



Summary of capabilities

Basel, Switzerland

Overview

As a long-established and reputable provider in the industry, our EU center for clinical manufacturing is renowned for defining best practices. We specialize in cold chain supply management, ensuring end-to-end control with zero time-out-of-environment (TOE) from truck to dock.

Facility facts		Offerings
Opened:	1996	<ul style="list-style-type: none"> Comprehensive service line supporting all aspects of clinical trial supply—clinical manufacturing (over-encapsulation, API microdosing), primary and secondary packaging, labeling, distribution, returns, and destruction Track record of excellence in managing high volumes of clinical supplies: <ul style="list-style-type: none"> - Full support for clinical studies in all phases of development - Support for compounds that are light-sensitive and/or compounds with zero tolerance for TOE, as well as highly potent beta-lactam/penn/ceph (processed in a separate building) - In-house engineering capability for tooling, equipment customization, and production automation
Audited:	Swissmedic	
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Basel clinical storage and packaging capabilities

Capacity and services			
Storage conditions	Controlled ambient (15°C to 25°C)		76,531 sq. ft. (7,110 sq. m.)
	Refrigerated (2°C to 8°C)		263,165 cu ft. (7,452 cu. m.)
	Frozen	-20°C	3,701 cu. ft. (103 cu. m.)
		-40°C	Acquired based on customer need
		-60°C	Acquired based on customer need
		-80°C	Seven standalone units; based on customer need
Engineering and facilities	Controlled substance CRT (15°C to 25°C)		124 sq. ft. (11.5 sq. m.)
	Backup power		Three full-load standby diesel generators
	Environmental		Building management system with fire, smoke, temperature, and humidity monitoring
	Security/access		CCTV; employee access to secured areas via system-managed electronic badges
Clinical manufacturing	Over-encapsulation		Capsule filling and placebo encapsulation
	API microdosing		De-blistering and de-bottling
	Blinding solutions for vials, bottles, syringes, inhaler devices, tubes, nasal sprayers, and others, including printing/blinding system to print codes/text/graphics on blisters, inhaler devices, and wallets		

Basel clinical storage and packaging capabilities

Capacity and services		
Primary packaging (nine production rooms)	Capabilities	Bottle filling, solid dosage forms (automated, semi-automated, and manual) with induction sealer
		Automated blistering, cold and thermoform, single and multi-pack with in-process vision control systems
		In-house tooling design and manufacturing
	Controls/environments	Controlled ambient (15°C to 25°C)
		Low-humidity
		Light-sensitive
		Containment suite with dedicated washroom
Secondary packaging (39 production rooms)	Capabilities	Bottle/vial/card labeling/de-labeling
		Carding/walleting with child-resistant technology
		Syringe/pre-filled syringe, manual and semi- and fully automated lines
		Needle safety device automated assembly
		Patient kit assembly
		Automated, semi-automated, and manual label application, including high-precision labeling
	Controls/environments	Controlled ambient (20°C to 25°C)
		Refrigerated (2°C to 8°C)
		Frozen (-20°C)
		Light-sensitive
		Highly potent beta-lactam/penn/ceph
		Bar code control (Production Assembly Scanning System—PASS) for identification, confirmation, and material reconciliation of kits
Label services	Capabilities	Label proof design and approval, including regulatory review of text
		Text translation (ATLAS™ software)
		Single and booklet label bulk production and variable text printing (on-site)
		Cold chain labeling through frozen
		Expiry date labeling/relabeling
	Types	Booklet labels
		Single-panel labels
Enhanced services	Demand and supply management optimization	Auxiliary and expiry update labels
		Comparator and placebo sourcing and management
		Biorepository and related laboratory services
Distribution	Pick and pack services with QP release	Returns, storage, destruction
	Domestic and international transportation management	Total transportation management services
	Importer of Record	

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