

## Weil am Rhein, Germany cryocentre

### Facility Facts:

Opened:	January 2021
Audited:	Regierungspräsidium Tübingen July 2021
Licensed for:	Import  Secondary packaging of Investigational Medicinal Products (IMO)  Secondary packaging of commercial Cell and Gene Therapy products  Batch release
Facility Size:	450m <sup>2</sup>
Contact Info:	Facility address: Hegenheimer Strasse 5 79576 Weil Am Rhein, Germany  Legal entity: Fisher Clinical Services GmbH Im Wörth 3 79576 Weil am Rhein, Germany

### Overview:

The Weil am Rhein cryocenter is our first dedicated Cell & Gene therapy storage and distribution facility in mainland Europe. This location is designed to support BioSafety Level I and II, packaging, labeling and distribution of GMOs or advanced therapy medicinal products (ATMP).

### Offerings:

- GMP cold storage for MCB/WCB, drug substance, drug product, patient samples, and raw materials associated with ATMPs
- Kit production apheresis or patient sample collection or dose administration
- Multi-language, patient specific secondary labeling; Just-in-Time options available
- Customized secondary packaging solutions to protect drug product during transportation
- Batch record execution for chain of custody documentation
- Qualified Persons (QP) Release
- Cold chain logistics and specialty courier services utilizing qualified fleet of shippers

### Capabilities:

Storage Capacity		Capabilities / Services
Refrigerated (2°C to 8°C)	1300 cu. ft. (42m <sup>3</sup> )	<ul style="list-style-type: none"> <li>• Designed to be certified, validated, and commissioned to GMP standards for storage and supporting infrastructure.</li> <li>• Equipped with validated backup generator with automatic transfer switch.</li> <li>• Equipped with HVAC to maintain +15°C to +25°C with no humidity requirements.</li> <li>• Equipped with a bulk liquid nitrogen storage system with telemetry for auto-replenishment.</li> <li>• Equipped with 21CFR part 11 compliant Elpro temperature monitoring system.</li> <li>• All reach-in and walk-in equipment is validated to IOPQ standard.</li> </ul>
Frozen (-20°C)	1500 cu. ft. (49m <sup>3</sup> )	
Frozen (-40°C)	4 units	
Frozen (-70°C)	36 units	
Frozen (-80°C)	35 units	
Cryogenic (-150C)	6 storage systems	

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

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