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: INSPECTORATE AND REGULATORY COMPLIANCE
Ref No.: SAHPRA 004/2019 (5-Year Contract)

SALARY: An all-inclusive remuneration package (Level 14). Basic salary consists of 70% of total package, the State's contribution to the Government Employee's Pension Fund (13% of basic salary) and a flexible portion. The flexible portion of the package can be structured according to Senior Management Service Guidelines.

CENTRE: Pretoria

REQUIREMENTS: A four-year Bachelor's degree in Medical or Natural Science, including registration with the relevant Council. 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: ***Extensive knowledge and application of the Medicines & Related Substances Act, (Act 101 of 1965) and its Regulations and working knowledge of Criminal Procedure Act. *Extensive knowledge of Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good wholesaling Practice (GWP), Good Clinical Practice (GCP) and Good Distribution practice (GDP). *Good understanding of the pharmaceutical industry in South Africa is required. *Detailed knowledge of various international standards and norms on the quality aspects of medicines. *Good understanding of concepts of quality management systems. *Knowledge of complaint management system. *Knowledge of various pharmaceutical marketing codes. *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 and co-ordinate systems for management of all operations of the Regulatory Compliance and Inspectorate Programme.
- Develop a strategy, an annual performance plan, operational plans and budget for the program aligned with organisational needs and ensuring the most effective utilisation of resources.
- 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.
- Directs the enforcing of relevant legislation by overseeing the monitoring and managing the importation and use of narcotic drugs; the legal handling, product recalls, sale and advertisement of medicines, the investigation of alleged counterfeiting of medicines, the execution of inspections (GMP, GCP, GWP, GLP and GDP).
- Oversees preparation and endorses reports to be submitted to relevant advisory committee for their information, discussion, review and/ or recommendation in accordance with prescribed legal requirements and standard operating procedures of SAHPRA.
- Oversees the effective, timeous communication and consulting thereon regarding issues relating to inspections, regulatory compliance and licensing in order to guide public health and other authorities on appropriate policies and interventions.
- Oversees the development, implementation and maintenance of regulations, guidelines, policies and procedures pertaining to regulatory compliance, inspections, licensing and laboratory services to ensure alignment with international and national protocols, legislations and other legal requirements.
- Liaises with representatives from industry and international regulators, law enforcement agencies and other relevant stakeholders to ensure appropriate and correct information and establishment of productive and relevant relationships.
- Ensure active and meaningful participation by South African regulatory functions in the global arena.
- Oversees 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 are able to 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 or the Chief Executive Officer may duly allocate or delegate from time to time.

INSTRUCTIONS TO APPLICANTS: All applications must:

- Be made on Z83 forms (obtainable http://www.dpsa.gov.za/dpsa2g/ documents/forms/employ.pdf or from any Government department).
- Be completed in full, clearly reflect the name of the position, name and date of the publication (candidates must use the **post reference numbers**), 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 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.

Enquiries: Ms S. Molepo, Tel: +27 71 605 1508. Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 24 January 2020 at 16H00.