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: PHARMACEUTICAL EVALUATION - POST-REGISTRATION
DPSA Equivalent Salary Level 12 (Non-OSD)
Ref No.: SAHPRA 035/2021

CENTRE: Pretoria

REQUIREMENTS: • B. Pharm degree or a Bachelor of Science degree in related health sciences with an NQF 9 level post-graduate qualification in Pharmaceutical Policy or Medicines Regulatory policy or Pharmaceutics or Pharmaceutical Chemistry. • A qualification in general management will be an added advantage. • A sound and in-depth knowledge of local and international requirements and policy basis for the regulation of medicines.
Experience: • A minimum of 6 years relevant experience in technical and regulatory aspects of both pharmaceutical quality (CMC) and bioequivalence. • Supervisory or middle management experience in medicines regulatory environment will be an added advantage.

COMPETENCIES, KNOWLEDGE AND SKILLS: * Knowledge of medicine regulation. Knowledge and understanding of relevant legislations, protocols, SOPs and work instructions. * Good clinical practice knowledge. * Good technical knowledge of area managed. * Financial and budgeting skills. * Knowledge of eCTD. * Planning and organising skills. * Computer skills and knowledge of MS Office. * Drive and self-management skills. * Communication skills (verbal, writing reports and minutes, presentation, training). * Research skills. * Interpersonal skills. * Analytical skills * Team leadership. * Ethical behaviour. *A valid driver's licence.

DUTIES: • Develop and implement an annual strategic plan and budget (APP) for own area of responsibility that supports the achievement of the overall organisational strategy. • Appropriate management of the budget and revenue aspects. • Oversee technical post-registration pharmaceutical assessment of applications submitted by industry for variations to registered medicines, to ensure compliance with appropriate standard operating procedures and processing benchmarks (i.e., time, quality, etc.). • Monitoring of review timelines and ensuring that evaluation targets are achieved. • Review documentation prepared by evaluators for peer review approval or submission to relevant technical advisory committee to ensure compliance with quality standards, relevant legal requirements and standard operating procedures of SAHPRA. • Oversee processes development and/ or amend technical policy documents, regulations, standards, protocols, guidelines and standard operating procedures pertaining to the regulation of medicines. • Have regulatory policy oversight. • Consolidate inputs from evaluators and prepare management reports in accordance with work instructions and prescribed formats and timeframes. • Consult with representatives from the relevant industry and other relevant stakeholders to advise on administrative procedures and technical matters in ensuring compliance to relevant local and international legal and regulatory

requirements. • Communicate with counterparts in other regulatory authorities on matters of common regulatory interest. • Be aligned with ICH and other international regulatory and global best practices. • Respond to queries and provide information and/ or guidance to the public regarding the quality, safety and efficacy of medicines - This includes education of stakeholders to ensure that they are informed of the expected regulatory requirements and standards. • Perform the role of an evaluator when required. • Liaise with internal auditors to identify risks, and external auditors, and provide information as required for completion of audits. • Manage the associated risks and audit queries. • Prepare annual budget estimates, quarterly performance reports and monthly financial reports for the Unit. • Develop, train and manage employees reporting to this job to ensure that they have the required skills and are able to perform and achieve their key job accountabilities and performance objectives. • Complete performance agreements of staff reporting to the manager and perform assessments as per human resource requirements. • Investigate and attend to industry/applicants' queries. • Record statistics of generated and peer reviewed reports. • Submit weekly work-plan and output to the Senior Manager: Pharmaceutical Evaluation (quantitative and qualitative reports) and APP reports as scheduled**.** • Perform other related functions that may arise from time to time and as delegated by the Senior Manager.

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,** 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.