Biologics

Accelerate your biologics development

With Thermo Fisher Scientific's integrated platform

Accelerate to IND/IMPD submission and Phase I clinical trials

Your fast track to success

We deliver drug substance (DS) and drug product (DP) manufacturing services—along with clinical packaging, labeling, and distribution—all in one platform, in as little as 8 months.*

Our new integrated service solves present-day biologics development challenges by delivering drug substance (DS) and drug product (DP) manufacturing services—along with clinical packaging, labeling, and distribution—all in one platform, in as little as 8 months.* This specialized platform combines Thermo Fisher's extensive experience in biologics development with cutting-edge tools and methodologies. This dependable solution is tailored to scale up recombinant antibodies from development to Phase I clinical trials, providing:

- **Flexibility:** Starting with either a gene sequence or research cell bank, our platform offers options tailored to your specific needs.
- **Accelerated process development:** Rapidly optimize your biologic production processes with our state-of-the-art platform.
- **Regulatory support:** Confidently navigate complex regulatory landscapes with support form our regulatory experts.
- **Preclinical manufacturing:** High-quality standards and regulatory compliance throughout cell line development, production, and toxicology testing.
- **Analytical testing:** Comprehensive testing services to help ensure the safety, purity, and potency of your biologics products.
- **Performance analysis:** Multi-attribute method (MAM), leveraging liquid chromatography-mass spectrometry (LC-MS), to obtain glycan profiling, purity, and charge variant data.

Table 1. Integrated platform for IgG 1 and IgG4-based biologics

Timeline	What you provide	What we use	What we do	What you get
Option 1				
DNA to drug product (DP) release in as few as 8 months*	DNA sequence/gene	• Transposase technology in CHO-K1 GS knockdown cell line system, along with platform process, formulation, and analytics using commercially available raw materials.	• Cell line development	• **Early non-GLP toxicology material** • **Released drug substance** • **Released drug product** • **Stability data for IND** • **Templated quality-reviewed reports** • **Clinical trial packaging and labeling**
Option 2			**Plus ↓**	
Research cell bank (RBC) to drug product (DP) release in as few as 11 months*	RBC of stable pool or final clone	• Your cell line RCB, media/feed strategy*, and cell stability data. • Our platform process, as well as formulation and analytics development.	• Evaluation of our platform process • Platform formulation • Analytical methods • Toxicology batch • CGMP batch at any scale • Validation and characterization study • Stability testing	

Table 2. Integrated platform for bispecific and fc-fusion-based biologics

Timeline	What you provide	What we use	What we do	What you get
Option 1				
DNA to drug product (DP) release in as few as 12 months*	DNA sequence/gene	• Transposase technology in CHO-K1 GS knockdown cell line system, and our platform processes and analytics with commercially available raw materials.	• Cell line development	• **Early non-GLP toxicology material** • **Released drug substance (DS)** • **Released drug product (DP)** • **Stability data for IND** • **Templated, quality-reviewed reports** • **Clinical trial packaging and labeling**
Option 2			**Plus ↓**	
Research cell bank (RBC) to drug product (DP) release in as few as 13 months*	RCB of stable pool or final clone	• Your cell line RCB, media/feed strategy*, and cell stability data. • Our platform processes and analytics with commercially available raw materials.	• Evaluation of our platform process • Formulation development • Platform analytical method • Custom analytical method development • Toxicology batch • CGMP batch at any scale • Stability testing	

Why choose this accelerated platform?

Thermo Fisher's new platform is designed to address the unique challenges of biologics development, enabling projects to reach IND/IMPD in as few as 8 months. A critical aspect of any early development work is the cell line that underpins the platform process. This solution leverages transposase-based technology in a CHO-K1 GS knockdown cell line, a commercially ready option capable of delivering antibody titers up to 8 g/L.*

Key benefits

- **Speed to market:** Transfection to IND readiness in as few as 8-months* allows you to accelerate your biologic's journey to clinical trials with high-throughput technology, giving you a competitive edge.
- **Cost efficiency:** Optimize resources and reduce costs with our integrated, streamlined approach.
- **Expertise and support:** Leverage our global network, team of seasoned professionals, and industry-leading technologies to overcome development challenges.
- **Regulatory confidence:** Benefit from our deep understanding of regulatory requirements to help ensure compliance and mitigate risks.

Global network of experts and facilities

Cell line development, clinical-scale production process development, and analytical and formulation development are completed at our state-of-the-art facility in St. Louis, Missouri. Following this, technology is transferred to our Groningen, Netherlands facility for clinical scale-up (500 or 2,000 L), and finally moves to our Monza, Italy site for sterile fill-finish.

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Platform capabilities	St. Louis, MO, US	Plainville, MA, US	Groningen, NL	Monza, Italy
Cell line development	✓			
Process development	✓			
Analytical and formulation development	✓			
Preclinical-scale production	50–250 L			
Clinical-scale production		500 L	500–2,000 L	
Sterile fill-finish		✓		✓

Make the quick move

Transform your biologics development today

Discover how Thermo Fisher's integrated platform can accelerate your biologics development process.

Contact us to learn more about how we can help you bring life-changing therapies to patients faster and more efficiently.

*** 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 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. 8-month timeline will incur additional risk and is based on U.S. based sites only. Timeline for clinical trials is dependent on clinical trials being conducted in Australia or New Zealand.

Learn more at **patheon.com/biologics**
or email us at **pharmaservices@thermofisher.com**

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