Advanced therapies

End-to-end advanced therapy CDMO services

Personalized support and adaptability for your unique program needs

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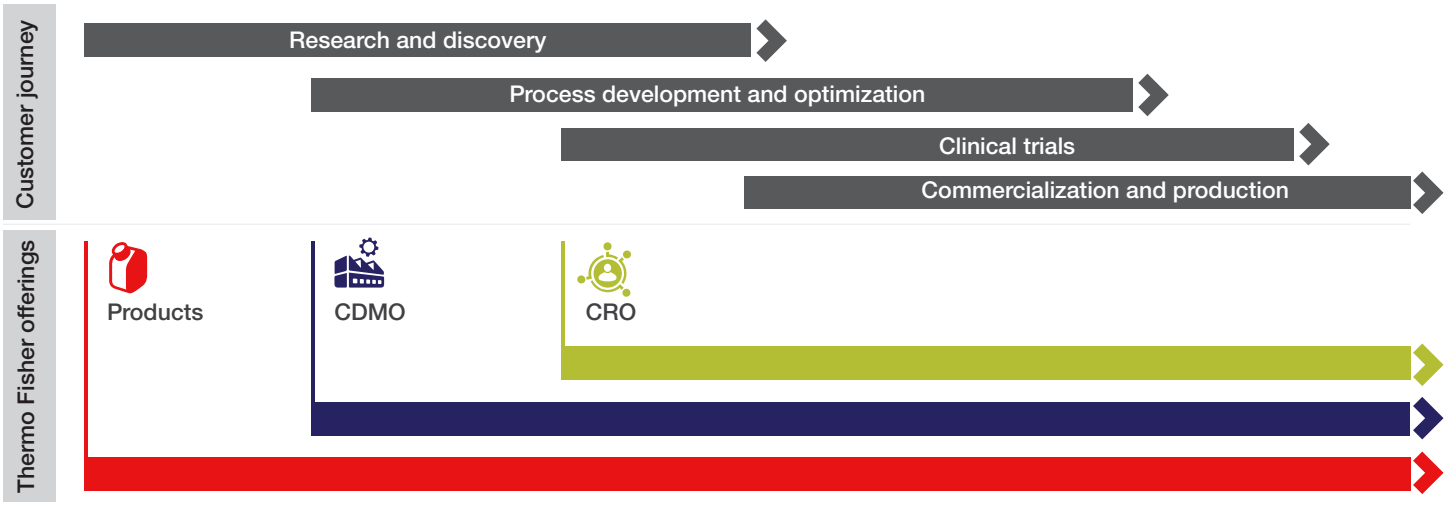
End-to-end advanced therapy CDMO services

Personalized support and adaptability for your unique program needs

Thermo Fisher Scientific provides comprehensive solutions for advanced therapy development and manufacturing to support your unique therapeutic product from discovery through commercialization. With our extensive technical expertise, global supply network, and expanding capacity, we are well-equipped to help you navigate the complex journey from molecule to medicine and get your transformative treatment to market faster.



In addition to our comprehensive CDMO/CRO services, we also offer the unique opportunity to leverage resources and expertise from across the broader Thermo Fisher Scientific network, including industry-leading starting material, raw material, and equipment.

~49%

of FDA-approved cell and gene therapy products supported by our CDMO/CRO services*

*As of August 2024

20+ years

of advanced therapy manufacturing experience

900+

viral vector lots manufactured including GMP and commercial lots over time

13+

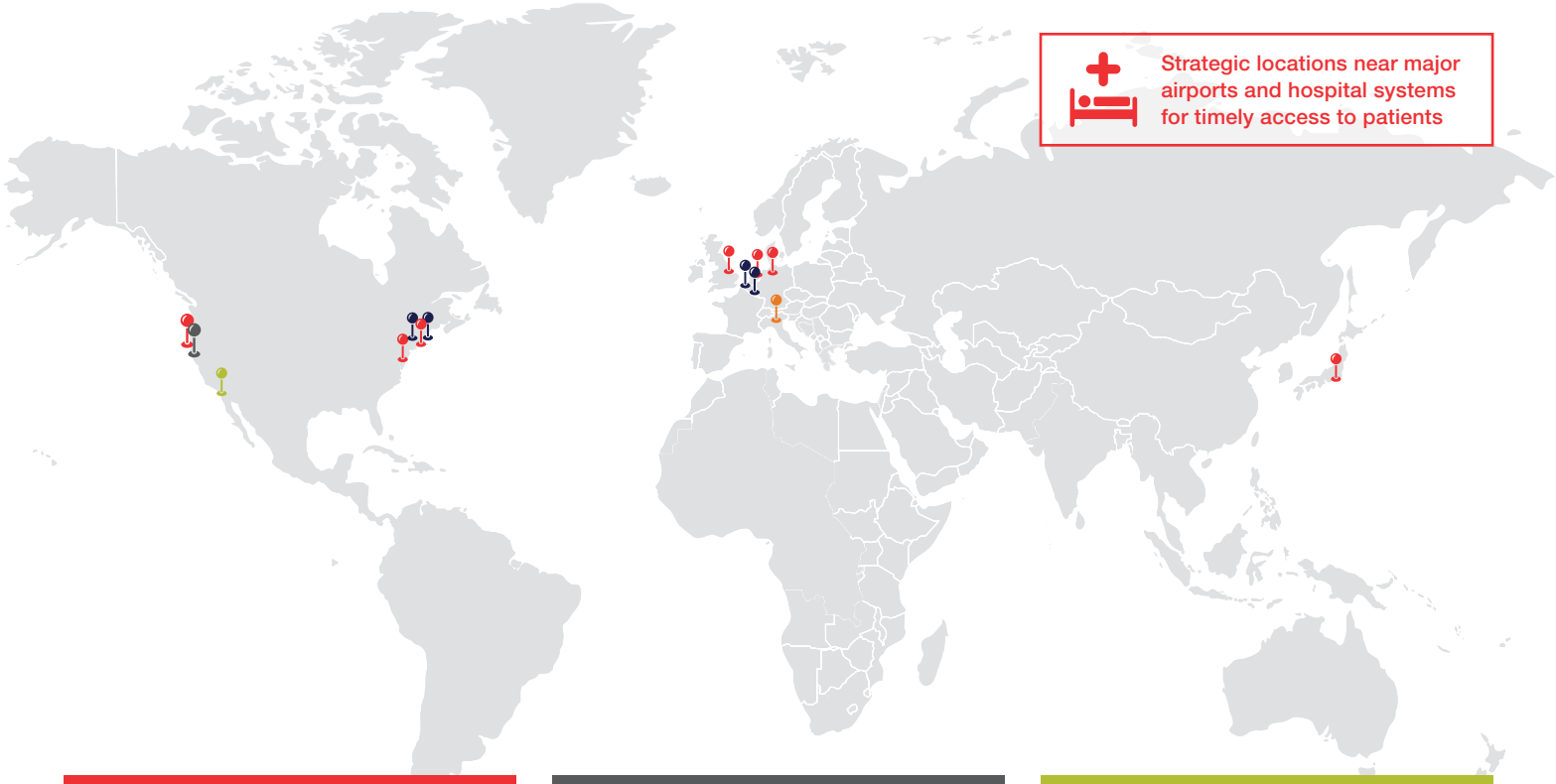
facilities worldwide supporting advanced therapy solutions

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

Global site network

Global network of strategically located sites to support advanced therapy customers

Our extensive global network encompasses more than 13 sites dedicated to advanced therapy development, manufacturing, and supply chain services worldwide. Leveraging our vast experience with various regulatory environments, we support customers globally with strategically located sites enabling prompt access to patients. Equipped with the necessary tools and infrastructure to maintain product integrity, we ensure the reliability of the supply chain for complex therapeutics and guarantee timely and specification-compliant deliveries.



Cell and gene therapy clinical services

- Bishop's Stortford, United Kingdom
- Bleiswijk, Netherlands
- Franklin, Massachusetts, USA
- Rockville, Maryland, USA
- Tokyo, Japan
- Vacaville, California, USA
- Weil am Rhein, Germany

Cell therapy

- San Francisco, California, USA

mRNA

- Monza, Italy

Translational services/science and technology

- San Diego, California, USA

Viral vector

- Cambridge, Massachusetts, USA
- Gosselies, Belgium
- Plainville, Massachusetts, USA
- Seneffe, Belgium

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

Translational research services

Standardized processes and qualifiable assays to de-risk and accelerate the transition to cGMP

Our translational research services produce small-scale molecular biology, viral vector, and cell therapy materials utilizing scaled-down processes that mirror cGMP workflows. This helps to proactively mitigate risk and enhance the transition from discovery to clinical research and ultimately commercialization, enabling an accelerated timeline from bench to bedside.

Leveraging a "start-with-the-end-in-mind" approach to avoid delays when transitioning to larger-scale, GMP-level production

- Access to emerging technologies through R&D, operational, and regulatory support
- Use of research use only (RUO) materials with cGMP-equivalent counterparts
- Qualified equipment, robust training, starting and raw materials vendor management, and processes to monitor performance drift
- Scaled-down processing models using qualified reagents and analytics
- Robust in-process testing and monitoring
- Methods based on the latest regulatory guidance, continuous understanding, and incorporation of regulatory requirements

Proof of concept → **Pre-clinical** → **Clinical and commercial**

Translational services supports cGMP-destined customers by offering*	
Viral vector	**Cell therapy**
• Scaled-down processes based on cGMP platforms • Suspension, serum-free LV and AAV production • Scale-specific downstream processing and purification	• Autologous/allogeneic process evaluation and establishment • Research cell banking • Viral and non-viral gene delivery • Assay establishment • Raw material evaluation
Molecular biology	
• Cloning (GOI; rep/cap) • Deletion of undesired sequence(s)	• Antibiotic resistance swapping • Small-scale plasmid expansion
Analytics	
• Same platforms used in GMP • Qualifiable assays	• Controls and standards • Predictive analytics

* Intended for research use only. Not suitable for IND-enabling applications.

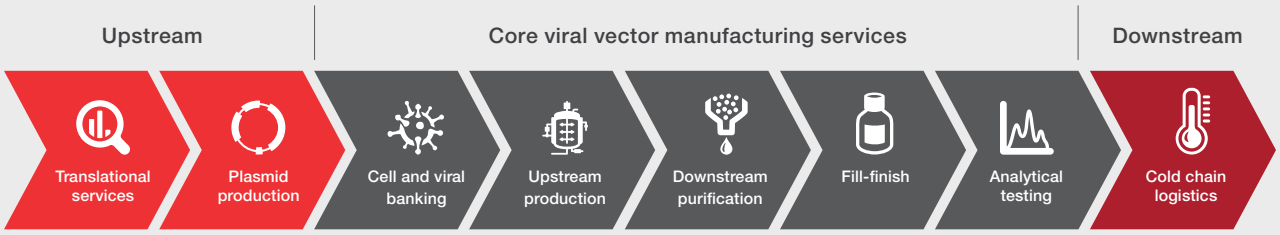
Learn more at **patheon.com/translationalservices**

Viral vector development and manufacturing services

Decades of unmatched viral vector expertise, from concept to delivery

Viral vector production poses challenges across the product lifecycle, from production system selection to product quality optimization and standardization for a robust CMC approach. With over 20 years of experience manufacturing a broad range of viral vector products, Thermo Fisher Scientific's viral vector services (VVS) team is well-equipped to support you in the development and commercialization of viral vectors and gene therapy-based vaccines.

Holistic approach to service supporting pre-clinical through commercial manufacturing



Proven experience and capabilities with unique scalability

- Up to 2,000L suspension and adaptable adherent technologies
- Utilization of flatstock and cutting-edge iCELLis® technology for superior outcomes
- Proficient in handling diverse vectors, including AAV, LV, AdV, RV, MVA, VSV, and more
- Comprehensive services include full process and analytical development with dedicated assistance for a seamless transition into late-phase and commercial stages
- Regulatory services and expertise to navigate an evolving landscape with confidence

Viral vector service offerings

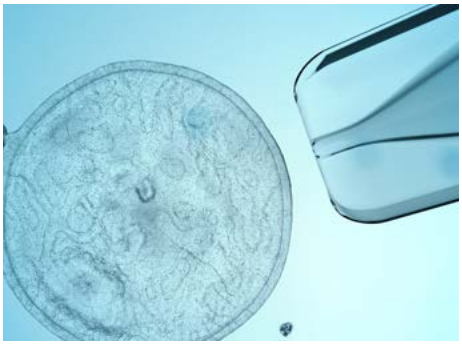
To provide flexibility and agility for our customers, we offer several different pathways for viral vector development to support various manufacturing strategies, timelines, and customization needs.

Program	Description	Time to delivery of GMP drug product
Rapid Development Framework™ (open platform)	Accelerated development approach for AAV and LV leveraging pre-established processes and analytics	9 months
Customizable development	Flexible development and process solutions for a variety of viral vector types (AAV, LV, AdV, RV, HSV, MVA, VSV, and others)	12+ months
Client tech transfer	Direct transfer and manufacturing of client process	9+ months

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

Cell therapy development and manufacturing services

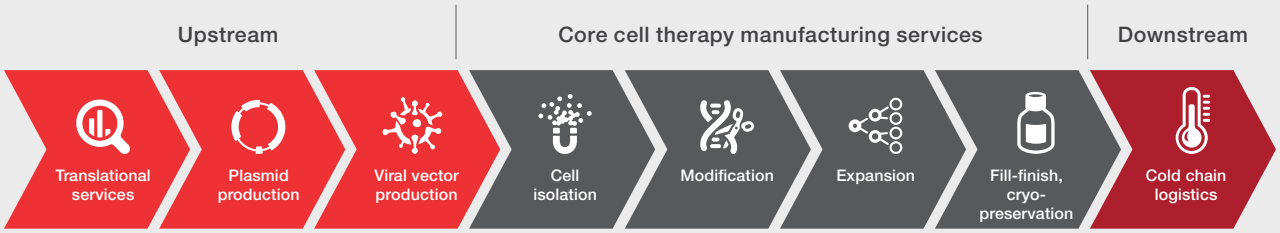
Technical expertise and agile execution to support a variety of therapeutic strategies and cell types



Due to the unique and complex nature of cell therapies, Thermo Fisher Scientific recognizes the importance of a personalized approach to service to help navigate industry challenges together. We provide a foundation of support systems and technical expertise in a variety of modalities, including:

- Autologous and allogeneic
- Viral and non-viral modified gene delivery systems
- T-cells, NK cells, iPSCs, MSCs, APCs, hESCs, blood- and bone marrow-derived stem cells, and more

Holistic approach to service supporting pre-clinical through commercial manufacturing



Innovative facility design to safeguard your product and ensure long-term scalability

- Individual, user-configurable GMP production suites
- ISO 5/6/7/8 (Grade A/B/C/D), BSL-2 compliant
- Self-contained HVAC and related infrastructure to protect against cross-contamination
- Built-in utilities for autologous/allogeneic processes
- Capacity to expand based on customer need

Rapid Development Framework™ for cell therapy

While traditional platform processes for cell therapies offer accelerated production timelines, they may involve restrictive protocols that can box users into a suboptimal system. As an alternative to this standard approach, Thermo Fisher Scientific has developed the Rapid Development Framework™ to expedite and de-risk the development and manufacturing of cell therapies while remaining adaptable to each product's unique needs. Options are available for CAR-T and iPSC workflows and associated analytics.

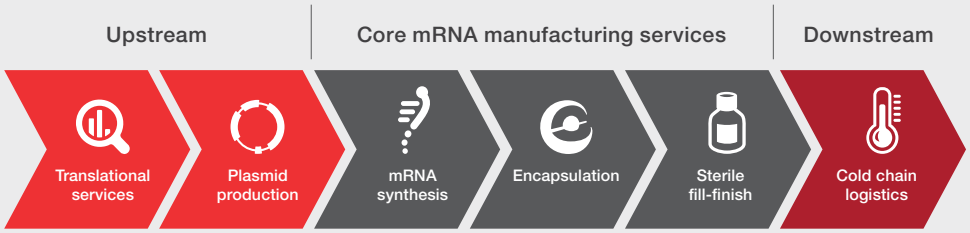
Learn more at **patheon.com/celltherapyservices**

mRNA development and manufacturing services

Innovative and flexible end-to-end solutions for mRNA workflow under one roof

Thermo Fisher Scientific offers a flexible solutions model for mRNA vaccine and therapeutic development that spans the entire operational value chain. Choose from our core mRNA service options and add upstream and downstream solutions as needed to fill any gaps in your capabilities or capacity. Our unique co-location of mRNA production, LNP, and fill-finish means you can consolidate key steps of the mRNA workflow under one roof, minimizing complexity and risk.

Holistic approach to service supporting pre-clinical through commercial manufacturing



Flexible scale and innovative technologies to support a variety of mRNA applications

With an increasing number of clinical applications for mRNA technology, production volume requirements and timelines may vary greatly. To address this evolving need, we offer flexibility in terms of:

- Scale options to support both small volume requests and larger projects up to 100g
- Support for existing mRNA processes or option to leverage in-house methods
- Access to full portfolio of mRNA services or ability to purchase individual offerings as needed

A legacy of innovation and technical expertise

Our Monza center of excellence brings 30+ years of sterile fill-finish, biologics, and advanced therapy manufacturing experience, with a proven track record of advancing molecules from concept to commercialization. Our technical expertise and production experience, coupled with our robust global quality systems, are leveraged in our latest mRNA solutions offering. And with all services available on the same campus, you can streamline your experience and minimize timelines/risks associated with transferring between facilities.

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

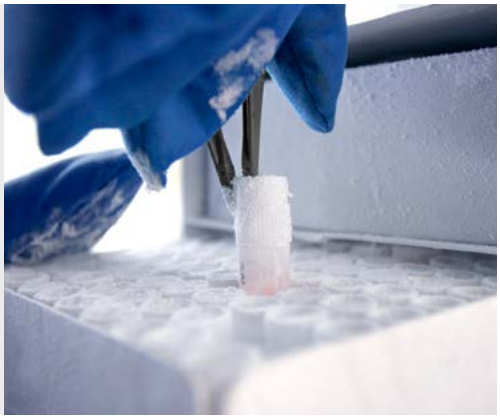
Cold and ultra-cold supply chain management and logistics services

Trusted solutions to maintain the speed, temperature, and integrity of advanced therapy products

Through our expansive global network of biorepositories, integrated quality systems, and a proven track record of safeguarding the integrity of millions of samples, we excel in storing, processing, and transporting specialized cell and gene therapies across the globe, spanning from cold to cryogenic temperatures.

With over 35 years of experience handling ultra-cold and cryogenic material, cold chain management is at the core of our expertise

- 150 million samples in freezers and LN2 tanks
- 10+ years of managing cell and gene therapy clinical trials
- 110+ cell and gene therapy customers
- Distribute to 35+ countries and regions

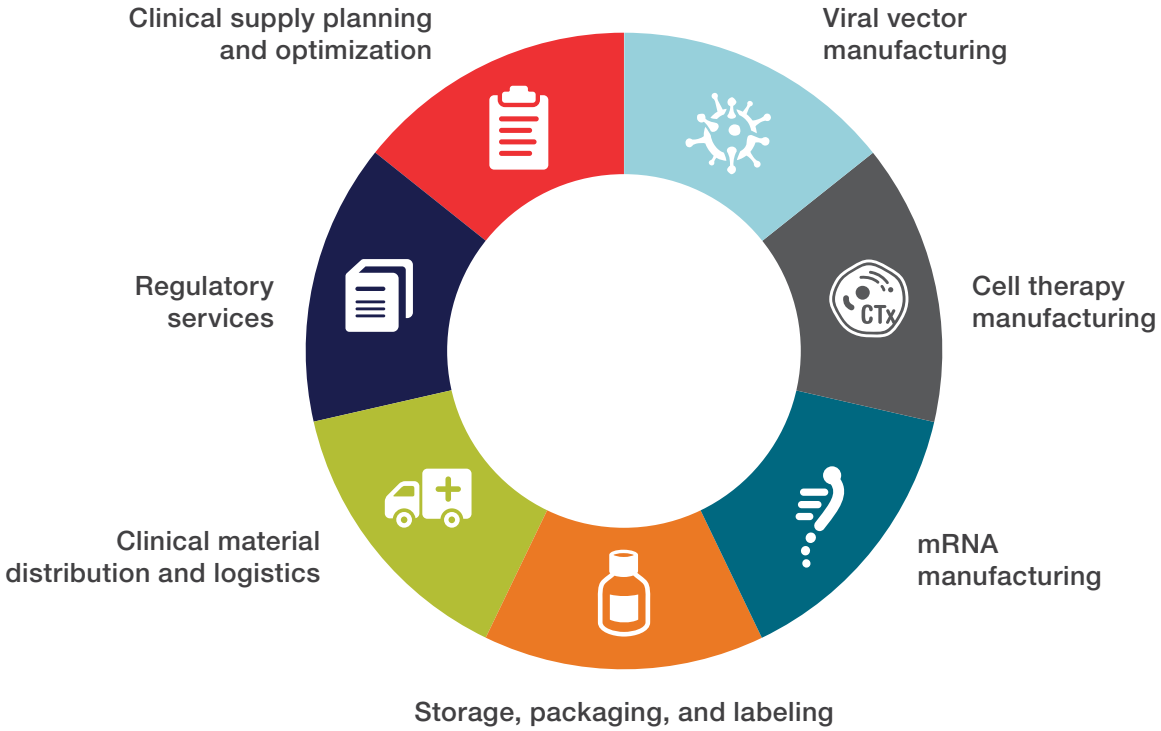


Learn more at **patheon.com/coldchainmanagement**

Quick to Care™ advanced therapies

Streamline your path to the clinic with comprehensive, flexible, and integrated solutions

The Patheon™ Quick to Care™ advanced therapies program streamlines contracting, communication, and coordination between all aspects of the value chain by integrating our manufacturing and distribution solutions across our network. Reducing the number of suppliers and touch-points helps to minimize risk and eliminate inefficiencies so you can focus on other critical tasks.



Comprehensive drug development plan enabled by communication and coordination

By contracting for two or more services in our advanced therapies portfolio, you receive additional support to manage your program and move materials between sites. Key features of the Quick to Care™ advanced therapies program include:

- **Global program manager:** Provides communication coordinated through a centralized point of contact, reducing efforts to manage multiple projects across different providers
- **Single invoicing entity:** Simplifies the process to track and pay invoices
- **Integrated timelines:** Enables agile planning with transparency to full view of cost and timeline burdens
- **Single MSA and contracting process:** Reduces contracting burden as terms cover all relevant services
- **Global governance process:** Provides a clear escalation process
- **Total transportation management:** Ensures product integrity and on-time delivery through overarching insights and management of your entire supply chain

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

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

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