

TOTAL TRANSPORTATION MANAGEMENT

patheon

• API • BIOLOGICS • VIRAL VECTOR SERVICES • EARLY & LATE PHASE DEVELOPMENT • CLINICAL TRIAL SOLUTIONS • **LOGISTICS SERVICES** • COMMERCIAL MANUFACTURING



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Introduction

The transportation of life science shipments has become increasingly more complex over the years, with patient pools expanding, often to remote locations across the globe. In addition, the growth of biologics has added increased complexity to the supply chain due to cold chain handling, storage and distribution requirements across the supply chain.

Given the ever-increasing value of today’s Investigational Medicinal Products (IMPs), mitigating risk in the supply chain has never been more important.



It’s no wonder that supply chain logistics are estimated to account for as much as 25% of total annual pharmaceutical R&D costs¹.



These cost pressures are projected to grow as a result of an evolution that is altering the clinical trial landscape and generating complex supply chain challenges.

The cost of failure is high.



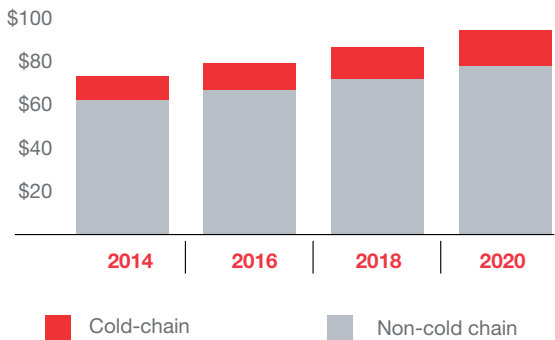
A supply shortfall, or the inability to deliver needed supplies to clinical sites can delay the start of a trial or cause an ongoing one to grind to a halt.



Supply shortages can imperil an entire development program and prevent study patients from receiving the drugs a Sponsor has committed to provide.

Cold-chain logistics spending is forecast to grow to more than \$16 billion by 2020.

Global biopharma logistics spending (\$ billions)



Spending on global

biopharmaceutical logistics in:

2014

\$72.5 billion

Spending on global biopharmaceutical logistics in 2014

2018

\$85.8 billion

Expected spending on global biopharmaceutical logistics in 2018

2016

\$78.8 billion

Expected spending on global biopharmaceutical logistics in 2016

2020

\$93.8 billion

Projected climb driven in large part by cold-chain logistics in 2020.²

Transportation experts

Sponsors and Clinical Research Organization's (CRO's) are faced with becoming logistics experts. Challenges they must be prepared to address include:



01

Coordinating movement of goods from manufacturing locations to distribution and investigator sites



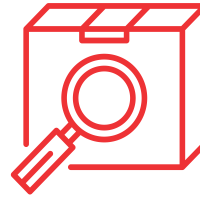
02

Understanding the latest packaging solutions to ensure safe and reliable transport



03

Tracking temperature from point of origin through to the distribution/investigator's site.



04

Optimizing transportation spend by selecting the best mode and supplier for each of the trial destination points



05

Managing the import/export process to ensure the customs clearance process does not introduce an unmanageable delay

It is no surprise that as trials expand to include increasingly sensitive product and global reach, in-house logistics teams are struggling to meet these needs. Once the product has been approved for commercial use, the same challenges must be addressed to ensure a secure, end-to-end supply chain that ensures optimal product integrity.

Total transportation management: A unique and innovative solution

Thermo Fisher Scientific provides a unique and innovative service for clients seeking to partner with an experienced third party logistics provider for transportation, courier, import and customs decisions across their complete portfolio.

Our Total Transportation Management service manages the complex supply chain processes required to move all types of life science shipments, including manufacturing API, IMP, comparator medication and ancillaries through to commercial goods, both internationally and within the country of destination.

Logistics specialists and our teams of in-country experts at Thermo Fisher Scientific can simplify the complexity associated with transportation planning and monitoring and, as a result, optimize transportation performance and costs across the supply chain.

The total transportation management service includes:

At Thermo Fisher Scientific, our unique transportation service offering has been designed to provide assurance that all products will get to their final destination on time and in full.

- + Dispatch Services
- + Proactive track & trace
- + Data objective monitoring & reporting
- + Consolidated billing



Supplier qualification



Mode optimization:
courier selection &
management



Customs & regulatory
guidance & facilitation



Cold Chain supplies
management including the
reusable shipper program



PARTNERING with Thermo Fisher Scientific

- Optimize transportation mode
- Mitigate risk across the supply chain
- Access supply chain and local, in-country expertise
- Increase on-time performance & efficiencies

Case study

One savvy manager sums up the pharmaceutical industry's flawed strategy for containing transportation costs as one of price and promises at the end.

Characterizations notwithstanding, clinical teams know the drill:



Assess your current level of service

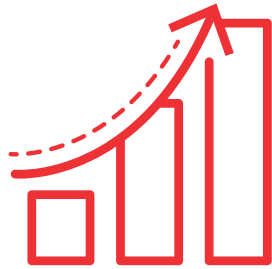
Find out how your level of service measures up. Take this quiz!

	Yes	No
1. Do you have access to data that guides you on best courier selection per country / region?	<input type="checkbox"/>	<input type="checkbox"/>
2. Do you have access to near real-time tracking data for your shipments?	<input type="checkbox"/>	<input type="checkbox"/>
3. Are you proactively made aware of delays in your shipments?	<input type="checkbox"/>	<input type="checkbox"/>
4. Are your couriers delivering on time 99%+?	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you act as Importer of Record in all countries where you are sponsoring trials?	<input type="checkbox"/>	<input type="checkbox"/>
6. Do you have visibility to when your shipments are clearing customs?	<input type="checkbox"/>	<input type="checkbox"/>
7. Are your shipments arriving at the correct temperature 99%+?	<input type="checkbox"/>	<input type="checkbox"/>
8. Do you want to risk resupply of product because of loss due to temperature excursion?	<input type="checkbox"/>	<input type="checkbox"/>
9. Are you satisfied with your transportation costs?	<input type="checkbox"/>	<input type="checkbox"/>
10. Do you have direct access to in-country logistics expertise to advise re: regulatory issues, customs clearance, documentation support, shipment status?	<input type="checkbox"/>	<input type="checkbox"/>

If any of the answers to these questions is no, there are options to improve the transportation quality, cost, and delivery of your clinical trial supplies.

Find out more

Realizing performance efficiencies across the supply chain



Data-Driven Courier & Mode Selection

Data objective analysis to choose the best courier for your routes based on high quality service and performance efficiencies over time.

While it seems counterintuitive, selecting the least expensive courier can lead to higher costs in the long term. That's because all couriers are not equal in their abilities. If they were, the solution of selecting the least expensive courier would work, every pharmaceutical company would elect it, and transportation costs would be reduced significantly.

Like people, individual couriers have strengths and weaknesses, both with respect to the geographic areas they service and the materials they manage. Lost or delayed shipments, especially when dealing with high value IMP and commercial product can be costly.

Thermo Fisher Scientific Global Logistics Help Desk tracks and compares performance metrics on 20+ couriers in 120+ countries. We have data that demonstrates while a courier may dominate a given market, they may not be as effective in other parts of the world and, in particular, within remote countries.

Similarly, some couriers perform well when handling non-controlled or ambient shipments, while others excel at managing temperature controlled materials. Furthermore, some couriers excel at transporting short-timeline shipments that must reach their destinations within a 24-48 hour window.

Using this comprehensive data set, Thermo Fisher Scientific selects couriers based upon individual strengths and metrics collated over a period of time, making it possible to provide clinical teams with customized transport plans. For example, the courier most suited to transport temperature controlled materials to Argentina receives the assignment, not a courier whose strength lies in continental Europe. This mitigates risk by ensuring that the right courier is selected from the beginning and then properly managed for each particular assignment.

The selection of carriers based on their strengths and track record is one key way in which the Thermo Fisher Scientific model differs from the procurement driven strategy. Overall costs improve, because customers are guided to use low-cost couriers where it is safe to do so, and premium carriers only when necessary. Most importantly, overall quality improves by ensuring the shipment is moved by a provider with a proven track record of performance.

Streamlining the customs clearance process to help avoid unnecessary delays



Customs Clearance & Regulatory Support

Considering the fact that temperature-controlled biological products are highrisk and high-cost – some valued at as much as \$1,500 a vial – delays can bear an equally high price tag.

Despite the substantial progress being made toward global regulatory alignment, customs requirements continue to evolve and may differ significantly amongst even neighboring countries.

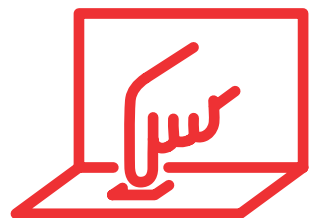
As part of the Total Transportation Management service offering, Thermo Fisher Scientific coordinates the import / export process working closely with the Sponsor / Manufacturer, their designated Importer of Record (IOR), the selected courier and local customs officials.

The role of Importer of Record can be particularly confusing as it varies from country to country; in some, the Sponsor / Manufacturer is the only entity that can assume the role of IOR, while in others, the IOR can be a third party. Thermo Fisher Scientific is fully vetted and compliant in regional and country specific laws providing IOR services across the globe. Our in-country logistics experts have excellent working relationships with local customs officials. This personal working relationship is invaluable as it brings visibility to critical shipments and can, often times, facilitate a faster clearance process.

Thermo Fisher Scientific provides customs clearance and regulatory support, to include:

- Documentation preparation for import/export
- Provision of Importer Of Record services in 25+ countries
- Understanding of regulatory requirements across all continents with local teams available to support customs enquiries
- Ability to adapt to changing regulations
- Expertise in emerging markets
- Proactive communication with customs officials to streamline the process and avoid delays

Standardized or customized shipper solutions based on biotech/pharma needs



Shipper Solutions for Transportation Supplies

Temperature Ranges:

Controlled Ambient
(15°C to 25°C)

Refrigerated (2°C to 8°C)

Frozen (-20°C)

Dry Ice (-80°C)

Ultracold (LN2)

While it's true that a person can board a plane and arrive in Moscow in less than 24 hours, a passenger is not required to clear customs the way a package must. Since it typically takes five days for packaged investigational drug to clear customs and reach a Russian depot, it's ineffective to use a temperature-controlled box validated for 48 hours for a trip that will actually span 100 hours. Thermo Fisher Scientific brings that knowledge and experience to the table.

Thermo Fisher Scientific offers a comprehensive suite of passive and active shipping systems. Whether the requirement is single use, high performance reusable systems, small parcel, bulk single or multi-pallet shipments, Thermo Fisher Scientific has an extensive range of qualified solutions to meet customer needs.

Shipping systems are qualified to Thermo Fisher Scientific global profiles which represent >95% of all shipping lanes for both winter and summer conditions. Where unique shipping challenges occur, additional qualification is performed to ensure temperature requirements of the IMP/ commercial goods are maintained from point of origin to final consignee. Where appropriate, temperature data loggers can be incorporated within the shipper to offer maximum assurance that product integrity has been preserved.

Thermo Fisher Scientific currently offers a shipper return and reuse program for shipments within Europe, USA or China with strategic plans to expand this program over time. This means you can benefit from high performance, lightweight systems at a significantly lower cost per use. In addition, there are benefits of waste reduction due to less waste being sent to land fill or for destruction. Pharmaceutical companies are often under pressure to improve their sustainability metrics through increased recycling measures and reduced carbon footprint. A reusable shipper program helps pharma companies to achieve these goals — prevents temperature excursions, reduces wastes, achieves sustainability metrics and makes happier investigator sites - Everyone's a winner!

Delivering enhanced control and compliance across the supply chain



Global Quality Management Systems

With exposure to multinational trials and thousands of protocols every year, Thermo Fisher Scientific has developed the industry's best practices in clinical supply chain management.



Each courier within the Thermo Fisher Scientific network is subject to a strict, quality-driven review and selection process. Their performance is tracked and reviewed quarterly to ensure we can stand by our commitment that each shipment will be delivered on time, in full, and at temperature.

Trial Sponsors benefit from identical quality standards and systems globally, including guaranteed GMP/GDP compliance networkwide and strict requirements governing response time when problems occur.

Regardless of the shipment origin or destination, clinical teams can rest assured that quality standards are consistent, enforced globally and in accordance with local regulations.

Real time visibility of all shipments via the global logistics help desk & local in-country teams



Data Objective Monitoring & Reporting

The Thermo Fisher Scientific Global Logistics Help Desk provides worldwide support for customers, with translation support as needed.



Services include track and trace capabilities incorporating proactive intervention and resolution of all shipment delays, as well as telephone and email support for anyone requiring assistance with a shipment. The Help Desk global team can provide assistance with:

- Shipment tracking queries
- Damaged or incorrect shipments
- Customs clearance issues
- Late or lost shipments
- Temperature excursion reporting

Shipment check points are monitored through the Global Logistics Help Desk irrespective of collection point anywhere on the globe. Pre-alerts are sent to the consignee to accommodate pre-set delivery appointments. Should delays occur, Thermo Fisher Scientific knows when, where and why they are occurring, and will intervene as required. In the event a service level is at risk, escalation takes place according to client specific procedures.

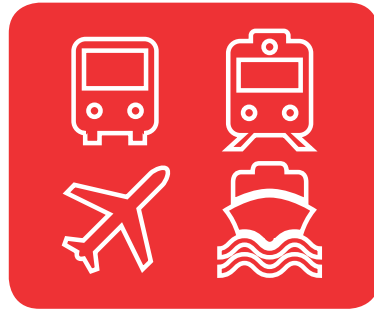
Benefits of total transportation management: Delivering results across the supply chain

Total Transportation Management is a unique service offering with a track record of excellence in the delivery of life science shipments to their final destinations On-Time, In-Full and At-Temperature.



Mitigates risk across the supply chain

- Global footprint, local presence
- Established facilities, systems and processes at global and local levels
- Supporting the end-to-end supply chain



Optimizes transportation modes

- Mode optimization – selecting optimal carrier/route for each shipment, based on quality, service and cost
- Data objective decisions based on data collated over time



Provides up-to-date regulatory knowledge & advice on international shipments

- Dedicated teams of logistics experts at global and local levels
- Streamlining of customs clearance, relieves overheads, administration burden, tax and duty payments associated with documentation for import/export



Commits to customer satisfaction

- Manages all shipments to final destination
- Support around the clock and around the globe from our Global Logistics Help Desk
- Proactive intervention to ensure all deliveries are On-Time and In-Full

Footnotes

1 Pelzel, Kristina. "What's Next for the Pharmaceutical Supply Chain?" [inventory-and-supplychain-blog.com](http://www.inventory-and-supplychain-blog.com/inventory-and-supply-chain-optimization). Inventory and Supply Chain Optimization, 12 January 2017. <http://www.inventory-and-supplychain-blog.com/whats-next-for-the-pharmaceutical-supply-chain/>

2 Pharmaceutical Commerce's annual Biopharma Cold Chain Sourcebook, 2016

