



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.

MEDICINE REGISTRATION OFFICER: CLINICAL TRIALS x3

Salary: R788 910 – R837 326 p/a (Total Cost to Company)

Ref No.: SAHPRA 028/2023

CENTRE: Pretoria

REQUIREMENTS: • Appropriate 4-year Bachelor of Pharmacy Degree from a recognised university or tertiary institution. A post graduate qualification in Health Science (NQF 9 Level) is a strong recommendation. • Registration as a Pharmacist with the South African Pharmacy Council (SAPC).

Experience: • A minimum of at least 8 years' experience.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: * Knowledge and application of the Medicines and Related Substances Act (101 of 1965) as amended and its related Regulations and Guidelines. * Comprehensive knowledge and understanding of relevant legislation, protocols, standard operating procedures and work instructions. * Knowledge of technical aspects for evaluation of quality and efficacy (bioequivalence) of medicines. * Evaluation guidelines as prescribed by the relevant regulatory authorities. * Technical and scientific aspects of medicine regulation. * Self-motivated and able to work independently. * Competent in problem solving and team building. * Information evaluation. * Computer literacy and sound working knowledge of computer software packages. * Planning and organisational skills. * Leadership skills. * Coordination skills. * Written and verbal communication skills. * Diversity management. * Time management. * Good telephone etiquette. * Supervisory skills. * Must be willing to travel and work irregular hours when so required. * A valid driver's licence.

DUTIES:

Technical screening of new clinical trial applications to ensure adherence to SAHPRA requirements; * Technical Evaluation of applications to conduct clinical trial applications; * Provide recommendations on review of applications to Clinical Trials Expert Committee / SAHPRA; * Review applicant responses and recommend for approval or rejection of clinical trial applications; * Communicate the recommendations queries, approval or non-approval to the Applicants; * Communicate with other units: medical device, complementary unit or inspectorate and regulatory compliance on referred Clinical Trial applications; * Communicate with the finance unit on acceptability of the documentation on clinical trial applications, if required and resolve queries from finance; * Complete/Ensure completion of the status tracker to ensure timely reporting (Finance, performance and WHO); * Manage submission of clinical

trial application cycles.

Technical screening of new Bioequivalence studies to ensure adherence to SAHPRA requirements; * Technical Review of Bioequivalence studies applications; * Provide recommendations on applications to Authority (Clinical Trials Expert Committee, if required); * Review applicant responses and recommend for approval or rejection of Bioequivalence studies; * Communicate the recommendations, approval or non-approval to the Applicants; * Complete/Ensure completion of the status tracker to ensure timely finance and performance reporting; * Manage submission of Bioequivalence from receipt to finalization; * Allocate clinical trials to the external evaluators in accordance with expert areas; * Coordinate clinical trials applications and monitor progress of review (follow up with external evaluators); * Liaise advisory committee members and external reviewers; * Prepare agenda and documentation to serve at the Clinical Trials Expert Committee; * Support the proceeding of the Clinical Trial Committee meetings, including the expert consultation meetings; * Prepare minutes and recommendations following the meeting of the Clinical trials expert committee; * Evaluate and provide opinion on performance of external expert reviewer; * Communicate the recommendations to the external stakeholder following the Clinical Trials Committee meetings.

Review Serious Adverse Events (SAE) reports, progress reports and other safety reports during the Conduct of Clinical Trials and Bioequivalence studies; * Validate the SAE report on the system after review; * Present the SAE Reports to Clinical Trials Safety Monitoring Committee / Clinical Trial Committee on critical findings; * Set up systems and advise on implementation of the process of SAE reporting; * Advise on improvement of system or any other processes in the Unit; * Communicate with other units: PV, medical device, complementary unit or inspectorate and regulatory compliance on matters during review of safety reports; * Liaise with advisory committee members Clinical Trials Safety Monitoring Committee; * Prepare agenda and documentation to serve at the Clinical Trials Safety Monitoring Committee; * Support the proceeding of the Clinical Trial Committee meetings; * Prepare minutes and recommendations following the meeting of the Clinical Trials Safety Monitoring Committee; * Communicate the recommendations to the external stakeholder following the Clinical Trials Committee meetings.

Screening and technical review of applications for protocol amendments in line with set timelines in annual operations plan; * Allocation of clinical trials protocol amendment to the external evaluators in accordance with expert areas; * Advise on improvement of system or any other processes in the Unit; * Check the status of all applications received to monitor timeline in line with Annual performance plan or annual operations plan; * Respond and attend to queries and complaints timely related to applications from external stakeholder; * Update spreadsheet on regular basis. Provide statistics on applications reviewed and outstanding in preparation for monthly finance and performance reporting; * Review investigators, change in investigators/Principal investigators or additional sites in line with the set timelines; * Check the status of all applications received to monitor timeline in line with Annual performance plan or annual operations plan; * Advice by responding to queries and complaints timely related to applications from external stakeholder; * Advise on improvement of system or any other processes in the Unit. *Update spreadsheet on regular basis; * Provide statistics on applications

reviewed and outstanding in preparation for monthly finance and performance reporting.

Drafting and review of policies and Preparation of Policy document; * Develop SOPs, review SoPs and ensure availability of SOPs at a point of service. *Ensures the business unit complies with the approved Standard Operating Procedures; * Manage Admin staff to ensure compliance with timelines and attend to queries; * Perform Performance assessment of admin staff; * Investigate and advise pharmaceutical industry / applicant's queries or other members of the Public; *Manage resolution of the queries in area of work; * Provide advice or recommend to inspectorate or regulatory compliance unit; * Represent SAHPRA in the local, regional and/or global sphere; * Arrange and attend Industry Task Group working groups and external stakeholder meetings; * Attend and support the internal and external Audit, including resolution of queries. *Manage and keep records regularly of clinical trial related activities.

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: 25 July 2023 at 16H00.