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: CLINICAL EVALUATIONS AND MANAGEMENT
Ref No.: SAHPRA 003/2019 (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: ***Experience should include the analysis of technical evaluation data submitted for registration of medicines as well as the application of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and its regulations. *Good understanding of the conduct and control of clinical trials. *Sound knowledge of medicine registration with respect to safety and efficacy of medicines. *Familiarity with ICH and WHO technical guidelines required. *Broad knowledge of the Public Finance Management Act, 1999 (Act 1 of 1999) (PFMA) and its regulations, the Labour Regulations Act, 1995 (Act 66 of 1995) and the Employment Equity Act, 1998 (Act 55 of 1998). *Exposure to the evaluation of applications for registration of new chemical entities and generic applications will serve as an advantage. *Good understanding of Pharmacovigilance and Post-Marketing Surveillance. *General management, 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 Clinical Evaluations and Management.
- 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.
- 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 safety and efficacy of applications 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 clinical trials regulation, clinical evaluations, names and evaluations, vigilance and special approvals of unregistered products to ensure alignment with international and national protocols, legislations and other legal requirements.
- Establishment of surveillance mechanisms to detect, assess and prevent adverse reactions to drugs.
- Liaises 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 South African regulatory functions in the global arena.
- 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.