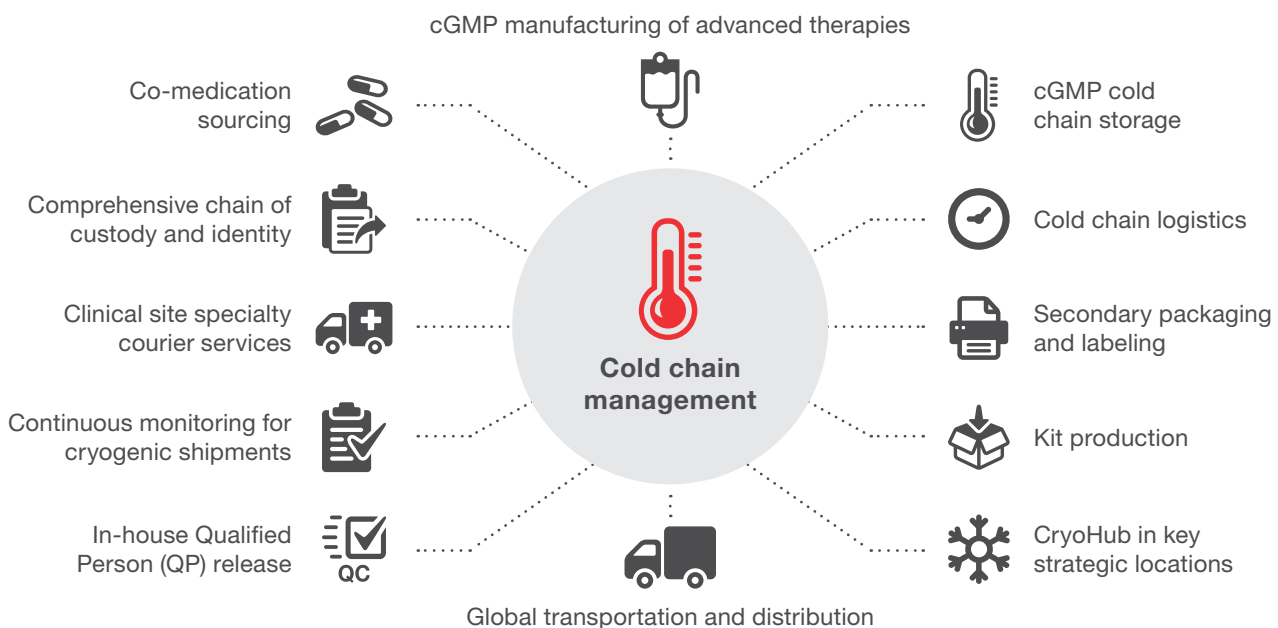


**ADVANCED
THERAPY
SUPPLY CHAIN
SOLUTIONS**

patheon

Managing and moving your advanced therapeutic product so you can focus on your path to market

With the rapid advancements of mRNA therapeutics and continued interest, investment, and positive clinical progress in cell and gene therapies, the advanced therapeutics market is expected to outpace current capabilities. That's why Thermo Fisher Scientific is continually investing in the capabilities and capacity needed to provide a solid infrastructure of supportive services. With offerings ranging from early kit production to customized packaging and labeling to secure storage, distribution, and logistics for patient samples, drugs, and critical drug substances, our end-to-end supply chain services can help de-risk nearly every part of your value chain.



With over 35 years of handling ultracold and cryogenic material, cold chain management is at the core of our expertise.

**cGMP cold chain storage**

- Global network of cGMP storage facilities for cell bank, plasmid, viral vector, patient sample, and other intermediaries, or drug product storage and distribution
- Controlled storage environments for a wide range of temperatures, from ambient to cryogenic
- Risk-mitigating operational redundancies
- 24/7 on-call staff

**Cold chain logistics**

- 27 cGMP-compliant facilities and depots located in key locations throughout the world
- Fleet of qualified shippers from CRT to cryogenic shipments
- Real-time temperature monitoring devices
- Pre-alert shipment notifications and shipment exception management
- Strict adherence to the requirements of Good Distribution Practices (EudraLex Annex 15, EU GDP guideline, 21CFR211.142 and 21CFR211.150)
- Temperature mapping and excursion sensors

**Clinical site specialty courier services**

- 24/7/365 control tower and dedicated customer care
- Expertise and capabilities for traditional and decentralized clinical trials
- Ability to ship direct-to-patient if appropriate for clinical study design
- GDP-certified transportation services with risk-based route assessment
- 99%+ on-time pickup and delivery performance
- 99% delivered within temperature specification
- Real-time transit studies and shipping lane validation

**Continuous monitoring for cryogenic shipments**

- 24/7 tracking and monitoring of GPS, payload temperature, and dewar orientation through our in-house specialty courier
- Controlled-access web portal provides enhanced visibility into shipment status for peace of mind from collection to delivery
- Just-in-time deployment of mission-ready shippers with 21 CFR Part 11 compliant temperature reports
- Easy mobile access to payload temperature data for clinical site use
- Real-time temperature monitoring devices, pre-alert shipment notifications, and shipment exception management services

**Comprehensive chain of custody/identity capabilities**

- Serialization services to create a unique product identity that can be tracked from the packaging site through distribution to the hospital or point of care
- Compliant with Drug Supply Chain and Security Act and Falsified Medicines Directive
- Comprehensive processes and verification steps are implemented throughout the entire product journey to minimize the risk of mix-ups
- Data capture for all touch points in case of temperature excursions or other issues, including staff, actions performed, and the location/date/time of those actions

**Secondary packaging and labeling**

- Custom secondary packaging and labeling solutions, including just-in-time processes, at temp
- Patient-specific, multi-language, and artwork design labeling options
- Ability to track exposure time of product down to unit level
- Label test for ultra-cold and cryogenic storage

**Kit production**

- Pre-manufacture collection of biological materials
- Patient administration kits
- Post-administration sample collection kits
- Just-in-time production

**Co-medication sourcing for combination trials**

- Access to secure sourcing directly from the manufacturers or through our network of qualified wholesalers
- Coordinated activities including blinding, packaging, labeling, analytical testing, storage and distribution
- Market intelligence and comprehensive planning for fluctuations in demand

***Let us manage and move your advanced therapeutic
so you can focus on your path to market.***

Contact your local Thermo Fisher Scientific representative to learn more.