

## Summary of capabilities

### Horsham, United Kingdom

Facility facts		Benefits to sponsors
Opened:	1997	<ul style="list-style-type: none"> <li>• Long-established reputable provider in defining best practices in the industry with continued investments in capacity, capabilities, and expertise</li> <li>• Comprehensive service line supporting all aspects of clinical trial supply, including primary and secondary packaging, labeling, regulatory support, distribution, returns, and destruction</li> <li>• Commercial secondary packaging including pen/ autoinjector assembly</li> <li>• Collaborative and flexible approach to meet client needs, serving both new and emerging pharmaceutical companies, as well as a large pharma portfolio of clients across all phases and therapeutic areas</li> <li>• Track record of excellence in managing high volumes of clinical supplies</li> <li>• Full support for clinical studies in all phases of development</li> </ul>
Audited:	MHRA, Home Office	
Licenses:	Manufacturer's Importer's License Manufacturer's Authorization — IMPs Manufacturer's "Specials" License Wholesale Distribution License Controlled Drugs License (schedules 1 to 5)	
Contact info:	Langhurstwood Road, Horsham, West Sussex, RH12 4QD, United Kingdom Tel: + 44 140 321 2700	
<b>Offerings</b> <ul style="list-style-type: none"> <li>• A dedicated and flexible GMP-compliant facility offering comprehensive services including autoinjector assembly, labeling, and kitting — all under one roof</li> <li>• Experienced Qualified Persons (QPs) with comprehensive understanding of current legislation for all aspects of clinical trial management in Europe, the US, and ROW</li> <li>• A center of excellence learning laboratory dedicated to offline training for operational employees, keeping them current with the latest SOP procedures and industry best practices</li> <li>• Accredited with BS OHSAS 18001, ISO 14001, and ISO 45001:2018</li> <li>• "Goods for testing relief services" resulting in zero VAT and zero duty payments</li> <li>• Qualified Person (QP) cross agreements with Germany facilities to allow efficient trade flow</li> </ul>		

### Horsham clinical storage and packaging capabilities

Capacity and services			
Storage conditions	Controlled ambient (15°C to 25°C)	62,900 sq. ft. (5,844 sq. m.)	14,109 pallets
	Refrigerated (2°C to 8°C)	506,554 cu. ft. (14,344 cu. m.)	2,787 pallets
	Frozen (-20°C)	via Thermo Fisher Bishop's Stortford	
	Controlled substance CRT (15°C to 25°C)	26,639 sq. ft. (2,475 sq. m.)	120 pallets

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## Horsham clinical storage and packaging capabilities:

Capacity and services		
Engineering and facilities	Back-up power and redundant systems in warehouse and walk-in cold chain storage	Full-load standby diesel generators
	Environmental	ELPRO environmental monitoring system
	Security/access	Fenced and gated facilities with 24/7/365 security Employee access to secured areas via system-managed electronic badges
Primary packaging and manufacturing (9 production rooms)	Capabilities	Bottle filling, solid dosage forms (automated and manual)
		Automated blistering, cold- and thermo-form, single and multi-pack
	Controls/environments	Controlled ambient (15°C to 25°C)
		Low humidity Low-sodium light Dedicated washroom
Secondary packaging (24 production rooms)	Capabilities	Bottle/vial/card labeling/de-labeling
		Carding/walleting in-line and mobile
		Autoinjector/cartridge semi-automated and fully automated assembly
		Blinding of multiple components Patient kit assembly
	Controls/environments	5 controlled ambient (20°C to 25°C) rooms, 9 refrigerated (2°C to 8°C) rooms Light-sensitive packaging 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)
		Variable text
		Cold chain labeling
		Expiry date labeling/re-labeling
	Manual and semi-automated application	
	Just-in-time and late-stage customization	
Types	Booklet labels Single-panel labels Auxiliary and expiry update labels	
Enhanced services	Clinical supply optimization services	Comparator and placebo sourcing and management
	Clinical ancillary management	In-house CAD and 3D printing
Distribution	Pick and pack services with QP release	Returns, storage, destruction
	Domestic and international transportation management	Total transportation management services
	Importer of record	Goods for testing relief service

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