ThermoFisher SCIENTIFIC

MANAGING TEMPERATURE EXCURSIONS

KEY POINTERS THAT MUST BE ADDRESSED

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

Introduction and overview

The maintenance of cold chain product integrity across the entire supply chain demands rigorous processes and cold chain expertise of the highest calibre—from packaging, handling, storage & distribution of temperature sensitive Investigational Medicinal Products (IMP), all the way to the investigator site. These eBooks outline industry trends and reviews how Fisher Clinical Services solutions are meeting the challenges of the cold chain distribution of clinical trial supplies all over the world.

COLD CHAIN INDUSTRY TRENDS provides an industry overview and a framework for discussion. The importance of a robust supply chain is addressed. It includes planning recommendations for biopharmaceutical companies preparing to scale up to global vaccine trials.

COLD CHAIN SHIPPING CONSIDERATIONS takes a deep dive into passive shipping options and how they work, with information on the advantages and disadvantages of various coolants.

EVALUATING & QUALIFYING TEMPERATURE MANAGED SHIPPERS provides insight into how we qualify shipping options with a case study example of a 'return and reuse shipper pilot' which delivered very positive results.

MANAGING TEMPERATURE EXCURSIONS provides top tips on the best course of action to take, and provides summary recommendations for Sponsors on how to handle cold chain or temperature sensitive IMP across the supply chain, up until delivery to the investigator site.

What to do when a temperature excursion occurs

A temperature excursion occurs when clinical trial material is stored at a temperature outside of the specified temperature range as defined on the label. This can have a substantial impact on a clinical trial study; it can impact the quality, efficacy and safety of products. More importantly, an excursion can significantly impact patient safety if not detected and communicated effectively.

Here are a few pointers:

Notify the party who advised of the temperature excursion to **keep the material in a quarantined status** until a 'fit'/'not fit-for-use' statement has been obtained from the manufacturer. This instruction should also be included as part of the paperwork that was sent to the investigator site at the point of dispatch by the distributor

Ask the site to **email a copy of the temperature reading** if they hadn't already in their initial correspondence. Most temperature monitors allow for the site to download the report directly onto their computer.

Review the temperature excursion report and **forward the data to the drug manufacturer** for drug disposition. Make sure to receive back a written statement which contains information linking the 'fit-for-use' statement back to that particular shipment (i.e. the shipment or waybill number).

Advise the site if the drug is fit for use and ensure the temperature reading is kept within the study folder regardless of the outcome.

It is advisable to **keep a record** of any excursion and supporting data—lot number or material specific numbers—together with any other correspondence in case this information is needed again in the future, for example during an audit.

Patient visits may need to be rescheduled until the effected material is deemed fit for use, or the material is resupplied by the pharmaceutical company. This may take some time, leading to patient and site frustration, as well as potential patient dropouts impacting the overall success of the trial.

Conclusion

Concluding recommendations for a Sponsor's clinical supply chain for cold chain and temperature sensitive IMP:

Planning + **Pro-activity** = **Success**

1 Agree on a distribution strategy

In logistics, anything is possible, but bear in mind that overcoming challenges in an outsourcing project requires a partnership of supplier and sponsor.

2 Use qualified couriers with local expertise & global values

We have a global footprint of 27 cGMP facilities with logistics experts within its project management teams. It is important for these logistics experts to establish good working practices with local couriers, encouraging them to uphold the high standards of transportation that are established by their global counterparts.

3 Define a range of shippers based on a review of stability data and destination

The Fisher Clinical Services team uses rigorous testing, quality and performance metrics in identifying and selecting shippers. A time period is selected to reflect every eventuality. All data is reviewed objectively.

4 Monitor and ensure safest passage from hour 1 to delivery

Appropriate packaging and shipping choices can spell the difference between product that maintains integrity and product that requires costly replacement. Last mile distribution is of paramount importance. Why go to extensive effort to ensure integrity of cold chain supplies if the parties involved in that last mile of distribution do not uphold defined specifications? Liaise with the investigator site to support continued cold chain conditions once clinical supplies are delivered to site.

5 Be flexible in your processes and choices

Rely upon supply chain experts to make recommendations and changes as necessary to address issues as they develop to ensure safe passage of product to depots and clinical sites. Allow the experts to do what they do best.

6 Communicate clearly with all parties

Clear communication enables supply chain managers to do the best job possible for sponsors, helping them to meet their goals.

7 Remember: Planning + Pro-activity = Success

Whenever possible, allow 6–12 months for advance planning. The biggest mistake made by sponsors in preparing for vaccine/biologics trials is failing to build in sufficient planning time.

8 Balance risk, cost, compliance and timelines

First and foremost, remember that the safety of study subjects is the primary concern for all clinical studies.

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