

Investigational Vaccines and Biologics Facility

The CSIR Investigational Vaccines and Biologics Facility in Pretoria is a development and manufacturing facility designed to bridge the gap between laboratory research and early clinical evaluation. As part of the CSIR's broader FuturePharma initiative, the facility 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.

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 gap can result in promising projects relying on overseas development and manufacturing services, increasing cost, extending timelines and creating dependence on external capacity. The facility is designed to strengthen this critical link by providing a South African base for process development, analytical characterisation, quality control and, subject to facility and quality system qualification for the intended use, phase-appropriate investigational manufacture.

Vaccines and biologics are technologically complex products manufactured using living systems, where quality depends on factors such as the expression platform, process controls, purification methods and

analytical testing. The facility is being progressively equipped to support adaptable upstream and downstream process development, together with analytical and quality control capabilities. This enables development teams to refine processes, characterise candidates, identify critical quality attributes and establish reproducible approaches for producing investigational batches.

This flexible approach can accommodate different candidate types and expression systems, with controls appropriate to each stage of development. Scale-up and transfer to commercial manufacturers remain product-specific and require further development, validation and regulatory consideration.

The facility has the potential to accelerate the development of locally relevant vaccines and biologics, including candidates that address endemic diseases and future outbreak threats, while strengthening the skills and expertise required to sustain Africa's biopharmaceutical sector. It can provide practical



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development and training opportunities for scientists, engineers and quality specialists, while creating opportunities for technology providers, suppliers, biotechnology companies and industrial partners. By strengthening the pathway from discovery to clinical development, the facility can contribute to more resilient regional pharmaceutical value chains and greater capacity to develop products aligned with African health priorities.

The facility also creates opportunities for researchers, biotechnology companies, manufacturers, funders and public health partners to collaborate with the CSIR on candidate development and shared technology platforms. Potential areas of engagement include process and analytical method development, candidate characterisation, investigational manufacturing planning, skills development, technology transfer and jointly funded development programmes.

Each collaboration will be considered according to facility suitability and readiness, product requirements, intended use, intellectual property considerations, timelines and commercial terms.

This facility represents a critical capability within Africa's biopharmaceutical development pathway, connecting research, technology and manufacturing to help promising vaccines and biologics move closer to clinical evaluation and, ultimately, potential patient access.



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