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Summary of capabilities

Pretoria, South Africa

Facility Facts:

Opened:	2009
Audited:	South African Health Products Regulatory Authority, (SAHPRA) South African Pharmacy Council (SAPC)
Contact Info:	36 Parkview Street, Unit 1 - 4 Highway Business Park, Rooihuiskraal Centurion, Pretoria, 0157 Tel: +27 12 649 0260

Unique Offering:

- Sub-Saharan Africa 3rd 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 & labeling production rooms
- Wholesaler for Medical Devices, IVD's Storage, Importer, Exporter, Distributer and Manufacturer for Medical Devices, IVD's, (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 offer Clinical Trial Sponsors complete end-to-end clinical supply chain solutions
- Collaborative, flexible approach to meet client needs for new emerging pharma & large pharma portfolio of clients, across all phases & therapeutic areas
- A Proven Track Record, achieving Industry leading performance and quality. Offering control, compliance, risk management and visability 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, 30000+ shipments with over 435000 kits to over 1300 locations across 9 provinces and over 180 suburbs @ 99.95% OTIF and 99.86% quality performance
- IOR, our vast experience in clearing Clinical Trial Investigational Medicinal Product through customs and our up-to-date knowledge on customs regulations across the region reduces delay time and mitigates risk across the clinical supply chain. Our Global Trade and Compliance Policy with close working relationships through strategic partnerships places Fisher Clinical Services South Africa in a unique position to facilitate seamless customs clearance of Clinical Trial Investigational Medicinal Product.
- Long-established reputable provider in defining 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, Fisher Clinical Services South Africa understands this and maintains an updated database of regulatory requirements, import/export license requirements & processes, VAT & Duty implications which differ from country to country.

Pretoria Clinical Storage and Packaging Capabilities:

Capacity & Services			
Storage Environments	Ambient Shelf (15°C - 25°C)	7,965 sq. ft., (740 sqm)	1018 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 sqm	748 tote locations
	Frozen (-20°C) Walk-in Freezer	Walk-In Freezer 388 sq. ft. 36 sqm	48 tote locations
	Upright freezer (-40°C to -70°C)	4 x 710L Ultra Low upright freezers, (2448 m^3)	16 shelves
		2 x 1000L Ultra Low upright freezers, (1680 m^3)	8 shelves
	Upright freezer (-55°C to -85°C)	2 x 1000L Ultra Low upright freezers, (1680 m^3)	8 shelves
Facility and Environment Management	Back-Up Power	• Full load standby diesel generators with remote control & monitoring • All critical equipment on dedicated clean power, • 5-hour back up UPS for all critical systems • 24-hour diesel fuel supply	
	Environmental	• Mains Power & Building Lighting Surge Protection • Multiple alert/early warning systems with remote access (Temperature Environments, Mains Power, Generators, Security & 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 a access-controlled system	
Distribution	Project / Study Management	Assess, Understand, Initiate, Plan and Execute study set up for Clinical Trials with leading technology and process	
	Storage	Our Good Wholesale Practice (cGWP) facility offers secure temperature-controlled storage of Investigational Medicinal Product for Vaccines, Oncology, Beta Lactams, GMO's, General Medicines and Controlled Drugs at multiple temperature ranges	
	Transportation Management	Giving chain of custody / visibility on Domestic, Sub-Saharan Africa, 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, IVD's	Storage, Importer, Exporter, Distributer and Manufacturer for Medical Devices, IVD's, (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 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 of entire Thermo Fisher Scientific portfolio.	
	Environmentally friendly Reusable Shipper Solution	Reusable shippers with extended validation periods reduce risk of temperature excursion during transport, improves site satisfaction and positively impacts sustainability metrics across the clinical supply chain.	
Secondary Packing and Labelling	A cGMP facility with Controlled Ambient and Refrigerated Secondary packaging & labeling production rooms	• Single or double blinding of investigational medicinal product packaging • Label design, translation, regulatory review & production • Local and required languages for clinical trial sites • Single panel, booklet, tear off, variable text labels • Expiry date labeling/relabeling, Over labelling, Investigator labelling • Just in time labeling • Secondary kit assembly, Kitting (various) configurations, De-kitting • Carton labelling, Blister labelling, Randomized labelling • Auxiliary Labelling, Patient information leaflets • Foam inserts for kitting operation	

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

Thermo Fisher SCIENTIFIC

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Published 12/21

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