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: HEALTH PRODUCTS AUTHORISATION
Ref No.: SAHPRA 020/2020 (5-Year Contract)

CENTRE: Pretoria

REQUIREMENTS: A four-year Bachelor's degree in Medical, Health or Natural Science, including registration with the relevant Council, complemented by a Project Management qualification. A post-graduate degree will be an added advantage. Minimum ten (10) years relevant experience of which 5-7 years of middle management with project management experience including managing teams, developing and evaluating budgets, creating and implementing work plans, and monitoring both project and staff performance.

COMPETENCIES/SKILLS: * 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 requirements. *Sound and in-depth knowledge of the administrative processes for regulation of medicines, medical devices, radionuclides and electronic generation of ionizing and non-ionizing radiation. *Good understanding of the pharmaceutical industry, devices and radiation control *Detailed knowledge of various international standards and norms. *Good understanding of concepts of quality management systems. *Knowledge of complaint management system. *Identify and problem-solve obstructions in the project workflow and recommend and implement process improvements. Ensure robust tracking and reporting of program progress; ensure coordination and implementation of identified tasks / process improvements. *Comprehensive knowledge and understanding of the Public Finance Management Act, including proven experience in its application; Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. A track record in preparation and management of strategic plans, business plans and budgeting; *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 Health Product Authorisation programme.
- Contribute as a member of the senior 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.
- Develop and manage a project monitoring tool/s to track deliverables and resources
- Develop quality measurement standards and assure quality throughout the project deliverables.
- Develop systems for performance information collection to ensure accurate reporting of data
- Ensure efficient project management procedures are implemented to enable monitoring of activities and accurate reporting of progress.
- Support the collection and accurate reporting of impact data related to the project.
- Manages receipt of all applications (in electronic Common Technical Document (eCTD) format and other acceptable formats) submitted to SAHPRA and recording of payments from applicants.
- Directs screening and checking of applications for administrative completeness in line with prescribed requirements.
- Manages allocation of all applications to the appropriate evaluator / assessor for professional assessment (within a set time frame) depending on the type of application. This relates to the initial application and responses from applicants to recommendations following evaluation and/ or assessment.
- Sets policy for tracking progress of applications and assessment by evaluators/ assessors and assist assessment process to obtain additional information from applicants if so requested by evaluators/ assessors.
- Manage receipt acknowledgement of study documentations (change of address, ethics committee approval letters for the study and protocol amendments, updated professional information, updated malpractice insurances, registration with the HPCSA, Change in investigators, study staff, study coordinators, monitors, sponsors, etc.)
- Oversee feedback to applicants of decisions regarding applications and licenses by relevant SAHPRA programmes and issue of authorisation letter
- Authorisation of changes to electronic document management system (EDMS) and electronic common technical document (eCTD) parameters to ensure control over procedures, methods and correctness of system technical content.
- Recording of all approved changes in respect of medicines, clinical trials, complementary medicines, medical and in vitro devices, ionizing and non-ionizing radiation emitting devices; and radioactive nuclides in relevant registers (new registrations and all amendments).
- Oversee record of approved proprietary names in a central database.
- Direct processing and issuing of licenses to medicine manufacturers, wholesalers and establishments in the country.
- Approve and ensure publication of registrations approved in the Government Gazette and forwarding to the person responsible for publication on the website
- 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.

Candidates who applied previously are encouraged to apply provided they meet the minimum requirements.

INSTRUCTIONS TO APPLICANTS: (Re-advertisement) All applications must:

- Be completed in full, clearly reflect the name of the position, (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. SAHPRA reserves the right to fill or not to fill the vacant post/s.

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: 25 May 2020 at 16H00.