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.

Re- Advertisement of Ref no:. SAHPRA 042-2023. Candidates who previously applied are encouraged to reapply.

TECHNICAL OFFICER: MEDICAL DEVICES CLINICAL TRIALS
SALARY: R 657 376.00 – R834 199.00 per annum. (TOTAL COST TO COMPANY)
(Grade 1 – Grade 2) Market related salary will be determined by the years of experience obtained post qualification and community service.
Ref No.: SAHPRA 078/2023

CENTRE: Pretoria

Requirements: Matric certificate and appropriate 4-year Bachelor of Pharmacy Degree and registration as a Pharmacist with South African Pharmacy Council (SAPC) or / Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA. A relevant Master's qualification will be an added advantage.

Grade 1 – 4-year Bachelor of Pharmacy Degree NQF or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of five (5) of experience in pharmaceutical regulatory environment. Training in (i) regulation and/or registration of medical devices and (ii) assessment of quality, safety, performance of medical devices.

Grade 2 - 4-year Bachelor of Pharmacy Degree NQF level 8 as recognised by SAQA and registration as a Pharmacist with South African Pharmacy Council (SAPC) and minimum of three (3) years of experience in pharmaceutical regulatory environment. Training in (i) regulation and/or registration of medical devices and (ii) assessment of quality, safety, performance of medical devices or Honours Degree in Chemistry or equivalent related qualification at NQF level 8 as recognised by SAQA plus a minimum of ten (10) years of experience in pharmaceutical regulatory environment. Training in (i) regulation and/or registration of medical devices and (ii) assessment of quality, safety, performance of medical devices

COMPETENCIES (KNOWLEDGE, SKILLS AND ABILITIES): * Comprehensive knowledge and understanding of relevant legislation, standard operating procedures and work instructions. * Preparation of financial reports. * Performance measurement skills. * Self-motivated and able to work independently. * Ability to work with a variety of cross-functional team members. * Competent in problem solving. * Information evaluation. * Decision making.

* Objectivity. * Resilience. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Interpersonal skills. * Assertiveness. * Ethical behaviour. * Customer service. * Planning and organising skills.

DUTIES: Develop and maintain guidelines and standard operating procedures for medical device and IVD clinical trials. (Quality Management: * Internal review, draft, creation of new Guidelines and publications. * Review and drafting of SOPS related to technical review. * Call up notices for 1st phase drafted and review. * Phase drafted and review. *Review of MOU). Technical screening of new clinical trial applications and allocation of clinical trials to the evaluators. Finalisation of medical device clinical trials within 60 days (including RUO) Review protocol amendments and additional investigators and site. Attend to queries addressed concerning Clinical Trials Unit. Evaluate and manage applications for clinical trials of medical devices and IVDs and maintain relevant databases. To evaluate applications for clinical trials for medical devices being conducted in South Africa or Outside South Africa, if necessary. Support the work of committee (CEC and MDC): Prepare reports for SAHPRA and relevant advisory committees. Liaise with international regulatory authorities. Assist in minuting the recommendations of relevant advisory committees of SAHPRA applicable to the activities of the unit (Recommendations sent to application in a timely manner). Interview members from industry to discuss SAHPRA Board resolutions, requirements of the Act and medical device and IVD clinical trial issues. Investigate and attend to industry / applicant's queries. Perform other relevant functions that may arise from time to time. Capture and maintain data relating to measuring and monitoring performance metrics and peer reviewed reports, and record statistics generated, including the units quarterly report and monthly financial reports. Manage the associated risks and audit queries, and correspondence from applicants and stakeholders. Submit weekly work-plan and output to the Unit manager (quantitative and qualitative reports). Internal Audit: * No. of audit findings per internal audit per quarter (Technical Related). * Monthly Finance reporting.

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 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.
- 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: The closing date has been extended to the 12 January 2024 at 16H00. SAHPRA apologies for any inconvenience caused.