ThermoFisher SCIENTIFIC

Summary of capabilities

Bleiswijk, Netherlands

Facility facts:	
Opened:	May 2024
Audits/licences:	• IGJ -Q2 2024 • Clinical trial - Q2 2024 • Commercial - Q2 2024
Facility size:	53,820 ft2 (5,000m2)
Location:	Prismalaan Oost 13, Bleiswijk, Netherlands, 2665

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. Capabilites 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.

Specialized capabilities:

- 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 Manangement
- Project management

Clinical storage and packaging capabilities

Storage capacity	
Controlled ambient (15°C to 25°C)	2000m2 open warehouse space 2 vertical lift shuttle systems (80 pallet equivalent)
Refrigerated (2°C to 8°C)	25,427 ft3 (720 m2) 2 vertical lift shuttle systems (40 pallet equivalent)
Frozen (-20°C)	25,427 ft3 (720 m2)
Ultra-frozen (-80°C)	48 upright reach-in freezers (expansion available to 278 units)
Cryogenic (-150°C)	10 storage systems (expansion available to 78 LN2 storage systems)

Summary of capabilities

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

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

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