

High biologics growth in Europe fuels the need for cold chain management

Pharmaceuticals based on biologics and vaccines have grown tremendously over the past decade, with vaccines among the most rapidly expanding segments in today's market. Cold chain management is a top priority for the biopharmaceutical industry to ensure that the quality and efficacy of these drug products are never compromised.

With high growth expectations in Europe, the need for regional- and country-specific <u>cold chain expertise</u> and storage capabilities cannot be understated. Maintaining cold chain product integrity demands rigorous planning and attention across the European supply chain. A single broken link can result in the loss of scarce resources and time.



CONSUMED

are destroyed every year due to improper storage and distribution conditions²



CLINICAL TRIAL SUPPLIES MARKET FOR BIOLOGICS IN EUROPE

is expected to reach about \$240M by 2025 with an annual growth rate of $9.9\%^3$



1/5 OF ALL CLINICAL TRIALS WORLDWIDE

are conducted in the EU4

Sources:

- 1. Biologics Market Growth, Trends, and Forecast (2019 2024). Report by Mordor Intelligence
- 2. Centers for Disease Control and Prevention
- 3. Clinical Trials Supplies Market Global Forecast to 2025. Report by Market and Markets™
- 4. Clinical Trial Supply & Logistics Market for Pharma 2020-2030. Report by Visongain

Top tips on maintaining the cold chain in European distribution



Interactive graphic: Hover over the bullet points and icons to reveal more details



Map out your entire supply chain

Mitigate risk

Maintain cold chain integrity



LABELING

Choose the best label adhesive for your product

Apply a just-in-time label approach



Store your product in the right temperature environment

Follow EU GDP guidelines

Address the need for analytical and stability testing



Keep updated on regulatory guidelines

Get your documentation in order to avoid customs delays



QUALIFIED PERSON (QP) **Employ or contract Qualified Persons in Europe**

Understand the additional requirements that are necessary for vaccine release and for advanced therapies medicinal product (ATMP)

Include the QP's statement in the Clinical Trial Application (CTA)



Use temperature monitoring devices and tracking systems

Consider the use of real-time GPS location trackers

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Contract best-in-class biorepository and bioservices



Appoint a logistics provider with cold chain and specialty courier services to accommodate special handling requirements

Consider using a GMP facility as a centralized hub

Make provisions for final mile distribution

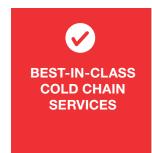
Cold chain: Regulatory definitions vary globally

European Pharmacopoeia (Ph. Eur.)



Partner with the experts for cold chain integrity across Europe

Powered by people with a **zero temperature excursions mindset** and an exceptional commitment to providing **best-in-class cold chain services**, Thermo Fisher Scientific sets the global standard for quality and assurance.











The power of Thermo Fisher Scientific's EMEA network

Our integrated EMEA network of **strategically located cGMP (current Good Manufacturing Practices) facilities and local cold chain experts** support the integrity of your drug product from molecule to medicine.



Interactive graphic: Hover over map points to reveal more details.



Partner with our experts in cold chain supplies management to ensure product integrity from molecule to medicine. Contact us to learn more.

About us

Thermo Fisher Scientific provides industry-leading pharma services for drug development, clinical trial logistics, and commercial manufacturing through our Patheon™ brand. We partner with customers in the pharmaceutical, biotech, and life sciences industries as their trusted CDMO to deliver medicine to patients faster. We believe that doing this successfully not only requires science, technology, and world-class expertise, but also requires a strategic partnership—bonded by key elements such as trust, communication, and collaboration. We embed these elements into every operation, interaction, and step in the drug development journey.