

## Summary of capabilities

# Weil am Rhein cryocentre, Germany

### Overview:

The Weil am Rhein cryocenter is designed to support biosafety levels I and II, packaging, labeling, and distribution of GMOs or advanced therapy medicinal products (ATMP).

Facility facts:		Offerings:
Opened:	January 2021	<ul style="list-style-type: none"> <li>• GMP cold storage for MCB/WCB, drug substance, drug product, patient samples, and raw materials associated with ATMPs</li> <li>• Kit production apheresis or patient sample collection or dose administration</li> <li>• Multi-language, patient-specific secondary labeling; just-in-time options available</li> <li>• Customized secondary packaging solutions to protect drug products during transportation</li> <li>• Batch record execution for chain of custody documentation</li> <li>• Qualified Persons (QP) release</li> <li>• Cold chain logistics and specialty courier services utilizing a qualified fleet of shippers</li> </ul>
Audited by:	Regierungspräsidium Tübingen, July 2021	
Licensed for:	Import Secondary packaging of investigational medicinal products (IMPs) Secondary packaging of commercial cell and gene therapies and batch release	
Contact info:	<b>Facility address:</b> Hegenheimer Strasse 5 79576 Weil am Rhein, Germany	
	<b>Legal entity:</b> Fisher Clinical Services GmbH Im Wörth 3 79576 Weil am Rhein, Germany	

### Weil am Rhein clinical storage, distribution, and packaging capabilities

Storage capacity		Capabilities and services
Refrigerated (2°C to 8°C)	1,300 cu. ft. (42 cu. m.)	<ul style="list-style-type: none"> <li>• Certified, validated, and commissioned to GMP standards for storage and supporting infrastructure</li> </ul> <b>Equipped with</b> <ul style="list-style-type: none"> <li>• Validated backup generator with an automatic transfer switch</li> <li>• HVAC to maintain +15°C to +25°C with no humidity requirements</li> <li>• Bulk liquid nitrogen storage system with telemetry for auto-replenishment</li> <li>• 21CFR part 11 compliant Elpro temperature monitoring system</li> <li>• All reach-in and walk-in equipment is validated to IOPQ standards</li> </ul>
Frozen (-20°C)	1,500 cu. ft. (49 cu. m.)	
Frozen (-40°C)	4 units	
Frozen (-70°C)	36 units	
Ultra-frozen (-80°C)	35 units	
Cryogenic (-150°C)	6 storage systems	



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