SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
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Kirkness Road
Arcadia
0083

CALL FOR EXPRESSION OF INTEREST

GOOD MANUFACTURING PRACTICE EXTERNAL EVALUATORS

The South African Health Products Regulatory Authority (SAHPRA) hereby invite expression of interest for candidates to serve as External Evaluators for Inspectorate Unit.
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 GMP Medicines Evaluation.Expression of interest is required for experts who are already familiar with PICs, ICH, SAHPRA and other recognised relevant international requirements for medicines as well as eCTD dossier reviews for both new medicines registrations and variations such that they are able to commence with immediate effect.

Expression of interest is required in the following disciplines:

- **Six (6)** external evaluators for the Inspectorate Unit in Programme 3: Inspectorate and Regulatory Compliance

Experience and knowledge in the following will be an added advantage:

- National Regulatory Authority experience within GMP evaluation or GMP expertise
- Reviewers who have review experience in National regulatory authorities (minimum 3 years in GMP medicines reviews)
- Experience in medicines regulations and understanding of new registration, variations, and GMP requirements
- Familiarity with SAHPRA regulations and procedures for medicine registration

Duties:

- Assess and evaluate GMP inspection reports of other regulatory authorities on international pharmaceutical manufacturing sites where medicines for exportation to South Africa are manufactured. Interpretation and implementation of relevant PICs, ICH guidelines, SAHPRA and other recognised relevant international requirements.
- Assess GMP related compliance of applications as determined by the unit relating to but not limited to,
- Evaluation of applications for New Registrations
- Desktop review for applications relating to Good Manufacturing Practice Certificates (GMP)
- Evaluation of applications for Certificate of Pharmaceutical Product (CPP) & Good Manufacturing Practice Certificates (GMP)
- Evaluations for Variations: Type I and Type II
- Evaluation of Once off deviations within prescribed GMP requirements
- Report writing for SAHPRA and relevant advisory committees.
- Understanding of Good Manufacturing Practice principles and application
- Evaluate Pre- and Post- Registration information submitted in a medicine application form (eCTD)

Output expected from the incumbent:

Minimum of 4hours daily solely dedicated to this function for productivity expected to meet the performance targets in line with organisational targets.

EXCLUSIONS:

- Where such person is conflicted in terms of SAHPRA Policy on Management of Conflict of Interest (OF-GOV-02B)
- 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 the Mental Health Care Act, 2002 (Act No. 17 of 2002), as amended.
- 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.

RELEVANT QUALIFICATIONS

Appropriate degree in pharmacy/pharmaceutical sciences, or other relevant sciences**.**
Registration with the statutory regulatory board/council relating to his/her profession where applicable is recommended.
Applicant must be in good standing with the regulatory board/ council with which he/ she is registered where applicable.

TERM OF OFFICE

The term of service for external evaluators is **two (2) years** from date of appointment and may be appointed for a further extension of term(s).

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 **Monday, 30 June 2024 at 16h30. No late applications will be accepted.**

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