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) X2 [Scientist / Pharmacist] **Gr 2-3**
(DPSA Equivalent Level OSD TCE: Grade 2: R692 433 p/a; GR 3: R784 278 p/a)
Ref No.: 020/2021

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree or BSc in Chemistry or Biological Science or equivalent. Proven experience within pharmaceutical industry will be an advantage.
Experience: • Grade 2: Chemistry degree or Biological Science degree - 10 years appropriate experience; B Pharm degree and SAPC registration as a Pharmacist / B-Pharm Degree - 8 years appropriate experience; **• Grade 3:** Chemistry degree or Biological Science degree - 18 years appropriate experience; B-Pharm degree and registration as a Pharmacist with minimum 8 years appropriate experience / B-Pharm degree – 16 years appropriate experience. Proof of registration as a Pharmacist must be submitted with your application.

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 and in-depth knowledge of the Pharmacy Act as it pertains to regulating the pharmaceutical industry. * 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, be away from home for weeks at time and work irregular hours. * Comprehensive knowledge and understanding of the international regulators and guidelines. * Planning and organising skills. * Performance measurement skills. * Knowledge and application of MS Office. * Computer skills and updating trackers including financial parameters. * Drive and self-management skills. * Communication skills (verbal, written, negotiation, conflict management, presentation, assertiveness). * Resilience. * Ability to work in a highly pressured environment and driven by a sense of urgency to meet deadlines. * Ethical behaviour. *A valid driver's licence.

DUTIES: * To conduct inspections across the following GXPs (Good Manufacturing Practice, Good Distribution Practice, and Good Laboratory Practice) across the full life cycle of medicines, both within the SA and overseas to ensure Safety, Quality and Efficacy of products with the aim of protecting Public Health. * Inspections may be done on an individual basis or as part of a team. ***** Inspect pharmaceutical manufacturing sites, locally and internationally for compliance with Good Manufacturing Practices (GMPs) as accepted by SAHPRA and other PICS aligned Regulatory Agencies. * Assess and evaluate GMP inspection reports of other regulatory authorities on international pharmaceutical manufacturing sites where medicines for exportation to South Africa are manufactured. * Compile SOPs for Inspectorate. * Evaluate Standards Operating Procedures (SOPs) of manufacturing sites for compliance with GMP Guidelines as accepted by SAHPRA. * Assess

GMP compliance of product registration applications, and Type I and Type II variations as per SAHPRA guidelines and portfolios of evidence to the support SAHPRA guidelines. * Perform Pre- and Post- Registration inspections on information submitted in a medicine application form (CTD). * Prepare reports within defined timelines for SAHPRA and relevant advisory committees. * Assess responses to audit reports within defined timelines for SAHPRA and relevant advisory committees. ***** Liaise with inspectors from international regulatory authorities and be part of and conduct remote and on-site audits as part of joint collaboration programs e.g., ZAZIBONA. * Assist in minuting the recommendations of relevant advisory committees of SAHPRA applicable to the activities of the Inspectorate. * Investigate and attend to industry / applicants' queries. * Perform other related 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 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 aforementioned documents/information 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: 17 September 2021 at 16H00.