

FREQUENTLY ASKED QUESTIONS

Investigational Vaccines and Biologics Facility



1. What is the Investigational Vaccines and Biologics Facility?

This is a CSIR development and manufacturing facility based in Pretoria, designed to bridge the gap between laboratory research and early clinical evaluation. It brings together process development, analytical testing, quality systems and small-scale production capabilities to help promising vaccine and biologic candidates progress towards the production of investigational clinical material.

2. Why are investigational vaccines and biologics important for Africa?

Africa has significant scientific expertise and emerging pharmaceutical manufacturing capacity, but limited access to specialised facilities that can translate locally developed candidates into well-characterised materials for early clinical development. This facility strengthens this critical link by providing local development and manufacturing capabilities, reducing reliance on external capacity and supporting the growth of resilient regional pharmaceutical value chains.

3. What development gap does the facility address?

The facility addresses the gap between discovery and early clinical development. Promising vaccine and biologic candidates often require specialised

process development, analytical characterisation and controlled manufacturing before they can progress to clinical evaluation. The facility is designed to provide these capabilities within South Africa, subject to the facility and its quality systems being qualified for the intended use.

4. What types of products does this facility support?

The facility is intended to support the development of vaccine and biologic candidates across different product types and expression systems. Its capabilities include adaptable upstream and downstream process development, analytical testing, product characterisation and quality-control activities. The suitability of the facility will depend on the specific product, development stage, process and intended use.

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5. What makes vaccines and biologics different from conventional medicines?

Vaccines and biologics are generally produced using living systems, making their development and manufacture highly dependent on the biological expression platform, process conditions, purification methods and analytical controls. Small changes in the manufacturing process can affect product characteristics, making process control, characterisation and quality assurance particularly important.

6. How does the facility support vaccine and biologic development?

The facility can help development teams refine manufacturing processes, characterise candidates, identify critical quality attributes and establish reproducible approaches for producing investigational batches. These capabilities support the progression of promising candidates towards early clinical evaluation, while scale-up and subsequent technology transfer require product-specific development and validation.

7. Will the facility manufacture vaccines and biologics commercially?

The facility is primarily focused on development and phase-appropriate investigational manufacturing rather than commercial-scale production. Commercial manufacturing would require appropriate scale-up, validation, regulatory approval and transfer to suitable manufacturing facilities. The facility therefore serves as an important development-stage link between research and larger-scale manufacturing.

8. How can this facility contribute to Africa's health security?

By strengthening local capabilities for vaccine and biologic development, this facility can support greater preparedness for diseases affecting African populations, including endemic diseases and potential future outbreaks. It contributes to building the infrastructure, expertise and partnerships needed to develop health technologies closer to the populations and health priorities they are intended to serve.

9. What skills and industrial opportunities does this facility create?

The facility support skills development for scientists, engineers and quality specialists in areas such as process development, analytical characterisation and phase-appropriate manufacturing. It can also create opportunities for biotechnology companies, technology providers, suppliers, manufacturers and other industrial partners to participate in development and technology transfer activities.

10. How can researchers, industry and strategic partners engage with the facility?

Researchers, biotechnology companies, pharmaceutical manufacturers, funders and public health organisations can engage the CSIR on specific candidates, technologies or shared platform development needs. Potential areas of collaboration include process development, analytical method development, candidate characterisation, investigational manufacturing planning, training, technology transfer and jointly funded development programmes. Each engagement will be assessed on a case-by-case basis according to facility readiness, product requirements, intended use, intellectual property, timelines and commercial considerations.

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