ThermoFisher SCIENTIFIC

10 STEPS

THAT RISK FAILURE IN THE TEMPERATURE CONTROLLED CLINICAL SUPPLY CHAIN

Maintaining product integrity is essential. If you are developing a drug that requires temperature management, eliminating the risk of an excursion throughout the supply chain is critical. Once your Investigational Medicinal Product (IMP) leaves your development facility, there are numerous points where it can be at risk.

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1 DELIVERY to Clinical Supply Provider

As your drug leaves the manufacturing facility it requires special handling to make sure it stays within the required temperature range.

Questions to help you identify your solution:

- Will you need refrigerated trucks or specialized containers as your product travels to the clinical supply provider for packaging / storage / distribution?
- Will you need the receiving operation to move your product into the required environment quickly or can your product be held in an ambient receiving area?

2 Cold Storage CAPACITY

Through each phase of the process (packaging / labeling / distribution) your product should be stored in the right environment.

Questions to help you identify your solution:

- Will your product need the packaging and labeling process to take place in the same facility where you've stored your product to maintain product integrity? If not, how will it be protected as it moves between the sites?
- If your product is packaged in a different facility, will your provider have sufficient capacity to store your product at the right temperature until they are ready to run the job?

3 PACKAGING Operation

If you don't have well defined stability data, you might not know how long your product can be out of environment before putting it at risk.

Questions to help you identify your solution:

- Will your packaging supplier be able to run the job in the required temperature environment?
- How long can your cold chain product be exposed in a controlled ambient environment to accommodate a packaging process before your product is no longer fit for use?

4 LABEL Selection

Adhesives behave differently at different temperatures and when applied to different surfaces.

Questions to help you identify your solution:

- How will your product's label be applied and in what environment? For example, will the drug be brought up to room temperature, labeled, and then brought back to cold?
- What material is the component made of i.e. glass vial vs. cardboard kit vs. plastic bottle? Each interacts with adhesive differently.

5 SHIPPPING Containers

Refrigerated trucks can be costly and aren't always required if you invest in a good shipping container that will protect your product.

Questions to help you identify your solution:

- Are you familiar with the range of available options, or will you need someone with expertise to make the recommendation?
- Do you need a returns / waste management program to alleviate the burden on your investigator sites?

6 MONITORING Devices

In a global trial, transit times between sites can take days. You have no control of how long the shipment might be exposed during handoffs between sites, ground and air transportation.

Questions to help you identify your solution:

- Will you require monitors to log the temperature throughout the shipment so that, upon delivery, you can ensure it remained within specification?
- Should you use real-time GPS location trackers to monitor for unexpected delays or diversions and to minimize the risk of further delays due to necessary replacement shipments?

7 COURIER Selection

There can be multiple companies involved in moving your product from the manufacturer to your clinical supply provider and investigator site.

Questions to help you identify your solution:

- Does your transportation provider have a proven track record working with temperature-managed shipments with minimal to no excursions?
- Do they have this experience for the origin/destination points involved in your trial?

8 CUSTOMS Clearance

Each country has its unique requirements and the clearance process might take hours, days or even weeks to complete.

Questions to help you identify your solution:

- When your shipment is going through the customs clearance process, will it be maintained in a temperature controlled environment?
- If the customs location does not have managed temperature capacity, do you have any ability to replenish coolant materials in the event of unexpected delays?

9 INVESTIGATOR Site

As clinical trials become more global in nature, they are reaching remote areas in emerging countries that often have limited infrastructure.

Questions to help you identify your solution:

- Do your investigator sites have sufficient, refrigerated/frozen storage to maintain your product at the required temperature?
- Will you need to supply the refrigerators or freezers to ensure the product is stored correctly?

10 PATIENT Residence

In many trials the patient administers their own medication without requiring a visit to the investigator site.

Questions to help you identify your solution:

- Will your product be protected when the patient travels from the clinical site to their home?
- Do they have appropriate storage at their home to ensure the product remains at temperature?

LEARN MORE

Managing a cold supply chain, especially in the context of a global clinical trial, can be extraordinarily complex. Each step in the journey needs to be carefully examined and planned for. By planning as early as possible, you'll be better positioned to ensure zero excursions and maximum product integrity.

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