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: LOT RELEASE
(Pharmaceutical Evaluations Management: Biological Medicines)
Salary (DPSA Equivalent Level SR 10 (Non-OSD TCE) – R653 613.00 p/a)
Ref No.: SAHPRA 029/2022

CENTRE: Pretoria

REQUIREMENTS: ● BPharm, Biological Sciences, Biochemistry or Microbiology degree from a recognised university or tertiary institution (Registration with the South African Pharmacy Council (SAPC) is a requirement with a BPharm degree - proof of active registration as a Pharmacist to accompany the application). ● A postgraduate qualification in relevant Science such as Biochemistry, Vaccinology, Pharmacology or equivalent and experience in biological medicines registration is an added advantage.
Experience: ● A minimum of 2 years' experience within a regulatory environment, such as a regulatory pharmacy, laboratory or within vaccine release environments (post registration as a community pharmacist). ● Experience as a Quality Officer in the Pharmaceutical industry would be advantageous.

CORE COMPETENCIES AND TECHNICAL PROFICIENCIES: * Comprehensive and sound knowledge of all relevant legislation, protocols, regulations, and guidelines pertaining to the Medicines and Related Substances Act 101 of 1965. * Good verbal and numerical reasoning skills to allow analysis and interpretation of written and numerical data, as well as clinical and/or biomedical research. * Good, effective communication skills (verbal, written, conflict management and resolution). * Delivery of service objectives with professional excellence and efficiency. * Ability to make effective decisions by using evidence and knowledge to support accurate, expert decisions and advice while carefully considering the implications of such a decision. * Ability to work unsupervised for long periods of time. * Ability to work within a team environment. * Good planning and organisational skills. * Ability to meet tight deadlines and manage multiple, often competing priorities. * Proficient knowledge of MS Office. * Proficient knowledge of EURS System. *A valid driver's licence. * Ethical behaviour and adherence to the SAHPRA Code of Conduct.

DUTIES: ● Lot Release Reports and evaluations: * Complete the Lot Release testing report. * Compile and submit a Lot Release decision-making report in the case of a verified OOS test result to present the data on which the recommendation for rejection is based. * Compile a recommendation of Lot Release testing outcome to SAHPRA, Biological Medicines Manager. * Review recommendation reports and generate a certificate or rejection letter for the applicant. * Forward the pack to the Unit Manager and Senior Manager for approval or rejection and to the CRO for sign-off. * Forward the signed Pack of Lot Release Testing

Outcome to HPA. * Communicate certificate or rejection letter to applicant. * Any related activity from a Lot Release report needs to be attended to within 3 (three) days or within the SOP as outlined. * Under exceptional circumstances, when a Lot Release for a particular lot should be expedited and prioritised, ensure that the review of the manufacturer's lot summary protocol is still adhered to. ● **Administration of Lot Release Reports:*** Receive signed Lot Release Certificate from CRO. * File the report and Lot Release certificate using SOP guidelines. * Compile the monthly report to indicate the number of lots received and processed. * Provide SANCLBP with a copy of the Lot Release Certificate/Rejection Letter for internal records. ● **Adherence to pharmacovigilance and quality assurance on Lot Releases:** * Identify all vaccine variations received and processed per month. * Compile the list of vaccine variations processed, reviewed and approved for that month and share with SANCLBP during the monthly SANCLBP/SAHPRA meeting. * Receive all Inspectorate, Recall and Market Surveillance Issues and schedule a meeting with Unit Managers for Inspectorate, Biological Medicines and Pharmacovigilance for discussion. * Assist with the investigation of out of specification Lot Release test results with the Inspectorate and SANCLBP.

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 and email addresses of 3 referees and recently certified copies of ID, required qualification/s (matric included) and driver's licence where applicable.
- Applications without the aforementioned documents/information 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: 27 May 2022 at 16H00.