

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. Additionally, we offer a comprehensive bioservices repository, including related CL3 laboratory services, aliquoting, DNA/RNA extraction, and tissue handling.

Facility facts		Capabilities
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, regulatory support, 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)	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	
		-40°C	Two standalone units; based on client need	
		-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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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
	Capabilities	Containment suite with dedicated washroom B
		Bottle/vial/card labeling/de-labeling
		Carding/walleting with child-resistant technology
Secondary packaging (37 production rooms)	Capabilities	Syringe/pre-filled syringe, manual, semi-, and fully-automated lines
		Needle safety device automated assembly
		Patient kit assembly
	Controls/environments	Automated, semi-automated, and manual label application, including high-precision labeling
		Controlled ambient (20°C to 25°C)
		Refrigerated (2°C to 8°C)
	Capabilities	Frozen (-20°C)
		Light-sensitive
		Highly potent beta-lactam/penn/cepf
Label services	Types	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)
Enhanced services	Clinical supply optimization services	Variable text printing
		Cold chain labeling through frozen
		Expiry date labeling/relabeling
Distribution	Pick and pack services with QP release	Booklet and label manufacturing
		Booklet labels
		Single-panel labels
	Domestic and international transportation management	Auxiliary and expiry update labels
		Comparator and placebo sourcing and management
		Biorepository and related laboratory services
	Importer of Record	Returns, storage, destruction
		Total transportation management services



Summary of capabilities

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