The South African Health Products Regulatory Authority (SAHPRA) is the National Medicines Regulatory Authority established in terms of the *Medicines and Related Substances Act, 101 of 1965,* as amended, to monitor, evaluate, regulate, investigate, inspect, register and control medicines, schedule substances, clinical trials and medical devices, including IVDs, and related matters in the public interest.

Organisation	**SAHPRA**
Unit	**Clinical Evaluation Management (CEM)**
Work arrangement	**On site**
Location	**Pretoria**
Position	**Manager: Clinical Post-Registration Evaluations**
Ref No	**SAHPRA 34 of 2026/27**
Salary	**R 1 010 600 – R 1 237 700.00 per annum (TOTAL COST TO COMPANY)**

EE	X	Permanent	X	Fixed term Contract		Disability	X

JOB PURPOSE

The role of the Manager for Clinical Post-Registration Evaluations is responsible for leading the Business Unit by enforcing compliance, develop and implement regulations, mitigate risks and protect public health among others.

RESPONSIBILITIES:

Operational Management:

- Manage the operations of the Business Unit with regards to the processes, inputs, targets, outputs and resourcing requirements.
- Offer technical advice and support to team members on a range of regulatory issues/ requirement.
- Implement SAHPRA policies and procedures to identify and resolve complex issues and inconsistencies and make recommendations on initiatives.
- Lead processes for appeals lodged against regulatory decisions taken by the national regulator.
- Manage the development of regulations, regulatory processes and guidelines within the Business Unit.

- Perform quality assurance of processes and outputs to ensure compliance with legislative and regulatory requirements.
- Apply scientific principles, regulatory requirements, best practices and quality assurance and review applications where applicable.
- Conduct reviews and/or adjudicate peer-reviewed reports and provide technical decisions regarding applications.
- Manage and support Clinical Technical Advisory Committee.
- Responsible to capacitate various operations or work streams of the Business Unit with skilled staff.
- Allocate program or project resources in line with strategic direction.
- Identify and prioritise resources across various initiatives or operations.
- Develop and monitor the implementation of the annual operational plan and Business Unit plans.
- Ensure operations and processes of the Business Unit are aligned to the relevant legal frameworks, prescribed local and international Guidelines.

Stakeholder Management:
- Conduct consultation meetings with representatives from the orthodox medicines industry to advise on administrative and technical issues.
- Respond to external enquiries by industry, Business Units within SAHPRA and other external stakeholders.
- Participate in industry engagements and regulatory forums regionally and internationally (e.g. Zazibona, WHO, ICH Working Groups, IPRP, Continental initiatives).

Financial Management:
- Develop or support the development of the programme's budget and manage its implementation.
- Work together with Finance Unit to develop and manage the Business Unit's annual budget.
- Ensure the effective implementation, management, monitoring of the Business Unit's budget, and mitigate and report on any variances.
- Prepare and submit accurate financial reports within the required timeframe.
- Ensure revenue information is collated and provided to the Finance office within the required timeframe.
- Manage and ensure effective utilisation of financial resources.

Governance, Risk and Compliance Management:
- Develop, review, update and implement policies related to Standard Operating Procedures and Guidelines.
- Adhere to SCM and PFMA aspects and other SAHPRA policies and procedures.
- Ensure process changes are processed through effective change control processes.
- Apply risk management in processes.
- Manage all relevant internal and external audits by responding to any non-conformances or audit findings that are raised and develop mitigation reports.
- Provide timely and accurate evidence and expert analysis to support the Legal Unit in addressing compliance issues and legal matters.
- Ensure deviations or non-conformances are recorded and responded to.
- Implementation of Quality Management Systems (QMS) Culture.
- Manage the development and continuous monitoring of the QMS in the Business Unit – processes, guidelines in alignment with best practices (i.e., National, Regional, Continental, international).
- Manage the development and review of internal policies, in collaboration with senior management. Ensure compliance with implementation of approved processes.
- Ensure training records on all processes are maintained.

- Compile Business Unit reports as required (monthly reports, internal reports, external reports).
- Identify risks for the Business Unit, develop mitigation plans and oversee the implementation of mitigation plans.
- Ensure readiness for internal and external audits by maintaining accurate records, documentation, and compliance with audit requirements.

People Management:

- Develop (i.e., training, coaching, mentoring) and manage (i.e., recruitment, retaining, onboarding, offboarding, daily operations) of Human Resources within the Business Unit.
- Foster a positive and collaborative team culture.
- Ensure maintenance of confidentiality, high ethical conduct, efficient, effective high-quality performance of staff members.
- Manage workstream, staff members' compliance with organisational policies and procedures by performing regular performance assessments and implementation of individualized interventions where applicable and escalating further non-compliance to the relevant Senior Manager.
- Lead and oversee the work stream team through task delegation, leave administration and planning, and cultivating a cooperative work atmosphere.
- Workstream staff members' training needs are identified, training programs are planned, and professional development is promoted to advance the workstream team's expertise and ensure retraining is executed where applicable.
- Support and manage development of annual performance reports.
- Peer annual performance report and 360 reports.
- Manage employee relations (Labour relations and wellness matters) within the Business Unit.

REQUIREMENTS

- A Matric or Grade 12 certificate and a four-year Bachelor of Pharmacy degree at NQF Level 8 and current registration with the South African Pharmacy Council, or an MBChB degree and registration as a Medical Officer with the Health Professions Council of South Africa (HPCSA) as recognised by the South African Qualifications Authority (SAQA).
- A post-graduate qualification in health sciences at NQF level 9 will be an added advantage.
- A minimum of ten (10) years' relevant experience in medicines regulatory field in evaluation/compiling safety, quality and efficacy data, including product information and patient information leaflets. At least five (5) years must have been at a supervisory / management level (Level 09 – 12) supporting business operations.
- Experience in medicine registration will be an added advantage.
- Experience in the application of the Medicines and Related Substances Control Act 101 of 1965 (as amended), and its related Regulations.
- A valid driver's licence.

COMPETENCIES AND SKILLS

- Knowledge and application of the Medicines and Related Substances Control Act (101 of 1965), as amended, and its related Regulations and Guidelines.
- Knowledge of technical aspects for the evaluation of quality, safety, and efficacy of medicines. Knowledge of Regulatory framework, policies, and process. Knowledge and understanding of clinical pharmacology.
- Understanding of medicine registration and harmonised standards.
- Knowledge of Good Clinical Practice.

- Organisational awareness.
- Principles of quality management.
- Performance and team management.
- Critical and analytical thinking.
- Projects management and leadership.
- Ability to manage a variety of cross-functional team members.
- Report writing.
- Communication skills (verbal, written, negotiation, conflict management, presentation).
- Risk based decision and Evidence-informed practice.
- Planning and organising.
- Change management.
- Problem analysis and solving.
- Interpersonal skills and team player.
- Integrity and flexibility.
- Attention to detail and results driven.
- Resilience and ethical behaviour.

Due to large number of applications anticipated, communication will be limited to short-listed candidates only. Applicants who have not been contacted within three (3) months after the closing date should consider their application unsuccessful.

- **Interested candidates who meet the above requirements should submit their applications, clearly indicating the title of the position and the reference number. Applications must include a signed cover letter, a detailed Curriculum Vitae (CV) with the names and email addresses of three (3) referees, and certified copies of the required qualifications (including matric). Only shortlisted candidates will be required to submit certified copies of qualifications and other relevant documents on or before the interview date, as communicated by Human Resources.**
- Should you have a foreign qualification, your application must be accompanied by an evaluation certificate (report) from SAQA.
- The above-mentioned documents are compulsory. Incomplete applications or applications without the aforementioned documents or information will not be considered.
- No late applications will be accepted. Any submissions received after the specified date and time will not be considered.
- **When applying for a position on the Recruitment Portal, kindly ensure that your documents are grouped and uploaded as follows:**
  - ❖ **Cover Letter and CV combined into one document.**
  - ❖ **Qualifications/Certificates and ID Copy combined into one document.**
- Shortlisted candidates will be expected to attend selection interviews on a specific date, time, and location as communicated by SAHPRA.

- Applicants should note that pre-suitability checks will be conducted after they have been shortlisted. The appointment is subject to positive outcomes from these checks, which include security clearance, verification of qualifications, criminal records, credit checks (where applicable), citizenship status, employment verification and work experience.
- SAHPRA reserves the right not to appoint any candidate to the advertised post.

- SAHPRA adheres to the provisions of the Protection of Personal Information Act (POPIA), 4 of 2013. CVs will not be returned, as the personal information you provide will be used solely for recruitment purposes, specifically for the position or vacancy you have applied for. If your application is unsuccessful, your personal information will be retained for internal audit purposes.

Employment Equity statement:

- SAHPRA is committed to being an equal opportunity employer. When filling vacant positions, the entity will consider the principles outlined in Section 195(1)(i) of the Constitution of the Republic of South Africa, Act 108 of 1996, and the Employment Equity Act, 55 of 1998.
- **People with disabilities (should indicate their disability status), males (all races) and females (Coloured and White) will be given preference.**

Application closing date: **02 October 2026**

- Applications should be submitted through the SAHPRA Website Online Portal: http://www.sahpra.org.za/vacancies.

NOTE: SAHPRA WILL NOT ACCEPT APPLICATIONS SENT THROUGH EMAIL ADDRESSES.

Enquiries

Name	Ms Bafedile Rakgotho, HR Business Partner
Email/ Tel No	Bafedile.Rakgotho@sahpra.org.za/ 012 015 5405