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.

TECHNICAL SCREENER x 3

Ref No.: SAHPRA 032/2023

SALARY: R473 552 – R502 629 p/a (Total cost to company)

CENTRE: Pretoria

REQUIREMENTS:

- Appropriate 4-year degree in Chemistry/Pharmacology or Bachelor of Pharmacy
- Minimum of 3 years relevant medicines regulatory experience
- Experience in product review or assessments will be an added advantage

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES:

Theoretical knowledge of technical aspects for evaluation of medicines across all fields, namely: *Safety and efficacy, *Quality and bioequivalence, *Naming and scheduling, *Good manufacturing Practice.

Comfort working with computers and on a computer software packages. *Displays a strong academic background. *Ability to communicate fluently in English with both written and verbal communication. *Ability to work precisely and efficiently. *Able to remain self-motivated with the ability to work independently. *Ability to prioritize and displays excellent time management skills. *Knowledge of the regulatory environment. *Positive attitude

DUTIES:

Assess each module of the application against the relevant technical screening form to ensure they are appropriate in terms of format and content as defined by the relevant guidelines; * Verify and confirm that the proof of payment is valid and correct; * Generate a list of queries to the applicant using the correct templates; * Technical screening outcome report should be signed and dated; * Technical screening should be completed within target timelines; * Submit the generated list of queries to another technical screener for peer review; *Communicate the technical screening outcome to an Evaluator Co-ordinator for upload to the relevant platform

for technical Manager's signature; * Capture outcome of the screening and completion date on the Tracker; * Classify applications according to Pharmacological Classification; * Classify application into Generics, New Chemical Entities, Biosimilars, and Vaccines;* Peer-review technical screening report (s) done by other technical screeners; * Assess query responses to confirm compliance; * Generate rejection letter for applications not compliant with applicable guidelines; * Provide relevant statistics and evidence for Performance Reporting; * Identify and report on trends for decision making.

Assess each relevant module of the application against the relevant technical screening form to ensure they are appropriate in terms of format and content as defined by the relevant guidelines; * Verify and confirm that the proof of payment is valid and correct; * Generate a list of queries to the applicant using the correct template; * Technical screening outcome report should be signed and dated; * Technical screening should be completed within target timelines; * Submit the generated list of queries to another technical screener for peer review; * Communicate the technical screening outcome to an EC for upload to the relevant platform for technical Manager's signature; * Capture outcome of the screening and completion date on the Tracker; * Assess and classify the type of variation application; * Timeous assessment and identification of medicine safety issues or signals stemming from pharmacovigilance recommendations; *Assess query responses to confirm compliance; * Generate rejection letter for applications not compliant with applicable guidelines; * Provide relevant statistics and evidence for Performance Reporting; *Identify and report on trends for decision making.

Verify and confirm that the correct and relevant documents are submitted for the selected review pathway; * Source reliance reports from the relevant Recognised Regulatory Authority (RRA) via the focal person; * Save the relevant reports in the folder structure for the specific application; * Capture details of the review pathway on the screening outcome report and on the Tracker; * Identify and confirm applications for internal reliance and capture on the screening outcome report and on the Tracker; * Standard operating procedures and guidelines must be adhered to; * Attend relevant training as may be necessary to support your function; * Provide weekly progress reports to the relevant Portfolio Co-ordinator.

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 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. SAHPRA reserves the right to fill or not to fill the vacant post/s.

Enquiries: Email: setlola.molepo@sahpra.org.za **(DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS).**

CLOSING DATE: 25 July 2023 at 16H00.