

Summary of capabilities

Allentown, PA, US

Overview:

Long-established reputable provider in defining best practices in the industry. Track record of excellence in managing high volumes of clinical supplies: 70,000+ shipments annually, including temperature-controlled/monitored materials (up to -80C)

Facility facts		Offerings
Opened	1999	<ul style="list-style-type: none"> Comprehensive service line supporting all aspects of clinical trial supply, including over-encapsulation, primary and secondary packaging, labeling, regulatory support, distribution, returns, and destruction Full support for clinical studies in all phases of development Support for compounds that are light-sensitive, highly potent compounds, and/or compounds with zero tolerance for time out of environment (TOE) Commercial secondary packaging services for syringe/pre-filled syringe/pen /auto-injector assembly and labeling Comprehensive engineering services enable streamlined/customized production: Includes in-house tool manufacturing, CAD services for packaging design, and in-house 3D print capabilities
Audited by	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	

Allentown clinical storage and packaging capabilities:

Capacity and services				
Storage conditions	Controlled ambient (15°C to 25°C)		247,000 sq. ft. (23,300 sq. m.)	21,000 pallets
	Refrigerated (2°C to 8°C)		61,000 sq. ft. (5,665 sq. m.)	6,600 pallets
	Frozen	-20°C	4,000 sq. ft. (372 sq. m.)	230 pallets
		-30°C	1,200 sq. ft. (112 sq. m.)	75 pallets
		-40°C	28 units	112 shelf positions
		-70°C	18 units	72 shelf positions
		-80°C	101 units	404 shelf positions
	Controlled substance (15°C to 25°C)		7,445 sq. ft. (688 sq. m.)	898 pallets
Controlled substance refrigerated		216 sq. ft. (19.5 sq. m.)	4 pallets	

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Allentown clinical storage and packaging capabilities:

Capacity and services		
Engineering and facilities	Back-up power and redundant systems	Diesel and natural gas 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 (33 production rooms)	Capabilities	Bottle filling for solid dosage forms (automated and manual)
		Automated blistering, cold form and thermoform, single and multi-fill
		Over-encapsulation and placebo manufacturing
	Controls/environments	Low humidity
Light-sensitive		
Containment suites		
Dedicated washrooms		
Secondary packaging (30 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
		Patient kit assembly and consolidation
	Controls/environments	19 CRT ambient (15°C to 25°C) rooms
		9 refrigerated (2°C to 8°C) rooms
		2 frozen (-20°C) rooms
		Light-sensitive packaging
		Bar code control (Production Assembly Scanning System – PASS) for identification, confirmation, material reconciliation of kits

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Allentown clinical storage and packaging capabilities:

Capacity and services

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
		Just-in-time and late-stage customization
	Types	Booklet labels
		Single and multi-panel labels
Auxiliary and expiry update labels		
Engineering services	Capabilities	In-house tool manufacturing, 3D print technology, CAD services
Enhanced services	Clinical supply optimization services	Comparator 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	



Summary of capabilities

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