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 (GMP) [Scientist / Pharmacist]
Ref No.: SAHPRA 031/2020

DPSA Equivalent Level OSD TCE: Medicine Control Officer Gr 1-3 (11)

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree or BSc in a Biological Science or equivalent. Registration with SAPC or HPCSA. Proven experience. • Grade 1: No experience needed. • Grade 2: Chemistry degree - 10 years, B Pharm Degree - 8 years, Registration as Pharmacist - none. • Grade 3: Chemistry Degree - 18 years, B Pharm degree – 16 years, Registration as a Pharmacist - 8 years.

COMPETENCIES, KNOWLEDGE AND SKILLS: * Sound and in-depth knowledge of the Medicines and Related Substances Act 101, 1965 as amended and the regulations pertaining to the Act. * Sound knowledge of regulatory scientific and technical requirement (to assess the quality, safety and efficacy aspect). * Sound and in-depth knowledge of the administrative processes for registration of medicines in the Republic of South Africa. * Experience in the pharmaceutical industry. * Prepared to travel and work irregular hours. * Comprehensive knowledge and understanding of the international regulators. * Planning and organising skills. * Performance measurement skills. * Knowledge of MS Office. * Computer skills. * Drive and self-management skills. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Resilience. * Ability to work in a highly pressured environment and driven by a sense of urgency to meet deadlines. * Assertiveness. * Ethical behaviour. *A valid driver's licence.

DUTIES: * Inspect pharmaceutical manufacturing sites, locally and internationally for compliance with Good Manufacturing Practices (GMP) as accepted by SAHPRA. * Assess and evaluate GMP inspection reports of other regulatory authorities on international pharmaceutical manufacturing sites where medicines for exportation to South Africa are manufactured. * Evaluate Standards Operating Procedures (SOPs) of manufacturing sites for compliance with GMP Guidelines as accepted by SAHPRA. * Perform Pre- and Post-Registration inspections on information submitted in a medicine application form (MRF1). * Prepare reports for SAHPRA and relevant advisory committees.

***** Liaise with inspectors from international regulatory authorities. * Assist in minuting the recommendations of relevant advisory committees of SAHPRA applicable to the activities of the inspectorate. * Interview members from industry to discuss SAHPRA Board resolutions, requirements of the Act and medicines quality issues. * Investigate and attend to industry / applicants' queries. * Perform other functions that may arise from time to time. * Record statistics of generated and peer reviewed reports. ***** Manage the associated risks and audit queries. * Submit weekly work-plan and output to the Unit manager (quantitative and qualitative reports).

INSTRUCTIONS TO APPLICANTS: All applications must:

- Be made on Z83 forms (obtainable http://www.dpsa.gov.za/dpsa2g/ documents/forms/employ.pdf or from any Government department).
- Be completed in full, clearly reflect 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, 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: Ms S. Molepo, Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 20 July 2020 at 16H00.