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.

Medical Devices - Medicine Registration Officer: Licensing
DPSA Equivalent Non OSD: TCE SL Level 10 (+ in leu of 37% benefits)
Ref No: SAHPRA 043/2022 Permanent
CENTRE: Pretoria

REQUIREMENTS:

- An appropriate 4-year Pharmacy Degree or equivalent NQF level 7 or Life Sciences
- At least two (2) years' regulatory experience in Medical Devices including IVDs
- An understanding of Medical Devices Vigilance requirements

COMPETENCIES/ATTRIBUTES REQUIRED:

- Sound knowledge of regulatory scientific and technical requirement of medical Devices (including IVDs)
- Knowledge of quality, safety and efficacy aspects of medical Devices (including IVDs).
- An understanding of the Medical Device Establishment licensing requirements, Pre- and Post-Marketing Surveillance processes
- Preparation and management of operational and tactical plans, and budgeting
- Computer literacy and MS Windows computer skills, Excel and database applications
- Good report writing and presentation skills
- Good planning, organizational and 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 details and Information evaluation

DUTIES:

Technical requirements:

*Develop and maintain guidelines and standard operating procedures for medical device and IVD registration. *Evaluate and manage licence applications for medical device establishments and maintain relevant databases. *Evaluate and manage applications and request for advertising and promotional material* Management of queries management database

(technical)*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. *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 functions that may arise from time to time. *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).

Evaluation and Risk Management:

Investigate non-compliance to the Medicines and Related Substances Act 101 of 1965 as amended, General Regulations, Medical Device Regulations, internal processes. * Ensure all identified CAPA's are implemented as per agreed (tasks and timelines). * Peer-review reports done by other reviewers. * Attend, present, and participate in peer-review and Regulations and licensing working groups/Committee discussions. * Compile minutes and or reports of peer reviewed discussion and recommendations as applicable.

Partnerships, Collaboration & Communication:

Prepare and attend Industry engagements and other Regulatory Forums. * Respond to stakeholder queries timeously. * Review and facilitate the finalization and publication for Media Release, & Newsletters as per request from the 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 or faxed applications will be accepted. CV's 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: Email: Matshepo.mokotong@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: **15 August 2022 at 16H00**