Welcome to Lengnau, Switzerland
A Thermo Fisher Scientific EU facility

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Thermo Fisher Scientific's site in Lengnau, Switzerland, is a state-of-the-art biomanufacturing facility strategically located in the heart of Europe. The site offers comprehensive services from early-stage biologics drug substance development through commercial production.

The facility spans 140,000 sq m (1.5 million sq ft), with 16,200 sq m (174,400 sq ft) dedicated to CGMP manufacturing, and employs 200 highly specialized staff members. The site features both single-use and stainless steel biomanufacturing and has the capacity to produce 120 batches per year. It holds a QC Swissmedic license (no. GMP-CH-1007415), with a Swissmedic manufacturing license expected by Q1 2026.

Our expert teams have access to significant capital and resources. The 12,500 L stainless steel production line (currently dedicated) includes USP, DSP, solution preparation, and a tank farm. Our single-use production line features 5,000 L Thermo Scientific™ DynaDrive™ Single-Use Bioreactors, a downstream processing suite, and a single-use buffer hold.

Our Lengnau site is fully integrated into the Thermo Fisher network, enabling seamless collaboration with our global sites for efficient tech transfer and expanded capabilities. We offer analytical development (St. Louis, Missouri, US; Lengnau, Switzerland), bioprocess development (St. Louis, Missouri, US; Lengnau, Switzerland), cell line development and cell banking (St. Louis, Missouri, US), drug product manufacturing (Monza, Italy; Ferentino, Italy; Greenville, North Carolina, US), and analytical services, both at Lengnau and through Thermo Fisher CRG sites.

Core capabilities:

- **Bioprocessing services (BPS):**
  More than 371 sq m (4,000 sq ft) of lab space, fully equipped with state-of-the-art technology and equipment. Services include high-throughput process development and characterization, analytical development, liquid formulation development, and non-GMP pilot scale.
- **Process development:**
  We have developed more than seven programs, with three transferred to commercial manufacturing and one to clinical manufacturing (2022–2025). Our site is dedicated to early- and late-stage process development, including process characterization and scale-up, analytical method development, and qualification. We also offer scale-down model establishment, transfer, and qualification.
- **Commercialization:**
  - Robust process control strategy for every commercial product, including comprehensive process characterization (PC) and process validation (PV) services; CMC- and regulatory-supported PC and PV risk assessments, experimental testing design, and data analysis.
  - Commercial production of one active commercial process in a dedicated 12,500 L stainless steel bioreactor using fed-batch production mode. One PPQ batch campaign has been completed (2025).
  - We specialize in end-to-end CGMP manufacturing and testing services for fed-batch production at 5,000 L scale. Typical downstream process batch sizes range from 15 kg to 35 kg.
  - The site offers a single-use suite featuring 5,000 L DynaDrive Single-Use Bioreactors (three bioreactors operational by Q2 2026) and runs a dedicated 2x 12,500 L stainless steel production line.

Technology transfer

Pilot batches of 50 L and 250 L are available to support manufacturing optimization. One project has been transferred (2022–2025).

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Advanced analytical capabilities

More than 929 sq m (10,000 sq ft) of lab space is available for monitoring, in-process controls (IPC), drug substance (DS) release testing, and raw materials release testing. The site offers HPLC, LC-MS, GC, IC, and other analytical capabilities. Digital tools are utilized throughout, including end-to-end LIMS tracking of materials, samples, and testing.

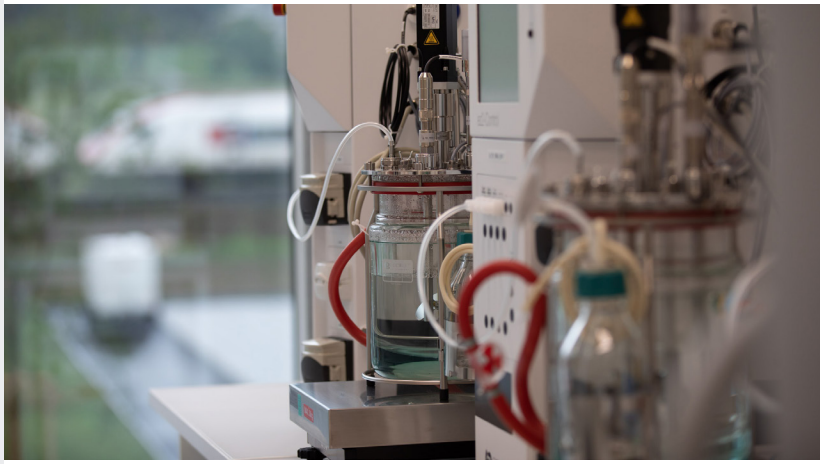
Key features and offerings:

- **Advanced automation:**
  To increase efficiency, the site features fully automated processes. Stainless steel bioreactors have fully automated manufacturing processes for upstream and downstream operations, integrating a manufacturing execution system (MES) and process control systems (PCS). The single-use, multiproduct line has paper-on-glass MES, including a SAP interface for material consumption and traceability. Electronic batch reports are created automatically.
- **Single-use technology:**
  The site is currently expanding its single-use technology capabilities with the addition of 5,000 L DynaDrive Single-Use Bioreactors. These can be integrated into a hybrid seed-train for the 12,500 L stainless steel bioreactors.

Recent investments

- A $130 million expansion in 2023.
- Addition of two manufacturing suites capable of producing multiple products using single-use technology.
- Equipment investment of $30 million to support the 5,000 L processing scale.

To learn more about our expanding capabilities, contact a Thermo Fisher Scientific representative.



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For more information or to discuss specific project needs. visit **patheon.com/lengnau**, To request a site tour, visit **patheon.com/visitlengnau** or schedule a virtual appointment with our site manager.

Learn more about Lengnau

Schedule a site visit

From molecule to medicine

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

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