



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.

QUALITY MANAGEMENT SYSTEMS - SPECIALIST

Ref No.: SAHPRA 063/2022

**DPSA Equivalent Non OSD: TCE SL Level 09 (+ in leu of 37% benefits)
24 Months Contract**

CENTRE: Pretoria

REQUIREMENTS:

- Bachelor's degree in quality or technical related field plus 3+ years of work experience in Quality or Regulated Industry
- ISO 9001 certificate
- Certificate such as Lead Quality Auditor
- Knowledge of regulatory requirements
- Knowledge of QA terms, tools, and methodologies.

KNOWLEDGE AND SKILLS: *Sound knowledge of regulatory requirements. * Sound knowledge of ISO9001 standard. * Communication Skills. *Problem solving Skills. * Planning and organizing skills. * Facilitation skills. * Attention to details. * Deadline driven & customer focused. * Objectivity. * Resilience.

JOB PURPOSE AND DIMENSIONS:

- Supports in developing and implementation of Quality Management System (QMS) and ensure system maintenance in all operations of the Authority in accordance to ISO 9001

KEY PERFORMANCE AREAS:

- **Business Support and Advisory** *Contribute to the creation and implementation of QMS best practices and improve operational performance. * Identify business improvement opportunities within the organisation. * Advise management on compliance of SAHPRA staff to established procedures, policies and regulatory requirements. *Supports the management team to share ideas and improve operations supporting and implementing continuous activities.
- **QMS Governance and Compliance** * Sets and oversees implementation of the policy and procedures with regard to quality management and in line with regulatory benchmarks. * Management and facilitation of quality documentation system. * Ensure compliance with current legislation, regulations and standards. * Support Introduction of new systems and procedures where necessary.
- **QMS Risk Management** * Prepare an internal quality audits plan taking into account technical factors. * Conduct planned internal quality audits of SAHPRA processes to

verify effectiveness of the Quality Management System and follow up on post audit activities. * Handling of internal and external customer complaints. * Ensure corrective actions are undertaken to address non-conformities identified * Monitor implementation of recommendations of internal quality audit reports and submit reports to the Management for review.

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: Matshepo.mokotong@sahpra.org.za (**DO NOT SEND APPLICATIONS TO THIS EMAIL ADDRESS**).

CLOSING DATE: 08 November 2022 at 16H00.