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: MEDICAL DEVICES & IVDs (REGISTRATION, CLINICAL TRIALS & SECT 21)

(Readvertisement)
Ref No.: SAHPRA 015/2021

CENTRE:
Pretoria

REQUIREMENTS: * A 3 years university degree with honours in Health sciences or a 4-year university degree in Health Sciences. * A post-graduate degree will be an added advantage. *

Experience: * 10 years of experience in regulation and/or quality management of medical devices or medicines as a minimum requirement. * minimum 5 years supervisory experience. * Knowledge of and experience with relevant national legislation, international standards and best practices, e.g. IMDRF, WHO, AMDF, AHWP requirements.

COMPETENCIES/SKILLS: * Advanced knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. * Management of operational plans, business plans and budgeting. * Performance management and team management skills. * Self-motivated and ability to work independently. * Ability to manage a variety of cross-functional team members. * Competent in problem solving, research skills and team building. * Attention to detail. * Information evaluation. * Decision making. * Objectivity. * Resilience and ethical behaviour. * Communication skills (verbal, written, negotiation, conflict management, presentation). * Interpersonal skills. * Assertiveness. * Customer/Licensee service. * Planning and organising skills * Flexibility. *A valid driver's licence.

DUTIES:

- **Manages and controls the operations, processes, and innovations of the Medical Devices & IVDs Unit: Registration, Clinical Trials & Section 21 by:** * Developing and co- ordinating systems for management of all operations of the Medical Devices & IVDs Unit: Registration, Clinical Trials & Section 21. * Managing the regulation of medical devices and IVDs. * Managing the development, implementation and maintenance of regulations, guidelines, policies and procedures pertaining to regulation of medical devices and IVDs, to ensure alignment with international and national protocols, legislations and other legal requirements. * Preparing monthly, quarterly and annual reports for work done within the Medical Devices & IVDs Unit: Registration, Clinical Trials & Section 21 including monitoring of

the timelines. * Preparing reports to be submitted to relevant technical committee for their information, discussion, review and/or recommendation to the relevant advisory committee in accordance with prescribed legal requirements and standard operating procedures of SAHPRA. * Managing surveillance mechanisms to detect, assess and prevent adverse reactions related to medical devices and IVDs. * Managing compliance to service level agreements with outsourced support services to ensure achievement of agreed quality and delivery standards. * Managing general financial budgeting, human resources and performance of the Medical Devices & IVDs Unit: Registration, Clinical Trials & Section 21. * Performing such other functions as the Senior Manager: Medical Devices & Radiation Control may duly allocate or delegate from time to time.

- **Ensures effectiveness of Medical Devices & IVDs Unit: Registration, Clinical Trials & Section 21 operational processes by:** * Developing operational plans and budget for the Medical Devices & IVDs Unit: Registration, Clinical Trials & Section 21 aligned with organisational needs and ensuring the most effective utilisation of resources. * Managing, reviewing and optimising operations and processes. * Managing, developing, reviewing, and improving the accuracy of databases. * Managing operations, processes, and projects between the five sections within the unit. * Managing effective utilisation of resources to enhance value for money. * Developing (and reviewing) internal policies, in collaboration with senior management. * Evaluating and improving security (physical, information, cyber).
- **Manages the appropriate development, evaluation, and continuous improvement of regulatory control by:** * Advising on and leading processes to improve regulatory control and cooperative governance. * Managing research projects and new developments in these fields.
  * Managing international, regional and national technical cooperation projects. * Managing regulatory systems for medical devices and IVDs. * Identifying gaps, overlaps and shortcomings in the regulatory control and cooperative governance processes. * Maintaining confidentiality and ethical behaviour.
- **Builds human capital in the Medical Devices & IVDs Unit: Registration, Clinical Trials & Section 21 by:** * Training and managing the deputy manager reporting to this role to ensure they have the skills required by the organisation and can achieve their performance objectives. * Working with Senior Manager: Medical Devices & Radiation Control and relevant functional heads to develop plans and procedures for information and knowledge management and the sourcing, acquisition, and development of staff with required critical skills. * Ensuring that a high level of integrity is maintained by staff members by promotion of high ethical conduct and maintenance of high-performance standards.
- **Implements internal communication and incident reporting procedures by:** * Managing the effective, timeous communication and consulting thereon regarding issues relating to medical devices and IVDs. * Liaising with representatives from industry and international regulators, and other relevant stakeholders to ensure appropriate and correct information and establishment of productive and relevant relationships. * Liaising with senior management and the legal and communications departments for advice and to clarify established SAHPRA systems and methodologies. * Providing comments, inputs and advice on international standards and guidance documents, representing the interests of South Africa under the guidance of senior management. * Managing investigation of adverse events and the formulation of appropriate communications with licensees, other regulatory authorities, and general public, in collaboration with the Manager: Licensing, Vigilance & Compliance and under the guidance of the Senior Manager: Medical Devices & Radiation Control. * Representing SAHPRA interests on international, regional and national levels (forums, committees, etc.). * Maintaining confidentiality and ethical behaviour.

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 theirapplications.
- 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 and time, will not beconsidered.
- 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. M. Mokotong, Email: matshepo.mokotong@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS)**.

CLOSING DATE: 07 June 2021 at 16H00.