

Afrigen secures SAHPRA GMP certification for Africa's first end-to-end mRNA manufacturing facility

Afrigen earns SAHPRA GMP certification for Africa's first end-to-end mRNA facility, advancing vaccine manufacturing and health security

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[/EINPresswire.com/](https://www.einpresswire.com/) -- Afrigen Biologics has secured Good Manufacturing Practice (GMP) certification from the South African Health Products Regulatory Authority (SAHPRA) for its mRNA facility in Cape Town, marking a major milestone for South African biotechnology and African vaccine manufacturing. The certification means the facility now meets internationally recognised manufacturing standards and is authorised to manufacture investigational biological products for Phase I and II clinical trials.



Accreditation event ribbon cutting ceremony with Prof Terblanche in the middle (with the scissors)

The achievement positions Afrigen among a small number of advanced biomanufacturing platforms on the continent and strengthens Africa's ability to develop, manufacture and supply next-generation health products closer to where they are needed. It also gives practical effect to the strong investment in local scientific capability, regulatory readiness and manufacturing infrastructure in the wake of the inequities exposed during the COVID-19 pandemic. Afrigen is a key part of the mRNA Technology Transfer

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Professor Petro Terblanche

Programme co-led by World Health Organization (WHO) and Medicines Patent Pool (MPP), which supports a network of partners across four continents. In just four years, Afrigen has progressed from concept to a GMP-certified end-to-end facility designed to support research, development, technology transfer and clinical-trial-stage manufacturing.

Built through partnership

Prof. Petro Terblanche, CEO of Afrigen Biologics, said:

“This certification is a major moment for Afrigen and for the partners who have helped build this capability. It is also a tribute to the extraordinary commitment of the team here at Afrigen, whose work has taken us from concept to a GMP-certified facility in just four years. It confirms that we are ready to support clinical trial material production, advance technology transfer and contribute meaningfully to vaccine and biologics development and manufacturing.”

Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, said:

“Today marks an important milestone not only for South Africa and the African continent, but also for global health. Afrigen now serves as a quality-assured strategic platform for regional manufacturing, contributing to secure supply, pandemic preparedness and Africa’s health sovereignty. The next phase of the mRNA Technology Transfer Programme must focus on sustainability, strengthening product pipelines, partnerships and long-term capabilities.”

Charles Gore, Executive Director of the Medicines Patent Pool, said:

“Afrigen is a powerful example of what can be achieved through collaboration and sustained investment. In just a few years, the Programme has moved from concept to regulated manufacturing capacity and a growing global network. As we look to the next phase, maintaining and expanding this momentum will be absolutely essential.”

Bernd Lange, Chair of the Committee on International Trade of the European Parliament, said:

“The Good Manufacturing Practice certification of Afrigen’s mRNA facility – the first on the continent – marks a major milestone for African vaccine manufacturing. Supported through the EU’s Global Gateway flagship initiative, MAV+, this achievement demonstrates how EU-South African partnerships, backed by European funding and technology, can strengthen local vaccine manufacturing capacity and reinforce global health security.”

Regulatory recognition

The GMP certification awarded by SAHPRA confirms that Afrigen meets internationally recognised standards for pharmaceutical manufacturing.

Dr Thapelo Motshudi, Chair of the Board of SAHPRA, said:

“Afrigen’s GMP certification reflects the rigour of South Africa’s regulatory system and marks an important step forward for health manufacturing on the continent. It demonstrates that African facilities can meet globally recognised standards and helps build confidence in the continent’s growing scientific and manufacturing capability.”

Looking ahead

Afrigen is preparing for its next phase, including plans to transition towards a non-profit company structure in collaboration with the South African Medical Research Council (SAMRC) and with a focus on long-term sustainability and public health impact.

Dr Aaron Motsoaledi, Minister of Health of South Africa, said:

"Afrigen's GMP certification is a major achievement for South Africa and a proud moment for the continent. It reflects our commitment to strengthening local health manufacturing capacity and ensuring Africa is better prepared for future health challenges."

Prof. Nicholas Crisp, Director-General: Health, National Department of Health, said: "Afrigen's GMP certification is a major achievement for South Africa and an important step for the continent. Strengthening regional manufacturing capacity is essential to improving health security and ensuring that Africa is better prepared to respond to future pandemics and other health emergencies. This milestone reflects the value of sustained investment in the scientific, regulatory and manufacturing capability we will need for the future."

Dr Ntobeko Ntusi, President and CEO of SAMRC, said:

"Afrigen demonstrates what it looks like when scientific innovation is translated into real public-health and manufacturing capability. As Afrigen enters this next phase, SAMRC looks forward to working even more closely to help secure its long-term sustainability and ensure this platform continues to deliver on its promise for South Africa, the continent and global health."

Precious Matsoso, Co-Chair of the Pandemic Fund and former Director-General of Health of South Africa, said:

"This Afrigen's GMP certification is a major milestone for South Africa and the continent. It's proof that when Africa invests in African science, we don't wait for vaccines – we make them. It shows the significance of public investment and scientific leadership. This means Africa can sustainably manufacture products that save lives. That's how we can secure our health future and win on preparedness and access."

Zacharia Kafuko, Africa Director of 1Day Sooner, said:

"For civil society, this milestone is ultimately about the people of Africa – about whether communities can count on faster, fairer access to the vaccines and health technologies they need. It is also a powerful sign of what African scientists are making possible: building the knowledge, capability and confidence to shape our own health future closer to the people it is meant to serve."

Continuing the work

Afrigen will continue working with partners across sectors to support vaccine and biologics development, clinical development, manufacturing and access in South Africa, across Africa and globally.

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