ThermoFisher SCIENTIFIC

# MADE WITH

## GUIDANCE & GROWTH

## Getting your biologic to IMPD faster in EMEA

Your molecule has the power to change lives and shape the future. That is why it is important for you to get to IMPD* faster.

## Biologics growth in EMEA

### High growth forecasted to continue

Pharmaceuticals based on biologics and vaccines have grown tremendously globally in the past decade, with vaccines among the fastest growing segments of the market today, and the EMEA region is no different.

**What is driving the growth of the European biologics market?**

- Treatment for various illnesses and ailments such as anaemia, cancer, and autoimmune diseases
- The growing COVID-19 burden and huge demand for biologics during the pandemic
- Increase in prevalence of chronic diseases in the region year on year
- Development of personalised treatments
- Rising demand for innovative therapies

**BIOLOGICS MANUFACTURING SERVICES, EUROPE** expected to reach ~$4,948.6M by 2026 at CAGR of 6.3% (2021-2026)[1]

**TRADITIONAL mAbs, EUROPE** accounted for ~40% of the biologics development pipeline in 2021[2]

**CLINICAL TRIAL SUPPLIES MARKET FOR BIOLOGICS, EUROPE** expected to reach ~$240M by 2025 at an annual growth rate of 9.9%[3]

## The road to IMPD isn't always easy

### Balance speed, risk, and future needs

The challenges, risks, and costs of bringing complex large molecule products to market are growing exponentially. Want to get to IMPD faster without sacrificing quality and future commercialization goals? Follow our top tips:

1. Carefully design cell line development and process evaluation to balance speed and risk.
2. Use formulation screening vs. full formulation development.
3. Incorporate MAM (multi-attribute analysis) for larger data set around product quality, creating a solid foundation for Phase II and III production.
4. Use a trusted expression system.
5. Have your CMC regulatory dossier prepared and ready to meet filing requirements.

Find out more about how to accelerate and optimize your early development process.

*IMPD is the main document of the Clinical Trial Application (CTA) in the EU used for obtaining the authorization to conduct a clinical trial with an Investigational Medicinal Product (IMP). The aim of an investigational new drug application (IND) is to obtain approval from Food and Drug Administration (FDA) to perform clinical trials of an IMP in humans in the US.


1. MarketsandMarkets™ Pharmaceutical Contract Development and Manufacturing Market – Global Forecast to 2026
2. Thermo Fisher Strategic Business Intelligence, May 2022
3. MarketsandMarkets™ Clinical Trials Supplies Market – Global Forecast to 2025


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# There's no place like home

## Pharma seeking partners in EMEA region

From small-scale early development through to large-scale biologics production, many pharma and biotech companies are seeking biologics development and manufacturing expertise and resources closer to home. Are you looking for flexibility and speed to help you get ahead of schedule while maintaining the highest quality? We have been making unprecedented investments in our network of sites and capabilities around the world, with significant focus on investments in Europe, to drive growth and speed to market, to accelerate innovation and productivity, and to meet the needs of our European pharma and biotech community.

# Leverage our EMEA biologics expertise and resources

## To speed development and unleash the potential of your discovery

From EMEA scientists and engineers to line operators and business professionals, our objective is to help speed your molecule through early phase trials and prepare you for commercial success, faster. We apply a science-driven, risk-based approach to every step of the biologic development and manufacturing process. Our talented EMEA teams – built on expertise, experience, insight, and the passion to deliver the best possible outcomes – apply heart and science in all that they do. That way your discovery lives up to its promise to the patients who need it most.

***Leverage our flexible, end-to-end solutions and expertise in development and manufacturing, combined with advanced technical capabilities, to get you to market faster.***

**We bring:**

- Deep scientific expertise to every challenge
- Proven track record of scaling up biologics
- Cost and time savings at every stage of the biologic development process
- Understanding of the long and complex journey ahead
- Experience to solve complex large molecule challenges
- Commitment to your success

**~78%** of our biologics clients are new and emerging

**108+** tech transfers executed since 2015

**~63%** of new biologics projects are for monoclonal antibody products

**We provide:**

**Solutions aligned to drug development lifecycle**

**Early-stage market** → **Commerical supply**

### Preclinical

- Cell line development
- Upstream and downstream process development
- Analytical & formulation development
- Toxicology material

### Clinical supply PI-III

- Clinical Phase I – III supply
- Platform process solutions for FIH trials
- 250L – 2000L scale
- Fed-batch, perfusion cell culture
- Process optimization, tech. transfer

### Commercial production

- Process characterization
- Analytical method validation
- Process validation
- Registration batches
- Commercial production in 500L – 12kL scale

### Drug product clinical

- Development
- Clinical supply Phase I – II

### Drug product commercial

- Phase III supply
- Commercial production

**Access to proven expertise and resources across all scales of drug development and manufacturing**

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## Innovation: Patheon™ Quick to Clinic biologics™

Patheon™ Quick to Clinic™ biologics is an integrated early development offering designed for biotech companies looking for a dependable solution to scale up recombinant antibodies from discovery to first-in-human (FIH) trials and file for Investigational New Drug (IND) review in as little as 13 months from transfection. Our Quick to Clinic™ biologics solution helps you balance speed, risk, and future needs during early development through to commercialization.

**DNA to released drug product (months)**


Traditional Phase I program

Quick to Clinic™ program

## The power of the global biologics network

In addition to our EMEA manufacturing sites in Groningen, NL and Lengnau, Switzerland, Thermo Fisher's biologics manufacturing network includes Princeton, NJ and St. Louis, MO, USA; Brisbane, AU; and Hangzhou, China.

**From development to commercialization, your molecule is in good hands with our robust, innovative biologic end-to-end solutions**


### Lengnau, Switzerland

**State-of-the-art facility provides pathway from development to large-scale biologics production**

The Lengnau site is a 1.5 million sq. ft. facility with biologics process development capabilities. The site leverages highly flexible bioproduction technologies, including both single-use and stainless steel with up to 12,500L bioreactor capacity, providing a pathway from development to large-scale production as manufacturing needs evolve.

### Groningen, Netherlands

**Specialists in cGMP for preclinical and commercial manufacturing**

The Groningen site, with a strong regulatory and inspection history, specializes in cGMP for preclinical and commercial manufacturing including mammalian cell culture manufacturing, scale-up, and cGMP manufacturing of recombinant proteins and monoclonal antibodies.

***"We are excited to add the new Lengnau site to our global biologics manufacturing network. This site further strengthens our unique customer value proposition to leverage our scale and depth of capabilities for pharma and biotech customers. With the addition of new high-volume stainless-steel capabilities in Lengnau, we are enabling our customers to start their projects with us and stay with us as their manufacturing requirements grow."***

— Michel Lagarde, Executive Vice President of Thermo Fisher Scientific

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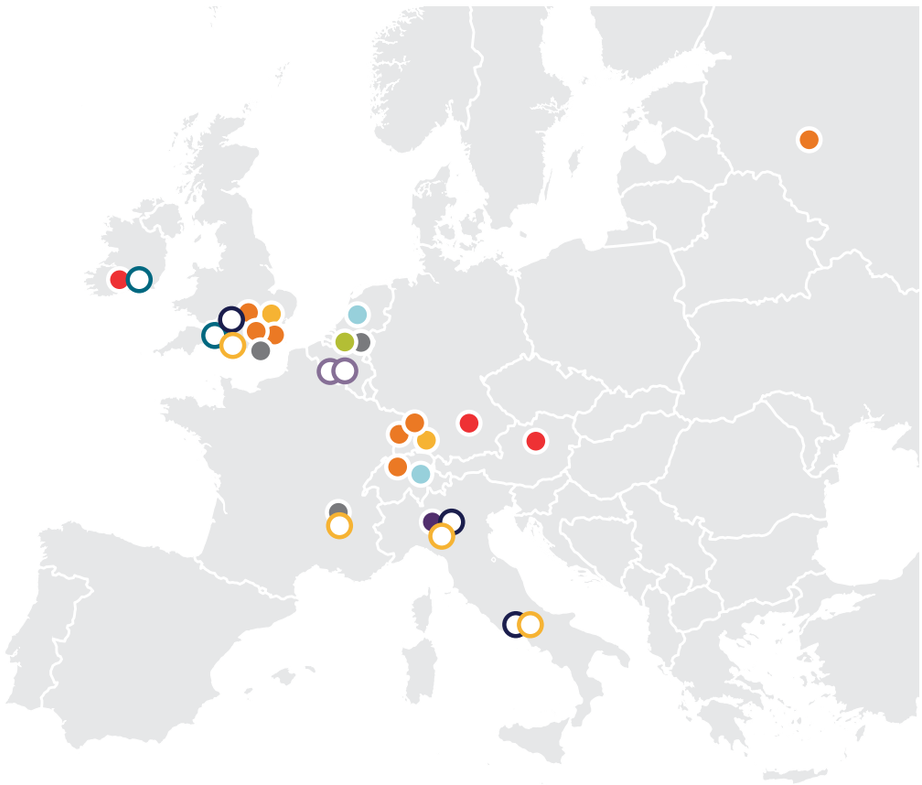
# The power of the end-to-end EMEA network

Leverage the depth and scale of our EMEA sites to support your drug development journey, from start to finish. Partner with us across all phases of development from drug substance to drug product to clinical trials and finally, to commercialization. Our integrated, end-to-end capabilities, in 21 sites across 10 countries in Europe, will help you get to IMPD faster.



- **API** (development + commercial)
- **Biologics** (development + commercial)
- **Cell and gene therapy clinical services**
- **Viral vector** (development + commercial)
- **mRNA**
- **Clinical services**
- **Drug product OSD** (development + commercial)
- **Spray drying**
- **Softgel**
- **Drug product steriles** (development + commercial)
- **Commercial packaging**

## Additional resources

- Five ways to get to IND/IMPD faster
- Biologics overview: Flexible biomanufacturing solutions
- Quick to Clinic™ delivers Phase I clinical trial material, fast
- Maintaining the cold chain in European distribution

***Partner with our biologics experts to speed development and unleash the potential of your biologics discovery. Contact us.***

## About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. Built on a reputation for scientific and technical excellence, we provide pharma and biotech companies of all sizes instant access to a global network of facilities and experts across the Americas, Europe, Asia and Australia. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. Our Quick to Clinic™ programs for large and small molecules help you balance speed and risk during early development so you can file your IND quickly and successfully. Digital innovations such as our mysupply Platform and Pharma 4.0 enablement offer real-time data and a streamlined experience. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

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