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.

SENIOR MANAGER: MEDICAL DEVICES AND RADIATION CONTROL
Ref No.: SAHPRA 049/2020 (5-Year Contract)

CENTRE: Pretoria

REQUIREMENTS: Appropriate Degree in Biomedical engineering, or Clinical engineering or Medical physics or equivalent. Registration with HPCSA where appropriate. A post-graduate degree will be an added advantage. Minimum ten (10) years relevant experience of which 8 years must be at the Deputy Director level (or equivalent).

COMPETENCIES/SKILLS: *Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. *Sound and in-depth knowledge of the Medicines and Related Substances Act 101, 1965 as amended and the regulations pertaining to the Act and the Hazardous Substances Act, 1973 and its regulations. *Sound knowledge of regulatory scientific and technical requirement (to assess the quality, safety and efficacy and or performance aspect). *Sound and in-depth knowledge of the administrative processes for regulation of the medical devices, radionuclides and electronic generation of ionizing and non-ionizing radiation in the Republic of South Africa. *Good understanding of the medical device and radiation industry. *Detailed knowledge of various international standards and norms *Knowledge of complaint management system. *A track record in preparation and management of strategic plans, annual performance and operational plans *Knowledge of budgeting and financial management system. *Broad knowledge of the Public Finance Management Act, 1999 (Act 1 of 1999) (PFMA), Labour Relations Act, 1966 (Act 66 of 1995) and the Employment Equity Act, 1998 (Act 55 of 1998). *General management including Human Resources, budgeting and financial management skills. *Good planning, organisational and presentation skills. *Performance measurement skills, *Excellent Communication skills (verbal, written, influencing, conflict management, presentation) and interpersonal skills. *Research and investigation, Analytical and report writing skills; Computer skills. *Resilience and ethical behaviour. *Must be willing to travel and work irregular hours. *A valid driver's licence.

DUTIES:

- Develop strategy, an annual performance plan, operational plans and budget for the division aligned with organisational needs and ensuring the most effective utilisation of resources.
- Develop and co-ordinate systems for management of all operations of the Medical Device and Radiation Control Programme.
- Contribute as a member of the executive management team responsible for strategic planning of the organisation in order to ensure the achievement of organisational objectives and meet the needs of all stakeholders.
- Prepare monthly, quarterly and annual reports for work done within the Programme including monitoring of the timelines.
- Direct the processes involved in the regulation of medical devices (including medical and industrial radiation emitting devices).
- Manage the regulation of radionuclides and electronic generation of ionizing and non-ionizing radiation.
- Oversee preparation and endorses 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.
- Oversee the effective, timeous communication and consulting thereon regarding issues relating to medical devices (including medical and industrial radiation emitting devices) and radionuclides and electronic generation of ionizing and non-ionizing radiation.
- Oversee the development, implementation and maintenance of regulations, guidelines, policies and procedures pertaining to regulation of medical devices, radionuclides and electronic generation of ionizing and non-ionizing radiation, to ensure alignment with international and national protocols, legislations and other legal requirements.
- Establish surveillance mechanisms to detect, assess and prevent adverse reactions to devices and radionuclides and electronic generation of ionizing and non-ionizing radiation.
- Liaise with representatives from industry and international regulators, and other relevant stakeholders to ensure appropriate and correct information and establishment of productive and relevant relationships.
- Ensure active and meaningful participation by the South African regulatory authority in the global arena.
- Oversee compliance to service level agreements with outsourced support services such as laboratories to ensure achievement of agreed quality and delivery standards.
- Train and manage managers reporting to this role to ensure they have the skills required by the organisation and can achieve their performance objectives.
- Ensure that a high level of integrity is maintained by staff members by promotion of high ethical conduct and maintenance of high-performance standards.
- General financial budgeting, human resources and performance management.
- Perform such other functions as the Chief Regulatory Officer and /or the Chief Executive Officer may duly allocate or delegate from time to time.

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 form 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 and time, 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 S. Molepo, Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS)**.

CLOSING DATE: 16 November 2020 at 16H00.