



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 (HPA)
Salary: Level 14 (R1 333 449.00 – R1 415 289.00) TOTAL COST TO COMPANY
Ref No.: SAHPRA 027/2023
CENTRE: Pretoria

REQUIREMENTS: 1. Appropriate 3-year degree in Chemistry or Bachelor of Pharmacy Degree (registered with SAPC). *Postgraduate or Management Degree preferable. *Sound and in-depth knowledge of the Medicines and Related Substances Act 101, 1965 as amended and the regulations pertaining to the Act. *Sound knowledge of regulatory scientific and technical requirement (to assess the quality, safety, and efficacy aspect). *Sound and in-depth knowledge of the administrative processes for registration of medicines in the Republic of South Africa. *A valid driver's licence.

EXPERIENCE: * Minimum 8 years appropriate experience in relevant profession after registration with HPCSA (where applicable).

TECHNICAL PROFICIENCIES:

- **Regulatory Sciences:** *Knowledge or work experience with health product registration applications, or possibly with assessing the compiled applications. *Thorough understanding of the Regulatory environment that SAHPRA operates within (applicable legislation knowledge and understanding).
- **Project Management:** *Project Management experience within a Prince2, Agile, Scrum etc. framework. *Customer services experience/exposure.

CORE COMPETENCIES: *Effective Communication Skills. *Solid Leadership and Management Skills. *Ability to communicate complex technical concepts to non-technical stakeholders. *Solid Project Management experience. *Critical/Conceptual & Strategic thinking skills – allowing ICT strategies and business goals to be efficiently aligned. *High level of self-awareness. *Problem solving skills *Report writing skills. *Resilience. *Business Acumen. *Adaptability. *Solid Stakeholder management skills. *Solid Vendor management skills. *Knowledge and understanding of the Public Finance Management Act, including proven experience in its application. *Knowledge, understanding, and practical experience working in an ISO 9001 quality management systems environment.

RESPONSIBILITIES & DUTIES:

The role involves planning, project co-ordination, implementing, and maintaining all programme operational initiatives that will ensure effective management of applications, related records, reporting requirements, management of stakeholder and representing the HPA programme at senior management level and on external forums.

- **Strategic Planning:** *Develops an annual strategy, plan and budget (APP) for the division aligned with organisational needs and ensuring the most effective utilisation of resources.
- **Team Management:** *Leading and managing a team of IT professionals, including assigning tasks, providing guidance, concluding annual performance contracts, evaluating performance at mid-year and year-end, managing poor performance or disciplinary infractions, Leave Planning and management and fostering a collaborative work environment.
- **Budgeting, Procurement and Resource Allocation:** *Managing the HPA budget which includes submitting annual budget plan to Finance at communicated deadline and ensure that any/all planned CAPEX items and current and planned OPEX items are correctly accounted for, track and manage monthly expenses and revenue plan against budget to ensure overspend is avoided, revenue is collected in full in a timely manner, that team resources effectively allocated to complete work load within the operational area to manage work prioritise of the programme.
- **Project Management:** *Leading and managing identified and agreed HPA projects from start to finish, ensuring that projects are delivered on time, within budget, and meet stakeholders' requirements and related project governance structures and documentation is in place, including Project scope, project plans, Resource, Issues, Risks, Decisions and Quality registers and Project SteerCo with scheduled and minuted meetings.
*Implement Project Management principles within the work streams to enable the Unit Manager(s), Portfolio Co-ordinators and Evaluator Co-ordinators to plan the work activities, co-ordinate support activities with the technical units, manage the resources in the workstream to ensure that ultimately, we progress rapidly with registration of new technologies and health products within identified target timelines.
- **Stakeholder Management:** *Cultivate and support Customer centric mindset within the HPA workstreams – ensuring that we follow our documented work practices to provide good and consistent service to all our stakeholders (internal and external)
Manage pro-active communication to various stakeholder groups to provide updates and pertinent information as it relates to HPA services and performance reporting.
- **Training and Development:** *Identifying training needs for HPA staff, organizing training programs, and promoting professional development to enhance the skills and knowledge of the HPA team. Ensure that all HPA Team members have been trained on all organisational policies and applicable standard operating procedures and guidelines and related proof of training/competence has been recorded and is on personnel file with HR.
- **Continuous Improvement:** *Staying updated on emerging operations and administrative trends within regulators, best practices, and regulatory requirements.
*Continuously evaluating and improving HPA work stream processes, systems, and policies to drive efficiency and effectiveness.
*Responding swiftly to any non-conformances or audit findings that are raised, ensure that that an Action plan and tracker is developed in collaboration with the whole HPA Team – detailing issue raised, responsible person, target due date, action to be taken and status of the open item. Ensuring that findings are closed with the 30-day timeline from when issue was raised to issue closed.
- **Provide ad hoc support as discussed and instructed by the Chief Operations Officer:** *Provide ad hoc support for additional tasks, as discussed, and instructed by the Chief Operating officer for interventions within the HPA functional area.
- **Manage reporting requirements within communicated and agreed timelines:**
*Ensure that weekly HPA department meetings are set up with COO. Prepare and agenda for the weekly department meetings and provide the rolling tracker with updates the morning before the meeting to allow COO adequate time to prepare for the discussions. *Ensure committed activities are completed and reported on in sufficient detail. (Agenda broken up into 15 min to spend on new issues raised by manager, 30 min allocated rolling tracker update and last 15 min for COO to raise/update manager on new issues/matters).
*Provide real-time updates to the COO on any matters that impact Key responsibility. *It is imperative that the HPA Manager keeps the COO abreast of events, deviations, performance related matters, incidents etc. that impact performance and service or might require escalated intervention. *Ensure that the quarterly HPA Performance Information Report and AOP reporting is submitted to the Business Planning Manner in accordance with communicated deadline and on the approved template. *Ensure that the quarterly TORS committee contribution is submitted to the Office Manager of the CRO in a timely manner so that the

presentation can be submitted to TORS on time. *Develop and maintain any additional reports that may be required as a consequence of project related activities or ad hoc reports as requested from time to time. *Develop and maintain any operational report that is required to monitor the performance of the individual workstream teams.

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 and email addresses of 3 referees and recently certified copies of ID, required qualification/s (matric included) and driver's licence where applicable.
- Applications without the aforementioned documents/information 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 applications will be accepted. CVs 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, Email: setlola.molepo@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS**).

CLOSING DATE: 27 JULY 2023 at 16H00.