



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.

INSPECTOR EVALUATOR (OFFICE BASED)

Ref No.: SAHPRA 051/2023

SALARY LEVEL 11(R788 910 to R837 326 per annum (Total cost to company))

CENTRE: Pretoria

REQUIREMENTS:

- 4-year bachelor's degree in pharmacy.
 - a. Proof of registration as a pharmacist must accompany your application if you have a B-Pharm degree.
- 3 years' experience in a pharmaceutical industry post community service, preferably GMP
- Extensive knowledge of GxP regulations and industry practice, as well as substantial experience of undertaking GxP inspections within a regulatory environment
- Sound knowledge of the Medicines and Related Substances Act 101 of 1965 as amended and all regulations pertaining to the Act.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES:

Comprehensive and sound knowledge of all relevant legislation, protocols, regulations, and guidelines pertaining to the Medicines and Related Substances Act 101 of 1965. * Good verbal and numerical reasoning skills to allow analysis and interpretation of written and numerical data. * Good communication skills (verbal, written, conflict management and resolution). * Delivery of service objectives with professional excellence and efficiency. * Ability to make effective decisions by using evidence and knowledge to support accurate, expert decisions and advice while carefully considering the implications of such a decision. * Ability to work unsupervised for long periods of time. * Ability to work within a team environment. * Good planning and organisational skills. * Ability to meet tight deadlines and manage multiple, often

competing priorities. * Knowledge of MS Office. * Valid Driver's License. * Ethical behaviour and adherence to the SAHPRA Code of Conduct.

DUTIES:

- To evaluate applications from HCRs and manufactures for the introduction of new medicine in line with the Medicine and Related Substances Act, No. 101 of 1965.
- To perform evaluations of once- off deviations by HCR or manufacturers
- To evaluate type 1 and type 2 variations as per guidance SAHPS-INSP-GMP-13
- To perform desktop reviews/ assessments for manufacturing and testing facilities, thus reducing duplication and frequency of inspections.
- To assess and evaluate the applications for Post Importation Testing exemptions.
- To evaluate and issue GMP and CPP certificates applications.
- Evaluate Standard Operating Procedures (SOPs) of Inspectorate for compliance with GMP Guidelines as adopted by SAHPRA.
- To work closely across inspection teams, SAHPRA departments and external regulators to ensure evaluation activities are planned and communicated effectively.
- To support inspectors by providing relevant and timely information related to any inspections that are to be carried out.
- To contribute to the Inspectorate's compliance management process by ensuring that instances of suspected or known non-compliance are handled in the appropriate manner.
- Liaise with inspectors across internal departments.
- Assist in minuting the recommendations of relevant advisory committees of SAHPRA applicable to the activities of the inspectorate.
- Record statistics of generated and peer-reviewed reports
- Attend on-the-job training and apply continuous professional development principles to ensure knowledge remains relevant and current in line with any regulatory requirements.

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 and email addresses of 3 referees and recently certified copies of ID, required qualification/s (matric included) and driver's licence where applicable.
- 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 or faxed applications will be accepted. CV's 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: Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS**).

CLOSING DATE: 26 October 2023 at 16H00.