



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.

MEDICINES REGISTRATION OFFICER – LICENSING: MEDICAL DEVICES
Ref No.: SAHPRA 018/2023

SALARY LEVEL 10: (R623 105 - R661 345)

CENTRE: Pretoria

REQUIREMENTS:

- An appropriate 4-year Pharmacy Degree or equivalent NQF level 7 or Life Sciences, relevant post graduate qualification maybe beneficial.
- At least two (2) years' regulatory experience in Medical Devices including IVDs
- An understanding of Medical Devices Vigilances requirements

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: *Sound knowledge of regulatory scientific and technical requirement of Medical Devices (including IVDs); *knowledge of quality, safety and efficacy aspects of Medical Devices (including IVD's); *an understanding of the Medical Devices 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 and organising 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 evaluated.

DUTIES:

- Develop and maintain guidelines and standard operating procedure for medical devices and IVD registration;
- Evaluate and manage licence applications for medical devices establishments and maintain relevant database;
- Evaluate and manage applications for registration of medical devices and IVD's and maintain relevant database;
- Prepare reports for SHAPRA 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 of the industry to discuss SAHPRA Board resolutions, requirements of the Act and medical devices and IVD quality issues;
- Investigate and attend to industry / applicants 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).

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: 05 May 2023 at 16H00.