Summary of capabilities

Pretoria, South Africa

Facility facts	
Opened:	2009
Audited:	South African Health Products Regulatory Authority, (SAHPRA), South African Pharmacy Council (SAPC)
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Offerings

- Sub-Saharan Africa third-party hub serving 36 countries, facilitated and project managed through South Africa, providing access to a large patient population
- A cGMP facility with controlled ambient and refrigerated secondary packaging and labeling production rooms
- Wholesaler for medical devices, IVDs storage, importer, exporter, distributor, and manufacturer for medical devices and IVDs (packing, repacking, labeling, and assembly of kits/procedure pack of medical devices)
- Management of high-risk pharmaceutical waste classes; compliant with local authorities, DAFF, SANS, provincial, and municipal by-laws through audited and approved vendors
- Comprehensive breadth of services and unique expertise supporting all aspects of clinical trial supply from project consultation, study planning and management, secondary packaging, labeling, storage, distribution, returns, and destruction
- Regulatory support for local and global studies — alignment across licenses

Benefits to sponsors

- A well-established cGMP and cGWP facility dedicated to supporting clinical trials in South Africa and Sub-Saharan Africa, offering clinical trial sponsors complete end-to-end clinical supply chain solutions
- Collaborative and flexible approach to meet client needs for new and emerging pharma and large pharma portfolio of clients across all phases and therapeutic areas
- A proven track record of achieving industry-leading performance and quality, offering control, compliance, risk management, and visibility across the entire clinical supply chain
- Our highly experienced team has supported over 283 studies to date, with 100+ active studies. In support of global trials, we've served as importer of record for 922+ shipments, streamlining the process for our study sponsors
- Since 2012, we've sent 30,000+ shipments with over 435,000 kits to over 1,300 locations across 9 provinces and over 180 suburbs at 99.95% OTIF and 99.86% quality performance
- As an importer of record, our extensive experience in clearing clinical trial investigational medicinal products through customs, coupled with our up-to-date knowledge of regional customs regulations, minimizes delays and mitigates risks throughout the clinical supply chain. Our global trade and compliance policy with close working relationships through strategic partnerships places Thermo Fisher in a unique position to facilitate seamless customs clearance of clinical trial investigational medicinal products.
- Long-established, reputable provider, helping to define best practices in the industry with continued investments in capacity, capabilities, and expertise

Challenges

- Sub-Saharan Africa presents many challenges for pharmaceutical and biotech companies conducting clinical trials as the patient pool can extend out to less developed areas of the countries. The importance of a secure supply chain cannot be underestimated; Thermo Fisher Scientific South Africa understands this and maintains an updated database of regulatory requirements, import/export license requirements and processes, and VAT and duty implications which differ from country to country

Summary of capabilities

Pretoria clinical storage and packaging capabilities:

Capacity and services			
Storage environments	Ambient shelf (15°C - 25°C)	7,965 sq. ft., (740 sq. m.)	956 tote locations
	Ambient pallets (15°C - 25°C)		80 pallet locations
	Refrigerated (2°C - 8°C)	Walk-in cold room 1,851 sq. ft. 172 sq. m.	746 tote locations
	Frozen (-20°C) walk-in freezer	Walk-in freezer 388 sq. ft. 36 sq. m.	57 tote locations
	Upright freezer (-40°C)	1 x 710L ultra low upright freezers	4 shelves
	Upright freezer (-60°C)	2 x 1,000L and 2 x 710L ultra low upright freezers	16 shelves
	Upright freezer (-80°C)	3 x 710L ultra low upright freezers	12 shelves
Facility and environment management	Back-up power	• Full-load standby diesel generators with remote control and monitoring • All critical equipment on dedicated clean power • 5-hour backup UPS for all critical systems • 24-hour diesel fuel supply	
	Environmental	• Main power and building lighting surge protection • Multiple alert/early warning systems with remote access (temperature environments, mains power, generators, security, and fire)	
	Security/access	• Located in a secure business park with 24-hour security • Secure 2.4m high fenced and gated facility with 24/7/365 security • External and internal intruder detection linked to backup response • CCTV cameras on building perimeter with remote access • Access to controlled environments is secure via an access-controlled system	
Distribution	Project/study management	Assess, understand, initiate, plan, and execute study set up for clinical trials with leading technology and processes	
	Storage	Our current Good Wholesale Practice (cGWP) facility offers secure temperature-controlled storage of investigational medicinal products for vaccines, oncology, beta lactams, GMOs, general medicines, and controlled drugs at multiple temperature ranges	
	Transportation management	Giving chain of custody/visibility on domestic, Sub-Saharan Africa, and international shipments	
	Returns reconciliation/storage/ destruction	Reconcile, store, and dispose of used or unused clinical trial materials across the region. All disposals are reconciled with appropriate destruction certificates	
	Healthcare risk waste (HCRW)	Management of high-risk pharmaceutical waste classes; compliant with local authorities, DAFF, SANS, provincial and municipal by-laws through audited and approved vendors	
	Medical devices, IVDs	Storage, importer, exporter, distributor, and manufacturer for medical devices, IVDs, (packing, repacking, labeling, and assembly of kits/procedure pack of medical devices)	
	Comparator sourcing	Assists sponsors with managing the full breadth of comparator, co-medication, and rescue medication sourcing requirements in the region. This eliminates the need for multiple suppliers and mitigates the risk of counterfeiting across the clinical supply chain	
	Clinical ancillary sourcing and management	Dedicated expertise for ancillaries, comprehensive sourcing based on complete study details, central or local sourcing, leveraging the entire Thermo Fisher Scientific portfolio	
	Environmentally friendly reusable shipper solution	Reusable shippers with extended validation periods reduce the risk of temperature excursion during transport, improve site satisfaction, and positively impact sustainability metrics across the clinical supply chain	

Summary of capabilities

Pretoria clinical storage and packaging capabilities:

Capacity and services		
Secondary packaging and labeling	A cGMP facility with controlled ambient and refrigerated secondary packaging and labeling production rooms	• Single or double blinding of investigational medicinal product packaging • Label design, translation, regulatory review, and production • Local and required languages for clinical trial sites • Single panel, booklet, tear off, variable text labels • Expiry date labeling/relabeling, overlabeling, investigator labeling • Just-in-time labeling • Secondary kit assembly, kitting (various) configurations, de-kitting • Carton labeling, blister labeling, randomized labeling • Auxiliary labeling, patient information leaflets • Foam inserts for kitting operation

For detailed capabilities and capacity information, please contact your Thermo Fisher Scientific representative.

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