

Basel, Switzerland

Facility facts:

Opened: 1996
 Audited: SWISSMEDIC, SUVA
 Contact info: Steinbühlweg 69
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 Switzerland
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Overview:

- EU center for clinical manufacturing
- Expertise in cold chain supplies management—zero time out of environment (TOE) from truck to dock
- Bioservices repository, with related CL3 laboratory services, aliquoting, DNA/RNA extraction, tissue, buffy coat, PBMC processing

Capabilities:

- Long-established reputable provider in defining best practices in the industry
- Comprehensive service line supporting all aspects of clinical trial supply—primary and secondary packaging, labeling, regulatory support, distribution, returns and destruction
- Track record of excellence in managing high volumes of clinical supplies:
 - Units Produced (2020): 41.4M encapsulation, 1.2M blistering, 934K bottling, 161K carding/walleting, 2.4M labeling
 - 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 and/or compounds with zero tolerance for TOE, as well as high-potent beta lactam / penn / cepf (separate building)
 - In-house engineering capability for tooling, equipment customization, production automation

Basel clinical storage and packaging capabilities

Capacity and services

Storage conditions	Controlled ambient (15°C to 25°C)		818,735 cu. ft. (23,184 m3)
	Refrigerated (2°C to 8°C)		263,165 cu ft. (7,452 m3)
	Frozen	-20°C	3,701 cu. ft. (103 m3)
		-30°C	Acquired based on client need
		-40°C	2 standalone units; based on client need
		-60°C	Acquired based on client need
		-80°C	81 standalone units; based on client need
	<-150°C	8 standalone LN2 tanks	
Controlled substance CRT (15°C to 25°C)		7,063 cu. ft. (200 m3)	

Basel clinical storage and packaging capabilities

Capacity and services		
Engineering and facilities	Back-up power	3 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	
Primary packaging (9 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 (42 production rooms)	Capabilities	Bottle/vial/card labeling/de-labeling
		Carding / walleting with child-resistant technology
		Syringe / autoinjector / cartridge semi-automated assembly
		Needle safety device automated assembly
		Patient kit assembly
	Controls/environments	Controlled ambient (20°C to 25°C)
		Refrigerated (2°C to 8°C)
		Frozen (-20°C)
		Light-sensitive
		High-potent beta lactam / penn / cepf
Bar code control (Production Assembly Scanning System—PASS) for identification, confirmation, material reconciliation of kits		
Label services	Capabilities	Label proof design and approval including regulatory review of text
		Text translation (ATLAS™ software)
		Variable text
		Cold chain labeling through frozen
		Expiry date labeling / relabeling
	Automated, semi-automated and manual label application, including high-precision labeling	
	Types	Booklet labels
		Single-panel labels
Tamper seals		
Enhanced services	Clinical supply optimization services	Comparator and placebo sourcing and management
	Clinical ancillary 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	

For detailed capabilities and capacity information please contact your Thermo Fisher Scientific representative.

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