

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.

MEDICINES EVALUATOR (2 X POSTS) Ref No.: SAHPRA 007/2020 (Full-time 2-Year Fixed Term Contract)

SALARY: DPSA Equivalent Level 10 TCE (Non-OSD)

CENTRE: Pretoria

REQUIREMENTS: Minimum requirement of BPharm Degree and MSc in chemistry. At least 2 years' proven experience as an evaluator for a medicines regulator.

KNOWLEDGE AND SKILLS: *Knowledge of technical aspects for evaluation of quality and bioequivalence of medicines. *Sound working knowledge of computer software packages. *Working knowledge of document management and workflow management software is an added bonus. *Knowledge of CTD and eCTD software applications is an added bonus. *Deep understanding and experience of the evaluation of quality, clinical and bioequivalence of medicines applications. *Ability to communicate fluently in English with both written and verbal communicates potential roadblocks to application manager timeously. *Willingness to receive feedback, dedicated to learning and, striving to continuously improve.

DUTIES:

- Assess and support assessment of medicines applications: *Provide training, mentoring and peer review of technical screeners and evaluators. *Evaluates the quality, clinical and bioequivalence aspects of the medicines registration application. *Consistently update the relevant PMO manager on the progress of the applications. *Prepare a comprehensive summary of the application status under reviewed. *Engages in technical conversations with the applicant should the Portfolio Coordinator deem it necessary. *Other responsibilities as identified by the backlog clearance PMO lead.
- **Risk Management and Audit:** *Standard operating procedures and guidelines must be adhered to. *Assesses applicant responses to queries on applications for registration of medicines. *Attend relevant training as may be necessary to support your function.

INSTRUCTIONS TO APPLICANTS: All applications must:

- Be made on Z83 forms (obtainable <u>http://www.dpsa.gov.za/dpsa2g/</u> documents/forms/employ.pdf or from any Government department).
- Be completed in full, clearly reflect the name of the position, name and date of the publication (candidates must use the **post reference numbers**), 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 form 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 <u>recruitment@sahpra.org.za</u>, including the required certified documentation as indicated. **DO NOT MAKE ENQUIRIES TO THIS ADDRESS**.
- No late or faxed applications will be accepted. CV's 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.

Enquiries: Ms S. Molepo, Tel: +27 71 605 1508. Email: <u>setIola.molepo@sahpra.org.za</u> (DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).

CLOSING DATE: 20 March 2020 at 16H00.