



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 (PEM: Veterinary)**  
**DPSA Equivalent Level OSD TCE: GR 1-3**  
**Ref No.: SAHPRA 041/2020**

**CENTRE: Pretoria**

**REQUIREMENTS:** • Appropriate 4-year Bachelor of Pharmacy Degree. • Regulatory experience will be an added advantage.

**COMPETENCIES, KNOWLEDGE AND SKILLS:** \* Knowledge and application of the Medicines and Related Substances Act (101 of 1965) as amended and its related Regulations and Guidelines. \* Knowledge of technical aspects for evaluation of quality of medicines. \* Computer literacy and sound working knowledge of computer software packages. \* Technical and scientific aspects of medicine regulation. \* Evaluation guidelines as prescribed by SAHPRA and the RRA. \* Planning and organisational skills. \* Coordination skills. \* Written and communication skills. \* Time management. \* Interpersonal skills.

**DUTIES:** • **Assess and peer review new applications for the registration of medicines:** \* Technical screening and evaluation of the quality aspects new applications and responses for registration of medicines. \* Generate evaluation reports for each application and submit report to second evaluator for peer review. \* Present report to the Advisory Committee where necessary. \* Amend report accordingly and generate queries to the applicant. \* Peer review applications and perform quality assurance of peer reviewed reports. \* Prepare the Summary Basis for Registration/Rejection. • **Evaluate quality variations for registered medicines:** \* Evaluate variations of registered medicines. \* Generate evaluation report for peer review. \* Prepare report for internal peer review. \* Amend report accordingly and generate queries. • **Form part of technical working groups and special projects to support the work of SAHPRA:** \* Participate in special technical projects to support the work of SAHPRA. \* Take comprehensive relevant notes of discussions. \* Review existing Guidelines/SOPs and update old ones when necessary. • **Assess clinical trial protocols and research on Section 21 referrals:** \* Technical screening of clinical trial protocols. \* Assessment of protocols and generation of reports. \* Present protocols for discussion at Advisory Committee meeting and compile queries to the applicant. \* Assess and research on complex Section 21 requests. • **Risk Management and Audit:** \* Implement the QMS: SOP and Guidelines must be adhered to. \* Compile and report weekly on progress of work allocated by the Manager. \* Respond to relevant technical queries timeously. \* Attend unit, other internal and external meetings, and workshops to upskill.

**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 form 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 or faxed 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:** 09 October 2020 at 16H00.