



Summary of capabilities

Bleiswijk, Netherlands

Overview:

The Bleiswijk, Netherlands facility stands as the EU's only GMP Center of Excellence, offering a comprehensive range of cold and ultracold services tailored for high-value therapies, including cell and gene therapies, biologics, antibodies, and vaccines. Capabilities include ambient to cryogenic storage, clinical and commercial packaging, labeling, and distribution, and clinical QP release services. Situated conveniently close to air and sea ports, Bleiswijk serves as a strategic gateway to the thriving European market.

Facility facts		Offerings
Opened:	May 2024	<ul style="list-style-type: none"> • GMP storage at controlled ambient (15°C to 25°C), refrigerated (2°C to 8°C), frozen (-20°C to -80°C), and cryogenic (-150°C) temperatures • Cold chain logistics and specialty courier services • Secondary packaging and labeling in controlled environments, including ambient to cryogenic • Clinical and commercial packaging with serialization • Just-in-time packaging for clinical and commercial applications • Validation/qualification services • QP services (including ATMP) • Clinical ancillary management • Project management
Audited:	Farmatec MIA License (109385 F) for Manufacturing (Secondary Packaging and Labelling) and Importation of Clinical & Commercial Products, QP Certification	
Facility size:	53,820 sq. ft. (5,000 sq. m.)	
Contact info:	Prismalaan Oost 13, Bleiswijk, Netherlands, 2665	

Bishop's Stortford clinical storage and packaging capabilities:

Storage capacity	
Controlled ambient (15°C to 25°C)	2,000 sq. m. open warehouse space 2 vertical lift shuttle systems (40 pallet equivalent)
Refrigerated (2°C to 8°C)	25,427 cu. ft. (720 cu. m.) 2 vertical lift shuttle systems (40 pallet equivalent)
Frozen (-20°C)	25,427 cu. ft. (720 cu. m.) (20 pallet equivalent)
Ultra-frozen (-80°C)	48 upright reach-in freezers (expansion available to 284 units)
Cryogenic (-150°C)	10 storage systems (expansion available to 78 LN2 storage systems)

Capabilities/services

7 packaging suites (includes refrigerated and frozen suites)	Multi-language, patient-specific secondary labeling
Clinical ancillaries sourcing	✓
Returns/destruction	✓
Logistics services	Transportation arrangement, provisions of qualified shippers, import/export support

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