Summary of capabilities

Lengnau, Switzerland

Facility facts:

Workforce:	200
Regulatory approval:	EMA & FDA (Planned)
Contact info:	Biotech innovation park, CH-2543 Lengnau BE, Switzerland Tel: +41 325601300 E: info.lengnau.thermofisher.com

Unique offering:

This 1.5 million sq. ft. facility leverages highly flexible bioproduction technologies, including single-use & stainless steel with up to 12'500 L bioreactor capability, providing a pathway from development to large-scale production as your manufacturing needs evolve.

Specialized capabilities:

- State-of-the-art large molecule technology and science
- Strategic guidance and flexible solutions for your programs
- Pre-clinical: Custom upstream and downstream process development services
- Clinical supply phases II & III: Technology transfer and process optimization
- Commercial production: 12'500 L scale & coming soon 5'000 L scale
- Capacity to produce 120 batches per year
- BPS laboratories for process development, analytical development, 50 L / 250 L pilot batches and manufacturing support for tech transfer and optimization

State-of-the-art multipurpose biomanufacturing site in the heart of Europe

Current services:

- 2 x 12'500 L stainless steel bioreactors suite
- One DSP suite customized for a commercial product
- Advanced execution systems and electronic batch records
- Process Development USP & DSP laboratories (BPS)
- QC Laboratories

Coming soon:

- One single-use production suite with 3 x 5'000 L single-use DynaDrive™ bioreactors ready, Q4 2024
- Hybrid DSP train, which can be combined with 12 500L bioreactors, Q4 2024
- Analytical development & pilot scale labs, Q1 2024

Future (2026 & beyond):

Building B :

- Up to 6 additional stainless steel 12'500 L bioreactors
- One large scale multi product DSP trains designed for campaigns

Building C :

- Up to 12 x 2'000 L & 5'000 L single-use bioreactors
- Several multi product hybrid DSP trains

BPS : Formulation development and cell-line development

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

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BPS laboratories capabilities:

- Over 4.000 sq. ft. of lab space, fully equipped with state-of-the-art equipment and utilities
- Early/late-stage process development including process characterization and scale-up, analytical method development and qualification
- Scale-down model establishment, transfer, and qualification
- Lab-scale investigation and manufacturing support / process implementation capabilities

Quality Control laboratories capabilities:

- Over 10.000 sq. ft. of available lab space for monitoring, IPC, and DS release testing
- Platform and non-platform assays
- HPLC, LC-MS, GC, and IC capabilities
- High-level of digitalization (E2E LIMS tracking of Materials, Samples and Testing)
- Raw material testing and release

Advanced automation:

- Fully automated manufacturing processes for upstream and downstream operations, equipment washing and sterilization operations, media and buffer preparation, dispensing operations
- Automatic interface between MES and SAP for material consumption and declaration (full material traceability)
- Automatic interface between PCS and Clean Utilities Automation (Water for Injection, Purified Water, Clean Steam, Gas and Compressed air, Waste water, Special waste water, Chemicals storage and distribution)
- Automatic generation of Electronic Batch Report

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