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:	Biological Medicine (Vaccine) Clinical Assessor (*3 Positions*)
Contract:	Ending 31 December 2026, with possible extension based on performance.
Location:	Pretoria, South Africa (Hybrid)
Reference:	SAHPRA 036/2024
Remuneration:	Competitive, depending on experience.

Why Join Us?

This role offers an exceptional opportunity for **international experts** to contribute to global health by providing expertise in the evaluation of biological medicines and vaccines. Working in a **hybrid environment**, you will collaborate remotely and in person, driving advancements in clinical assessments and regulatory science in South Africa and beyond.

Key Responsibilities include but are not limited to:

- Strategic Leadership: Provide technical leadership on clinical and non-clinical assessments for biological medicines, aligning with local and international regulatory strategies, WHO standards, and other National Regulatory Authorities (NRAs).
- Advisory Role: Advise on SAHPRA regulations, policies, and guidelines, ensuring compliance with global standards for biological medicines, including vaccines and biotherapeutics.
- Application Evaluation: Conduct detailed assessments of safety and efficacy aspects in applications for biological medicines (biotherapeutics, biosimilars, and vaccines) in compliance with the Medicines and Related Substances Act (Act No. 101 of 1965).
- Peer Review and Mentorship: Provide critical and analytical feedback as a peer reviewer, ensuring thorough evaluation of clinical and non-clinical sections of biological submissions. Train and mentor SAHPRA staff to enhance technical capacity.
- Global Collaboration: Represent SAHPRA in international regulatory forums, engage with industry stakeholders, and drive innovation in regulatory science.

Performance Expectation include but are not limited to:

- Collaborate effectively with multidisciplinary teams and engage with industry stakeholders on regulatory matters.
- Transfer skill to SAHPRA staff and stakeholders on Biological Medicine (Vaccine).
- Maintain resilience, adaptability, and a commitment to excellence in regulatory science.

- Champion innovation in regulatory science to improve the efficiency and effectiveness of clinical assessments for biological medicines.
- Adhere to South African data protection laws and SAHPRA's specific data protection policies

Application Criteria:

Qualifications and Expertise

- Essential:
  - B. Pharm Degree or MBChB with a Master's in Pharmacy (NQF) Level 09) as evaluated by South African Qualifications Authority (SAQA),
  - Registration with professional body
  - A minimum of 10 years of experience in evaluating safety and efficacy for biological medicines, including product information and patient information leaflets.
  - Proven knowledge of international guidelines and regulatory standards for clinical aspects of biological medicines.

- Preferred:
  - Postgraduate qualifications in virology, vaccinology, or pharmacology of biotherapeutics.
  - Expertise in clinical trials, biological dossiers, and regulatory compliance.
  - Experience in hybrid or remote collaboration models.

Core Competencies

- Comprehensive understanding of clinical and non-clinical evaluation for biological medicines.
- Advanced analytical, communication, and decision-making skills for complex regulatory challenges.
- Ability to lead and mentor multidisciplinary teams with a focus on knowledge transfer.
- Resilience, adaptability, and a commitment to excellence in regulatory science.

What We Offer

- **Hybrid Working Model:** Flexibility to work remotely with periodic travel to South Africa, supported by advanced technology.
- **Global Impact:** Contribute to the safety and efficacy of biological medicines worldwide, driving public health improvements.
- **Professional Growth:** Collaborate with global regulatory professionals and gain exposure to cutting-edge regulatory practices.
- **Collaborative Environment:** Be part of a diverse and dynamic team focused on advancing public health through regulatory innovation.

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 **Ms. Setlola Molepo** at Setlola.Molepo@sahpra.org.za (Note: Applications sent to this email will not be processed).

Only shortlisted candidates will be contacted.