes within the Regulatory Compliance Unit and report to manager on Improvement measures needed.
    - Supervise the admin personnel, their performance and conduct their performance reviews.
    - Participate in risk and audit queries.
    - Submit weekly work-plan and output to the Manager: Regulatory Compliance (quantitative and qualitative reports).
    - Prepare reports for consideration by the Manager: Regulatory Compliance, Senior Manager, and Executives.

- Prepare reports for the unit Manager in preparation for SAHPRA and relevant advisory committees.
- Investigate complaints regarding contravention of the Medicines Act.
- Issue warning letters to transgressing companies or individuals by Inspectors.
- Monitoring and control of border posts and mail centres for importation and **exportation of health products.**

2. **Monitor and enforce compliance with the provisions of the Medicines Act and other related Health Acts and collaborate with local and international organisations:**
    - Develop necessary processes that ensure compliance of Laboratory testing function.
    - Monitor the outsourced activities that are current and in compliance with service level agreements and relevant compliance standards.
    - Oversee the activities for laboratory testing throughout supply chain.
    - Develop, implement and evaluate the annual market surveillance programme involving sampling and testing of medical products throughout supply chain to ensure compliance of products.
    - Evaluate risks regarding the safety, quality and efficacy of health products available to the public and advise manager on measures to be adopted or actions to be taken by licence holders and/or law enforcement authorities.
    - Support the manager with any other matters relating to the unit expected outputs.

3. **Develop and maintain relations with local and international organisations:**
    - Liaise with SAPS and SARS Customs officials regarding law enforcement.
    - Conduct training for border management personnel on handling of importation and exportation of medicines.
    - Communicate with the industry, public and SAHPRA Board, health professional bodies and other stakeholders.
    - Communication to other government departments and healthcare industry on illegal medical products.
    - Foster and develop networks on pharmaceutical crime with other regulatory authorities and relevant stakeholders.
    - Develop and maintain relations with the International Narcotics Control Board and translating requirements for SAHPRA context.
    - Investigate and attend to industry / applicants' queries.

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 of 3 referees and recently certified copies of ID and qualification/s.
- Applications without the afore mentioned 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.
- Applications must be submitted by email to **recruitment@sahpra.org.za,** including the required certified documentation as indicated. **DO NOT MAKE ENQUIRIES TO THIS ADDRESS.**
- 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: 07 February 2022 at 16H00.