Welcome to Groningen, Netherlands
A Thermo Fisher Scientific EU facility

Site address
Zuiderweg 72/2,
9744 AP Groningen, Netherlands
Phone:
+31 (0)50 5222 222
Site coordinator
Esther Barree
Esther.Barree@thermofisher.com
Phone: +31505222315
+31615317548 (mobile)

Thermo Fisher Scientific's site in Groningen, the Netherlands, is a premier biologics production facility supporting both clinical and commercial manufacturing. The site provides end-to-end services, from scale-up through product commercialization.

The 18,000 sq. ft. (1,675 sq. m.) facility is dedicated to CGMP manufacturing and includes more than 3,700 sq. ft. (350 sq. m.) of space for analytical testing. Employing approximately 200 bioprocess experts, Groningen serves as a center of excellence for new program introductions (N.P.I.).

The site features Thermo Scientific HyPerforma™ Single-Use Bioreactors (250–2,000 L) for large-scale production.

Our experts have access to the latest capital equipment and resources, enabling them to create customized or optimized process designs and scale-up techniques for the manufacture of bispecifics, Fc-fusions, IgG1, IgG4, and various other complex protein-based biologics. Between 2018 and 2024, the site completed more than 212 batches, 40% of which were commercial. In 2024, we achieved a Right First Time (RFT) rate of 95%.

Our company has established a robust framework of compliance and quality assurance across multiple regions. We have successfully implemented essential Master Files, including the Site Master File (SMF) for the EU and the Foreign Manufacturer Authorization (FMA) for Japan. These files are acknowledged by regulatory authorities in the EU, United States, Australia, Canada, and Japan. Furthermore, our operations hold Good Manufacturing Practice (GMP) certifications from Brazil, Turkey, and Taiwan, as well as Crédit d' Impôt Recherche (CIR), a tax credit to support research and development work.

These certifications reflect our dedication to maintaining high-quality manufacturing processes and to ensuring product safety and efficacy. By adhering to these stringent regulatory requirements, we continue to build trust and reliability in our products and services globally.

The Groningen site is fully integrated into our global network, enabling seamless cross-border coordination for efficient technology transfers, as well as the potential for expansion. We can offer analytical development (St. Louis, Missouri, US), bioprocess development (St. Louis, Missouri, US, and Lengnau, Switzerland), cell line development and cell banking (St. Louis, Missouri, US), drug product manufacturing (Monza and Ferentino, Italy; Greenville, North Carolina, US), and analytical services, both on-site and through various Thermo Fisher CRG facilities.

Core capabilities:

- **CGMP manufacturing:**
  Groningen offers phase I/II/III/PPQ and commercial CGMP manufacturing, as well as analytics.
- **Advanced analytical analysis:**
  Robust in-house analytics or quality control (QC) and quality and assurance (QA), ensuring rigorous testing and compliance.
- **Commercialization:**
  - We develop a strong control strategy for every commercial product, including comprehensive process characterization (PC) and process validation (PV) services. These include CMC- and regulatory-supported PC and PV risk assessments, experimental testing design, and data analysis.
  - The site has been approved for two commercial programs (one active). Since 2018, three PPQ campaigns have been completed, and multiple PAI/PLI inspections have been supported.

Key features and offerings::

- **Path to IND for biologics:**
  Clinical-scale production ranging from 500 to 2,000 L can be manufactured at our Groningen site. This integrated, early-phase biologics development platform includes drug substance and drug product clinical manufacturing, as well as clinical packaging and labeling. By leveraging innovative technologies, modern capital equipment, and combined CDMO and CRO services, this novel platform can accelerate molecule development timelines from transfection to IND/IMPD and first-in-human clinical trials in as little as 9 months.* **Learn more**.
- **Single-use technology:**
  - The site specializes in single-use technology (S.U.T.). We utilize HyPerforma S.U.B.s ranging from 50 to 500 L as seed bioreactors and 500 to 2,000 L as main culture bioreactors. The site currently offers a total of 7,000 L of S.U.T production capacity, with infrastructure available for future expansion.
  - Downstream processing also utilizes S.U.T. for the chromatography skids, tangential flow filtration (TFF), and other systems, removing the need for process-specific cleaning validation.
- **State-of-the-art equipment:**
  - Capabilities include shake flask expansion and wave-mixed bioreactors for pre-culture growth. We utilize stirred single-use seed bioreactors ranging from 50 to 250 L and main culture bioreactors ranging from 500 to 2,000 L. For clarification, the site uses Pall Stax, Merck Mobius, and 3M Cuno systems.
  - Chromatography capabilities include prepacked columns with diameters from 10 to 80 cm, and bioprocess systems with gradient capacities up to 400 L/h and 2,000 L/h. AKTA Ready Gradient systems (including AKTA Ready XL) are used with single-use flow paths. The maximum flow rate of the XL system is 3,500 L/h.
  - Filtration systems include manual and automatic TFF skids from 0.1 to 20 sq. m.. Virus removal is achieved through low pH or solvent/detergent (S/D) inactivation, and nanofiltration is performed using Planova filters (1–4 sq. m.), Viresolve single-use membranes (up to 12.5 sq. m.), Virosart, and Planova filtration systems (up to 12.5 sq. m.).

Connect with us:
For more information, please visit **patheon.com/groningen**, where you can **request a site tour** or **watch our site video** highlighting our core capabilities.

Schedule a site visit

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**
or email us at **pharmaservices@thermofisher.com**
or call **+1 919 226 3200**