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.

TECHNICAL OFFICER: MEDICAL DEVICES REGISTRATION
SALARY: R788 910.00 – R837 326.00 (TOTAL COST TO COMPANY)
Ref No.: SAHPRA 039/2023

CENTRE: Pretoria

REQUIREMENTS: • Four year Natural / Medical Sciences / Clinical engineering / Pharmacy Degree (Proof of registration with the SAPC as a Pharmacist for B-Pharm degree). • Relevant post graduate qualification will be an advantage. • Training in: * Regulation and/or registration of medical devices. * Assessment of quality, safety, performance of medical devices.
EXPERIENCE: • A minimum of 3 years relevant experience in: * Regulation and/or registration of medical devices. * Assessment of quality, safety, performance of medical devices * Development and maintenance of standard operating procedures and technical guidelines. * Teamwork. * Scientific report writing.

REQUIRED 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 registration (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).
- Evaluate and manage applications for registration 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.
- 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).
- Liaise with international regulatory authorities.
- Interview members from industry to discuss SAHPRA Board resolutions, requirements of the Act and medical device and IVD quality 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.
- 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: 15 September 2023 at 16H00.