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.

This procurement will be managed by Supporting Health Initiatives (SHI), a Division of Wits Health Consortium Pty Ltd (WHC) for and on behalf of SAHPRA. SHI is dedicated to promoting and enabling public health activities that lead to new, significant advancements in healthcare and related fields and does this by providing resources, collaborative opportunities and project management support to partners and funders. SHI has developed a strong track record of delivering on assignments in Africa. SHI's operations and business teams have demonstrated capacity to quickly align with partners, distribute funds, and oversee implementation.

Specialist:	Good Manufacturing Practices (GMP)
Contract: Ending	31 December 2026, with possible extension based on performance.
Location:	Pretoria, South Africa (Hybrid) *(South Africans encouraged to apply).*
Reference:	SAHPRA 033/2024
Remuneration:	Competitive, depending on experience.

Why Join Us?

This is a unique opportunity for international subject matter experts to work in a hybrid model, collaborating with SAHPRA to advance Good Manufacturing Practices (GMP) within South Africa and beyond. This position offers an unparalleled chance to make a global impact, work alongside leading professionals, and contribute to the regulatory excellence that safeguards public health worldwide.

Key Responsibilities include but are not limited to:

- Conduct GMP Inspections: Lead local and international pharmaceutical manufacturing site inspections, ensuring compliance with GMP standards adopted by SAHPRA.
- Policy Development and Advisory: Shape GMP-related policies, guidelines, and inspection frameworks in line with global best practices.
- Global Engagement: Collaborate with international regulatory bodies and represent SAHPRA in global regulatory forums and conferences.
- Capacity Building: Provide training, mentorship, and capacity development on GMP regulatory practices for SAHPRA staff and stakeholders.
- Risk Management: Ensure ethical, accurate, and efficient management of inspection-related risks, resources, and records.

Performance Expectation include but are not limited to:

- Demonstrate strong leadership qualities in a regulatory environment.
- Excellent communication, analytical, and decision-making skills to navigate complex challenges.
- Implement effective risk management strategies to mitigate potential risks and ensure the quality and safety of pharmaceutical products.
- Thrive in a dynamic and multicultural environment while working effectively within diverse teams.
- Adapt and manage competing priorities efficiently.

- Conduct thorough inspections of local and international pharmaceutical manufacturing sites to verify adherence to SAHPRA's GMP standards.
- Consistently identify and document GMP deviations and compliance issues, and issue inspection reports that are accurate, timely, and well-supported by evidence.
- Play a key role in developing and implementing GMP-related policies, guidelines, and inspection frameworks.
- Transfer skill to SAHPRA staff and stakeholders on GMP regulations and inspection procedures.
- Contribute to capacity development initiatives to enhance GMP expertise within the organization.
- Adhere to South African data protection laws and SAHPRA's specific data protection policies

Application Criteria:

Qualifications and Expertise

- Essential:
  - Master's degree in Pharmacy.
  - Registration as a Pharmacist.
  - A minimum of 10 years of experience in pharmaceutical manufacturing or quality management systems (QMS), including GMP inspections.
  - Proven technical leadership in regulatory environments and participation in international regulatory forums or advisory bodies.

- Preferred:
  - A PhD in a related field.
  - Demonstrated experience with hybrid or remote international collaboration.

Core Competencies

- Deep knowledge of GMP legislation, regulations, and international protocols.
- Advanced analytical, communication, and decision-making skills for complex regulatory challenges.
- Proven ability to lead, mentor, and work within diverse teams in high-pressure environments.
- Adaptability and resilience to manage competing priorities effectively.

What We Offer

- **Hybrid Working Model:** Flexibility to work remotely with periodic travel to South Africa, supported by robust digital tools.
- **Global Impact:** Contribute to shaping GMP standards and advancing public health on a global scale.
- **Professional Growth:** Collaborate with leading regulatory professionals and institutions in a dynamic, multicultural environment.
- **Innovative Collaboration:** Join a team committed to regulatory excellence and transformative public health initiatives.

Application Process

Submit your application via email to SHIproposals@supportinghi.co.za, by c.o.b 17 January 2025. Applications must include:

- A detailed cover letter and curriculum vitae.
- Certified copies of qualifications, including professional registrations.
- A copy of a valid driver's license.

Please note: Applications must clearly state the position and reference number. Late or incomplete submissions will not be considered.

Diversity and Inclusion: SAHPRA is an equal opportunity employer committed to fostering diversity in its workforce. Candidates from underrepresented groups and individuals with disabilities are encouraged to apply.

For inquiries: contact Mr Itumeleng Mosenyi at Itumeleng. Mosenyi@sahpra.org.za. **(Note: Applications sent to this email will not be processed).**

Only shortlisted candidates will be contacted.