

Allentown, PA USA

Facility facts:

Opened:	1999
Audited:	DEA, TSA, FDA, MPA, FAA, NBP
Licenses:	DEA controlled substance manufacturer/distribution/import/export (schedule I-V), TSA cargo screening, VAWD accreditation
Contact info:	7554 Schantz Rd Allentown, PA 18106 United States Tel: + 1 610 391 0800

Overview:

- Long-established reputable provider in defining best practices in the industry
- Track record of excellence in managing high volumes of clinical supplies: 100,000+ shipments annually, 50% temperature managed with 98% on-time dispatch

Capabilities:

- Comprehensive service line supporting all aspects of clinical trial supply—primary and secondary packaging, labeling, regulatory support, distribution, returns and destruction
- Flexibility to handle all types of clinical studies from Phase I to Investigator Initiated Studies (IIS), to the larger, more complex Phase II and Phase III studies
- Ability to handle compounds that are light sensitive, high potent compounds and/or compounds with zero tolerance for Time Out of Environment (TOE)
- Commercial primary packaging of oral solid dose including blister packs and bottles, with additional secondary packaging services for syringe / pre-filled syringe / pen / autoinjector assembly and labeling.
- Comprehensive engineering services enable streamlined/customized production: ncludes in-house tool manufacturing, CAD services for packaging design and in-house 3D print capabilities

Allentown clinical storage and packaging capabilities

Capacity and services

Storage conditions	Controlled ambient (15°C to 25°C)		200,000 sq. ft. (18,581 sqm)	24,000 pallets
	Refrigerated (2°C to 8°C)		60,000 sq. ft. (5,574 sqm)	5,000 pallets
	Frozen	-20°C	4,000 sq. ft. (372 sqm)	300 pallets
		-30°C	1,200 sq. ft. (112 sqm)	75 pallets
		-40°C	15 units	109 shelf positions
		-70°C	15 units	58 shelf positions
		-80°C	88 units	352 shelf positions
	Controlled substance CRT (15°C to 25°C)		8,500 sq. ft. (790 sqm)	1,000 pallets
Controlled substance refrigerated		200 sq. ft. (19 sqm)	4 pallets	

Allentown clinical storage and packaging capabilities

Capacity and services		
Engineering and facilities	Back-up power and redundant systems	Diesel and propane generators for systems and all controlled temperature units
	Environmental	Monitored 24/7 by the building automation system with alarms sent to on-site monitoring personnel
	Security/access	On-site security staff 24 / 7 / 365 CCTV monitoring Employee access to secured areas via system managed electronic badges
Primary packaging and manufacturing (37 production rooms)	Capabilities	Bottle filling for solid dosage forms (automated and manual), powder in bottle
		Automated blistering, cold form and thermoform, single and multi-pack
		Over-encapsulation and placebo manufacturing
	Controls/environments	Low humidity
		Light-sensitive Containment suites Dedicated washrooms
Secondary packaging (26 production rooms)	Capabilities	Bottle/vial/card labeling/de-labeling
		Carding / walleting in-line and mobile
		Syringe assembly and labeling; manual, semi-automated and automated
		Needle safety device (NSD); manual and semi-automated assembly
		Pen / auto-injector semi-automated assembly
		Blinding of multiple components
	Controls/environments	Patient kit assembly and consolidation
		19 CRT ambient (15°C to 25°C) rooms
		5 Refrigerated (2°C to 8°C) rooms
		1 Frozen (-20°C) room Light-sensitive packaging Bar code control (Production Assembly Scanning System—PASS) for identification, confirmation, material reconciliation of kits
Label services	Services	Label proof design and approval including regulatory review of text
		Text translation (ATLAS™ software)
		Variable text
		Cold chain labeling (refrigerated and frozen)
		Expiry date labeling / relabeling
		Manual and semi-automated application
	Types	Just-in-time and late-stage-customization
		GlobalPly SM and DigiPly SM booklet labels Single-and multi-panel labels Tamper seals
Engineering services	Capabilities	In-house tool manufacturing, 3D print technology, CAD services
Enhanced services	Clinical supply optimization services	Comparator and placebo sourcing and management
	Clinical ancillary management	
Distribution	Pick and pack services	Returns, storage, destruction
	Domestic and international transportation management	Total transportation management services
	Re-usable shippers	

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