SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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Loftus Park
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Kirkness Road
Arcadia
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CALL FOR EXPRESSION OF INTEREST

CLINICAL TRIALS EXTERNAL EVALUATORS

The South African Health Products Regulatory Authority (SAHPRA) hereby invite expression of interest for candidates to serve as External Evaluators for Clinical Trials Evaluation (inclusive of Quality and Clinical safety and efficacy data).

SAHPRA is a Schedule 3A Public Entity established in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) to oversee the regulation of medicines, medical devices, and in vitro diagnostics (IVDs) intended for human and animal use; the licensing of manufacturers, wholesalers and distributors of medicines, medical devices and IVDs; and the conduct of clinical trials.

REQUIREMENTS

The External Evaluators are appointed in terms of section 3 (5) of the Medicine's Act, as amended to assist the Authority in carrying out its functions. These fully qualified external evaluators are crucial to supplementing the skills and experience of the Authority in the area of Clinical Trials.

Expression of interest is required in the following disciplines:

- **Three (3)** external evaluators for Clinical Trials Committee.

Experience and knowledge in the following:

- Extensive knowledge of Good Clinical Practice, clinical trials legislation, regulations, and global standards.
- Comprehensive Knowledge of technical aspects for clinical trials evaluation including safety and efficacy of health products.
- Extensive knowledge and application of the Medicines and Related Substance Act, 101 of 1965 and related regulations
  Sound working knowledge of document management and workflow management software is desired,

Applicable Skills

- Ability to evaluate scientific evidence on safety and efficacy of medicinal products.
- Ability to understand the clinical content and knowledge of therapeutic areas under evaluation.
- Understanding of clinical study design principles and impact on study results.
- Understanding of the pharmacology of chemicals under evaluation.
- Ability to interpret results of clinical studies and make clinical practice judgement.
- Understanding of bio statistical principles of medical research.
- Strong analytical and communication skills to interpret safety data and communicate complex information effectively.
- Manage multiple priorities and deadlines efficiently with strong organizational skills.
- Ability to mentor and lead multidisciplinary teams in dynamic regulatory environments.

Duties

- Review Serious Adverse Events (SAE) reports, progress reports, interim/final study reports and other safety reports during the conduct of Clinical Trials and Bioequivalence studies.
- Validate the SAE reports on the system after review.
- Consistently deliver high-quality, evidence-based clinical assessments that meet deadlines and contribute to well-informed regulatory decisions.
- Utilize advanced signal detection methodologies to proactively identify emerging safety issues.
- Proactively identify areas for improvement within SAHPRA's safety reporting. Advise on improvement of in safety reporting systems or any other processes in the Unit.
- Liaise with advisory committee members Clinical Trials Safety Monitoring Committee.
- Prepare agenda and documentation to serve at the Clinical Trials Safety Monitoring Committee.
- Present the SAE Reports to Clinical Trials Safety Monitoring Committee / Clinical Trial Committee on critical findings.
- Support the proceeding of the Clinical Trial monitoring/Expert Committee meetings. Prepare comprehensive minutes and recommendations following the meeting of the Clinical Trials Safety Monitoring Committee.
- Prepare and communicate the recommendations to the external stakeholder following the Expert Committee meetings.
- Collaborate effectively with multidisciplinary teams on Clinical Trials-related projects.
- Update the relevant trackers and align with QMS requirements.

Relevant Qualifications

- Appropriate degree in medicine (MBCHB) and/or Pharmacy (BPharm)
- Masters in Health Sciences will be an added advantage
- At least 5 years of experience in clinical research and Medicine Regulation experience

Hybrid Working Model: Flexibility to work remotely and will be required to work allocated hours per week.

Please take note: candidates need not possess all the above knowledge and skills to express interest.

EXCLUSIONS:

Where such person is conflicted in terms of SAHPRA Policy on Management of Conflict of Interest (GOV02).
is disqualified under the Relevant Act applicable to his or her profession from practising as such.

- has been found guilty of improper or disgraceful conduct at an inquiry held under ambit of the relevant Act.
- is a patient as defined in section 1 of the Mental Health Care Act, 2002 (Act No. 17 of 2002).
- has been convicted of an offence in respect whereof he or she was sentenced to imprisonment without the option of a fine or in the case of fraud.
- does not meet the minimum requirements.

TERM OF OFFICE
The term of service for external evaluators is two (2) years effective from date of appointment.

PROCEDURE

- A comprehensive CV, qualification/s and a motivation expressing area of expertise must be submitted **online at** https://apply.sahpra.org.za:6006/
- Only documents in pdf must be uploaded.
- Further communication will be limited to candidates with appropriate skill sets.
- Closing date for applications is **Thursday, 13 March 2025 at 16h30. No late applications will be accepted.**

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