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 & IVD TECHNICAL OFFICER: COMPLIANCE
Ref No.: 024/2022 (Permanent)
DPSA Equivalent NON OSD: LEVEL 10 (including in leu of 37% benefits)
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:

- 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 regulatory compliance related to Medical Devices
- Sound and in-depth knowledge of the administrative processes for regulation of the medical devices
- An understanding of QMS requirements (including but not exclusive Management of Non-conformances, Change control, document control)
- Preparation and management of strategic plans, business 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:**

Manage the Quality Management System (QMS) requirements of the unit (including but not exclusive management of non-conformances, change control, document control) ensure proper traceability and monitoring towards compliance to the QMS. * Compile, review and ensure compliance to service level agreements with outsourced support services such as laboratories to ensure achievement of agreed quality and delivery standards. * Receive and review applications for exclusion/exemption in terms of Section 36 of the Medicines Act. * Receive and review applications for borderline medical devices and respond to applicant or referring unit respectively. * Prepare review report for discussions at Peer Review/Medical Device Committee/Management. * Communicate the outcome of review with relevant stakeholders (internal and external).

- **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 Vigilance 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 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 M. Mokotong, Email: matshepo.mokotong@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: **09 May 2022 at 16H00.**