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 COMPLIANCE

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 022/2024
CENTRE: PRETORIA

REQUIREMENTS: Matric certificate and a 4-year degree in Pharmacy or Honours Degree in Medical Sciences /Clinical Engineering at NQF level 8 as recognised by SAQA. Registration with the relevant professional body. Postgraduate qualification will be an added advantage. Valid Driver's License.

EXPERIENCE: Grade 1 – 4-year degree in Pharmacy or Honours Degree in Medical Sciences /Clinical Engineering at NQF level 8 as recognised by SAQA. Registration with the relevant professional body. Minimum three (3) years' experience of which two (2) years' must be regulatory in Medical Devices and IVDs. Knowledge and/or understanding of Medical Devices Regulatory Compliance, QMS and Medical Devices Licencing and legislative requirements.
Grade 2 – 4-year degree Pharmacy or Honours Degree in Medical Sciences /Clinical Engineering at NQF level 8 as recognised by SAQA. Registration with the relevant body. Minimum eight (8) years' experience of which five (5) years' must be regulatory in Medical Devices and IVDs. Working knowledge and/or understanding of Medical Devices Regulatory Compliance, QMS and Medical Devices Licencing requirements.

CORE COMPETENCIES, TECHNICAL PROFICIENCIES, AND VALUES: Comprehensive knowledge and understanding of relevant legislation, Medicine and Related Substances Act 101 of 1965, Regulations relating to Medical Devices and IVDs. Computer literacy and MS windows computer skills, Excel and database applications. Good report writing and presentation skills. Good planning and organization skills. Good verbal and written communication skills. Self-motivated and able to work independently. Ability to manage a variety of cross-functional team members. Pay attention to detail and information evaluation. Ethical behaviour and adherence to the SAHPRA Code of Conduct. At SAHPRA we adhere to our core values: Ubuntu, Responsiveness, Integrity, Transparency, Efficiency, Excellence.

DUTIES:
Evaluate and manage licence applications for medical device establishments and maintain relevant databases. Prepare reports for SAHPRA and relevant advisory committees, for compliance related matters. Assist in minuting the recommendations of relevant advisory committees of SAHPRA applicable to the activities of the unit. Liaise with international regulatory authorities. Monitor compliance with the provision of the Medicines Act and other related Health Acts regarding medical devices and IVDs. Develop and review guidelines and standard operating procedures for Medical Devices Licencing. Proactively audit processes, practices, guidelines and standard operating procedures for Medical Devices Licencing. Acts as contact person and liaison between Regulatory Compliance, QMS and Medical Devices Licencing.
Facilitate training of Medical Devices Licencing staff on matters related to any legal changes and updates to compliance guidelines. Investigate complaints from Regulatory compliance for any transgressions against the Medicines Act and other related Health Acts regarding medical devices and IVDs. Communicate with the members from industry regarding the SAHPRA Board resolutions, legislative requirements for medical device and IVDs. Investigate and attend to industry / applicants' queries. Capture and maintain data relating to measuring and monitoring of performance metrics and peer reviewed reports, and record statistics generated. 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). Perform other related functions that may arise from time to time.

INSTRUCTIONS TO APPLICANTS (HOW TO APPLY): Interested applicants who meet the above requirements should forward their applications accompanied by signed covering letter attached to the comprehensive CV with the names and email addresses of three (3) referees clearly reflecting the **name of the position and post reference number**, 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. **All shortlisted candidates will be subjected to a technical exercise that intends to test relevant knowledge, skill and technical elements of the job.**
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.

Interested persons who meet the above-stated qualifications should forward their applications which should consist of a cover letter, detailed Curriculum Vitae, copies of qualification(s) and Identity Document. ONLY shortlisted candidates will be required to submit certified copies of qualifications and other related documents on or before the day of the interview following communication from Human Resources.

SAHPRA comply with the provisions of Protection of Personal Information Act (POPIA); Act No. 4 of 2013. We will use your personal information provided to us for the purpose of recruitment only and more specifically for the purpose of the position/vacancy you have applied for. In the event your application was unsuccessful, SAHPRA will retain your personal information for internal audit purposes as required by policies.

Applications should be submitted through the SAHPRA Website Online Portal: **SAHPRA website (**https://www.sahpra.org.za**) – About Us – Vacancies**.

Enquiries: Ms S. Molepo, Email: setlola.molepo@sahpra.org.za **(APPLICATIONS SENT TO THIS EMAIL ADDRESS WILL NOT BE CONSIDERED FOR THE RECRUITMENT PROCESS). The closing date is 28 June 2024 at 16H00.**