



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.

**MANAGER: REGULATORY COMPLIANCE**  
**Ref No.: SAHPRA 048/2020**

**CENTRE: Pretoria**

**REQUIREMENTS:** • Appropriate 3-year degree in Chemistry or Bachelor of Pharmacy degree. Registration with SAPC. • A Post-graduate or equivalent appropriate qualification or Management Degree is preferred. • Sound and in-depth knowledge of the regulatory compliance requirements in South Africa.

**Experience:** A minimum of 8 years relevant experience, 3 years at supervisory or middle management level.

**COMPETENCIES, KNOWLEDGE AND SKILLS:** \* A solid understanding of application procedures. \* Comprehensive knowledge and understanding of the international regulators. \* Planning and organisational and skills. \* Performance measurement 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. \*A valid driver's licence.

**DUTIES:** • **Plan, organise, co-ordinate and control the activities of the Regulatory Compliance Department:** \* Supervise the development and implementation of Standard Operating Procedures (SOPs) for regulatory compliance (law enforcement), to be accepted by SAHPRA. \* Monitor and evaluate implemented processes within the Regulatory Compliance Unit. \* Supervise the Regulatory Compliance department personnel and their performance. \* Manage risk and audit queries. \* Submit weekly work-plan and output to the Senior Manager: Inspectorate and Regulatory Compliance (quantitative and qualitative reports). \* Prepare reports for consideration by the SAHPRA Board, CEO and the Director-General and Minister of Health. \* Prepare reports for SAHPRA and relevant advisory committees. • **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.

• **Monitor and enforce compliance with the provisions of the Medicines Act and other related Health Acts:** \* Ensure investigation of complaints regarding contravention of the Medicines Act. \* Monitor the issuing of warning letters to transgressing companies or individuals by Inspectors. \* Ensure the monitoring and control of border posts and mail centres for importation and exportation of health products. \* Supervise the inspection programme for cultivators of cannabis for producing scheduled substances and pharmaceutical companies / permit holders where schedule 5, 6, 7 & 8 substances are kept. \* Evaluate risks regarding the safety, quality and efficacy of health products available to the public and advise SAHPRA Board on measures to be adopted or actions to be taken by licence holders and/or law enforcement authorities. \* Manage a permit issuing process that is controlled and accurate, ensuring that reporting requirements to the INCB are met timeously. \* Supervise the review and approval of Section 36 exemptions. \* Oversee the preparation of expert reports and attend to cases for prosecution.

**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](mailto: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](mailto:setlola.molepo@sahpra.org.za) (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS**).

**CLOSING DATE:** 16 November 2020 at 16H00.