

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	Comprehensive service line supporting all aspects of clinical trial supply — clinical manufacturing		
Audited:	Swissmedic	 (over-encapsulation, API microdosing), primary and secondary packaging, labeling, regulatory support, distribution, returns, and destruction Track record of excellence in managing high volumes of clinical supplies: Full support for clinical studies in all phases of development 		
Contact info:	Steinbühlweg CH-4123 Allschwil Basel, Switzerland Phone: +41 614 852 300	 Support for compounds that are light-sensitive and/or compounds with zero tolerance for TOE, as well as highly potent beta-lactam/penn/cepf (processed in a separate building) In-house engineering capability for tooling, equipment customization, and production automation 		

Basel clinical storage and packaging capabilities

		Capac	city and services	
	Controlled ambient (15°C to 25°C)		818,735 cu. ft. (23,184 cu. m.)	6,859 pallets
	Refrigerated (2°C to 8°C)		263,165 cu ft. (7,452 cu. m.)	1,987 pallets
	Frozen	-20°C	3,701 cu. ft. (103 cu. m.)	26 pallets
		-30°C	Acquired based on client need	
Storage		-40°C	Two standalone units; based on client need	
conditions		-60°C	Acquired based on client need	
		-80°C	81 standalone units; based on client need	
		<-150°C	Eight standalone LN2 tanks	
	Controlled substance CRT (15°C to 25°C)		7,063 cu. ft. (200 cu. m.)	
Engineering and facilities	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			



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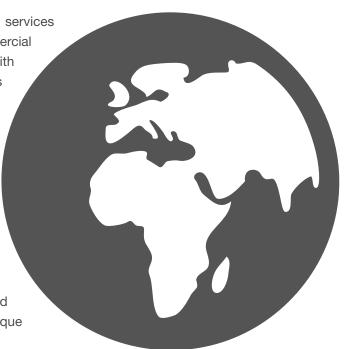
	Capa	city and services		
		Bottle filling, solid dosage forms (automated, semi-automated, and manual with induction sealer		
Primary packaging (nine production rooms)	Capabilities	Automated blistering, cold-and thermoform, single and multi-pack with		
		in-process vision control systems		
		In-house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



Summary of capabilities

From molecule to medicine: An integrated partner for every step in your drug development journey

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