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 GR 3 (Clinical Trials)
(DPSA Equivalent Level 11 OSD - TCE: GR 3 = R796 041)
Ref No.: SAHPRA 010/2022

CENTRE: Pretoria

REQUIREMENTS:

- A 4-year Bachelor of Pharmacy degree and registration with the South African Pharmacy Council (SAPC) as a Pharmacist.
- A relevant post-graduate qualification in the health sciences will be an advantage.

EXPERIENCE:

- B-Pharm degree, registration as a Pharmacist with a minimum of 8 years' appropriate experience. Proof of registration as a Pharmacist must be submitted with your application).

COMPETENCIES, KNOWLEDGE AND SKILLS:

- 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 requirements (in terms of quality, safety and efficacy aspects)
- Good knowledge of the conduct of clinical trials
- Comprehensive knowledge and understanding of international regulatory clinical trials guidelines
- Computer skills (knowledge of MS Office)
- Planning and organisational and skills
- Drive and self-management skills
- Communication skills (verbal, written, conflict management, presentation)

- Ability to work in a highly pressured environment and driven by a sense of urgency to meet deadlines
- Assertiveness
- Ethical behaviour
- Prepared to travel and work irregular hours
- A valid driver's licence

DUTIES:

- Evaluate clinical trials protocol applications and applicant responses
- Co-ordinate clinical trials activities and committee meetings
- Supervise administrative staff and attend to queries addressed to the Clinical Trials Unit
- Provide technical assistance and support to appropriate Advisory Committee/s and SAHPRA generally
- Develop Standard Operating Procedures (SOPs) for conducting clinical trials as well as related policies and guidelines
- Technical screening and allocation of new clinical trials applications
- Review of Serious Adverse Events and progress reports reported during the conduct of clinical trials
- Review any other clinical trials correspondence
- Liaise with applicants and advisory committee members
- Investigate and attend to pharmaceutical industry / applicants' queries
- Perform other related functions that may arise from time to time

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 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 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: **23 February 2022 at 16H00.**