



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: VIGILANCE

Ref No.: 025/2022 (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 the Post-Marketing Surveillance reporting process (Including and not exclusive serious AE, FSCA)
- 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 process of medical devices (including IVDs) PMS including Vigilance, technical screening, and review of vigilance reports; data capturing, uploading of vigilance reports. * Participate/Perform/support as applicable in causality assessment on serious cases and cases of interest. * Perform investigation and conduct follow-up with applicant on Vigilance reported as applicable. * 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 safety concerns and prepare review report for peer-review. * 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: setlola.molepo@sahpra.org.za **(DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 09 May 2022 at 16H00.