Summary of capabilities

St. Louis, MO, US

Facility insights

Thermo Fisher Scientific's site in St. Louis, Missouri is a premier biologics development, preclinical, and clinical manufacturing facility, offering comprehensive services from early-stage biologics drug substance development through commercial production.

Spanning over 525,000 square feet in size with over 105,000 square feet dedicated to cGMP manufacturing, and employing over 900 experts in the field, the facility is a Center of Excellence for bioprocessing and single-use technology (S.U.T.), featuring the Bioprocessing Collaboration Center (BCC) and Thermo Scientific™ HyPerforma™ DynaDrive™ Single-Use Bioreactors (S.U.B.s, 5 L to 5,000 L).

Our experts have access to high capital equipment and resources, enabling them to create customized or optimized process development and scale-up techniques for development of bispecific, Fc-fusion, IgG1, IgG4, and various other complex protein-based biologics, totaling over 650 batches completed, of which were 335 commercial batches (2018–2024). Our proven regulatory track record, which includes findings of compliance for all audits conducted by health authorities across the globe, including but not limited to the US FDA, EMA, PMDA, EAUA, make us a well-known and trusted partner, whether you are a small and emerging biotech company just getting started or a well-resourced biopharma company seeking extended lab space.

Facility facts

Contact info:
4766 LaGuardia Drive
St. Louis, MO 63134-3117 US

Core capabilities

- **Comprehensive bioprocessing services**
  Full mammalian cell line and process development, analytical development, liquid formulation development, cell banking, non-GMP pilot scale, and end-to-end cGMP manufacturing and testing services. We specialize in fed-batch, perfusion, and n–1 perfusion production modes, with downstream processing batch sizes ranging from 50 g to 20 kg.
- **Cell line development**
  Our experts leverage AI/ML for vector construction and optimization, transposase-based technology for improved gene integration, and CHO-K1 GS knockdown cell line.
- **Process development**
  With over 133 programs developed and 165 programs transferred to manufacturing (2018 and 2022), we have established platforms to manage multiple **upstream** and **downstream** projects that are tailored to fit various cell lines and molecules, as well as custom development services to meet Phase I to commercialization demands.
- **Cell banking**
  The St. Louis facility manufactures all cGMP cell banks on behalf of the biologics network using automated fillers, with over 35 banks and 8,900 vials manufactured since 2024.

- **Advanced analytical analysis**
  Robust in-house analytics for quality control (QC), quality assurance (QA), and analytical formulation sciences (AFS), ensuring rigorous testing and compliance
- **Commercialization**
  - Robust process control strategy for every commercial product, which includes comprehensive process characterization (PC) and process validation (PV) services: CMC and regulatory supported PC and PV risk assessments and experimental testing design and data analysis.
  - Commercial production of 6 total commercial processes historically (3 active) in stainless steel perfusion and single use fed batch production modes, for various recombinant proteins. Over 25 PPQ batch campaigns have been completed, with 18 PAI/PLIs supported to 2007-2025.

Key features and offerings

- **Path to IND for biologics**
  Integrated, early phase biologics development, including drug substance, drug product, and clinical packaging and labeling. This novel process development platform coupled with our capital equipment and innovative technology accelerates molecule development timelines from transfection to IND/IMPD and first-in-human clinical trials in as little as 9 months.*
- **Single-use technology**
  The site specializes in single-use technology (S.U.T.). We utilize DynaDrive single-use bioreactors (S.U.B.s) and Cytiva™ XDR™ bioreactors ranging from scales of 50 L up to 5,000 L. The flexibility inherent to this technology and our site enables us to accommodate expanded capacity by duplexing 500 L, 2,000 L, and 5,000 L S.U.B.s with infrastructure available for expansion, a total of over 35,000 L of production capacity available based on client need.
- **State-of-the-art equipment**
  Significant investment in multiple high throughput systems provides accelerated and robust development and manufacturing. The site uses **Beacon™ system** for cell line development, **Ambr™ 250 systems** for final clone and upstream process development, **Tecan™** systems for sample preparation and resin screening for downstream development, the **Prometheus system** for liquid formulation screening and development, **in-line conditioning/dilution (ILC/ILD) skid** for buffer preparation, and **multi-attribute modeling** (MAM) for analytical characterization.

Recent investments

- **$82.5 million expansion (2021)**
  Enhanced production capacity with the addition of two manufacturing suites and $15 million in updated equipment, supporting 5,000 L processing scale. The expansion created 169 new jobs and more than doubled the site's overall production capacity.
- **58,000 square foot expansion (2023)**
  Further increased manufacturing capacity to support biologic therapies for a range of diseases, facilitated by state and local tax incentives.

Connect with us

For more information or to discuss specific project needs, please visit patheon.com/stlouis where you can request a site tour or watch our site video featuring our core capabilities.

Scan the below QR code to request a site tour.

* Terms and Conditions: Titer levels provided are estimates based on third party results and may vary depending on molecule type or other factors. Timeline from DNA to drug product and start of clinical trials for all path to IND for biologics options may vary depending on molecule type or other factors and are estimates to be finalized after third party cell line development dates are available and confirmed. 9-month timeline will incur additional risk.

From molecule to medicine

An integrated partner for every step in your drug development journey

Thermo Fisher Scientific provides industry-leading pharma services for drug development, clinical trial logistics, and commercial manufacturing through our Patheon™ brand. We partner with customers in the pharmaceutical, biotech, and life sciences industries as their trusted CDMO to deliver medicine to patients faster. With more than 60 facilities around the world, we provide end-to-end pharma services across all phases of development and commercial manufacturing, including API, oral solid dose, biologics, cell therapy, mRNA, viral vectors, formulation, clinical trial solutions, logistics services, and packaging. We couple our scientific and technical excellence in these areas with a strategic partnership to provide customers of all sizes access to a global network of facilities and dedicated experts across the Americas, Europe, Asia, and Australia. Through our integrated service offerings, we provide tailored solutions to fit your unique drug development journey, accelerating your time to market.

Discover the power of our global network.

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

Learn more at **thermofisher.com/patheon**
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