



patheon

# **Cold chain management solutions**

Cold chain product integrity across the entire supply chain demands rigorous processes & cold chain expertise of the highest caliber—from packaging, handling, storage & distribution of temperature sensitive Investigational Medicinal Products (IMP), through to proper handing and receipt at the investigator site.

Thermo Fisher Scientific recognizes the challenges and complexities in managing a controlled temperature logistics network. Today's distribution network is becoming increasingly complex with pharmaceutical companies facing new challenges from regulatory adherence, sustainability initiatives, cost pressures and competing priorities.

#### Zero temperature excursion mindset

Our integrated processes, the latest technology and our zero temperature excursion mindset mitigates the risk of temperature excursion throughout the end-to-end supply chain.

- An extensive network of environmentally controlled facilities to handle a wide range of controlled temperature requirements (<-150°C, -80°C, -20°C, +2°C to 8°C and +15°C to 25°C)
- Packaging (including -20°C in environment packaging), handling, storage & distribution of temperature sensitive IMP, mitigating time out of environment

- Investment in proactive, automated management, oversight and full traceability of temperature sensitive supplies from point of production to delivery of and storage at the investigator site
- Adherence to GDP guidelines & compliance with strict quality standards
- A comprehensive suite of qualified, active and passive shipping systems
- Strategic partnerships with vendors for cold chain software and hardware technologies
- A dedicated team of global cold chain experts to advise on cold chain strategy across the supply chain

Our continued investment in cold chain (300% increase in cold production rooms; 200% increase in refrigerated storage; 75% increase in frozen storage), as well as distribution capability across the industry's largest network of fully owned cGMP facilities, mirrors the industry's evolution to handle increased quantities of complex cold chain biologics across many continents.

### TOP STATISTICS

300%

Increase in cold production rooms

200%

Increase in refrigerated storage

**75%** 

Increase in frozen storage

## **Shipping solutions**

We offer a comprehensive suite of passive and active shipping systems. Whether the requirement is single use, high performance reusable systems, small parcel, bulk pallet, RKN, RAP or cryo dewer shipments, our extensive range of qualified solutions is available to meet the needs of clinical trial sponsors.

- Strict adherence to the requirements of Good Distribution Practice (EudraLex Annex 15, EU GDP guideline, 21CFR 211.142 and 21CFR 211.150)
- Shipper qualification for all routes across regions with varying climatic conditions
- Global qualification profiles developed to represent >95% of all shipping lanes
- Risk assessments performed to identify best shipping lanes in terms of cost and performance
- Shipper return and reuse program in 13 countries across 5 continents
- Waste reduction—Reusable shippers are replenished for reuse, reducing local storage and removal/destruction costs.

## **Our expertise**

Powered by people with a zero temperature excursions mindset and an exceptional commitment to providing best-in-class cold chain services, Thermo Fisher Scientific is the global standard for quality and assurance. Along with proficient monitoring and tracking resources we optimize every level of the cold chain process to ensure the security of your clinical trial.



