

AdeptGroup

A Holistic Approach to Successful Cold Chain Solutions

AN ADEPT GROUP WHITE PAPER





Reliable Solutions to Protect Product

As the world moves more and more towards pre-packaged food, perishable produce and temperature-sensitive healthcare products, the need for maintaining temperature to preserve products throughout the supply chain increases daily.

Cold chain provides a reliable solution to protect the product from undesirable effects of high temperatures and temperature fluctuations throughout its distribution routes.

The intricate nature of the cold supply chain, in conjunction with unforeseen external changes that a shipment can experience in the distribution environment, makes cold chain package and logistics design complicated. For most new product development projects, the design and development of packaging revolves around the product attributes. However, external factors such as supply chain constraint, collaboration and coordination with secondary and tertiary logistics providers, and in-transit temperature fluctuation significantly impact the design of cold chain packaging solutions.

Done correctly, cold chain packaging design should maximize both protection against typical hazards in the distribution environment (impact, vibration, exposure to moisture, etc.) and protection against temperature excursions. Accounting for all the variables from development to distribution presents a unique challenge and often requires the capabilities of secondary and tertiary logistics providers (2PL and 3PL). Packaging systems designed without adequate collaboration and understanding of 2PL and 3PL supply chain partners can lead to the need for remediation efforts down the road or, in some cases, product recalls.

Cold chain packaging is part of a wider arena of cold chain logistics which includes:

- Cold chain packaging
- Shipping process and routes
- Qualification of distribution routes
- Supply chain
- IoT for track and trace

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Stages of Cold Chain Logistics

Planning During Early Design and Manufacturing States

Planning for cold chain logistics should begin during the early design and manufacturing stage of the product. Avoiding potential temperature excursions and protecting a product from losing its effectiveness requires a comprehensive approach ranging from preparation and manufacturing of the product to final delivery.

A Process Flow Diagram (PFD) can be used to assist in the identification of potential packaging solutions, mapping out the supply chain for potential risk areas and solutions for monitoring the package.

A successful cold chain methodology accounts for all of the variables involved in the cold chain process, from development through distribution, and includes the product's use by a patient or healthcare provider. The complexity of cold chain logistics requires understanding the intricacies in design and interaction to maintain integrity of the product.

THE 6 MAIN STAGES OF COLD CHAIN LOGISTICS

Recognizing each of these distinct stages as part of an interconnected, comprehensive solution facilitates the type of thinking required develop an effective cold chain solution.



Design and Development



Packaging, Components and Processes



Packaging Qualification and Validation



Cold storage



Transport



Monitoring



Temperature Excursion Studies

Design and development of a cold chain logistics solution starts early during product development. The products are tested over a wide range of temperature profiles to understand the degradation of the product. These are sometimes called temperature excursion studies, or target temperature profiles for the drug products.

These temperature ranges are often refined multiple times during the product development lifecycle and the final profile is a narrow range identified for the development of the cold chain solution. It is therefore highly beneficial to understand the product excursion studies in order to develop packaging solutions that will effectively protect the product from temperature excursions outside of the acceptable range.





The Complex Interactions of a Cold Chain Solution

The many interactions between components, materials and processes involved in controlled-temperature products are a big reason why developing a cold chain solution is complex. Understanding the interactions between those factors can impact the performance or temperature of the package.

For example, each of the raw materials in both the product and its packaging are subjected to various process steps which have an independent impact on product stability. Furthermore, processes such as hermetic sealing, heat seal technology, or radiation sterilization tend to increase the core temperature of the product during manufacturing and packaging stages.

Involving packaging engineers during the early design phase allows for development of in-process solutions such as custom dies and tooling, as well as a work-in-progress cold package system to protect the product even before it is packed and shipped through the supply chain. A packaging engineer who engages with the process from its inception will be able to apply lessons learned during the product's development through the packaging process and beyond.





Compliance for Cold Chain Regulatory Requirements

An important factor for successful qualification and validation of a cold chain solution is ensuring it complies with cold chain regulatory requirements. Enlisting a regulatory expert early in the process will help avoid rework further down the line.

Guidance on regulatory requirements for cold chain packaging can be found through the U.S. Food & Drug Administration's cGMP, the World Health Organization's GDP, China's GSP, EUMD as well as IATA due to potentially hazardous material like dry ice and liquid nitrogen used for cooling.

Process validation for cold chain logistics (packaging, storage, and distribution) is a required part of the regulatory submission for any pharmaceutical, biological or medical device product. Review of the dossier submitted to regulatory bodies will most likely require the following sections:

Stability testing

Temperature excursion profile and target product requirements

Thermal packaging qualification

1. ASTM 4169 conditioning and extreme temperature cycles per shipping route.
2. ISTA 7D (Temperature Test for Transport Packaging) and ISTA 7E (Testing Standard for Thermal Transport Packaging Used in Parcel Delivery System Shipment).
3. ASTM D4332 is a widely recognized standard prescribing various temperature profiles such as for different regional conditions. For example, Extreme Cold (low temp, low humidity), Desert (high temp, low humidity), and Tropic (high temp, high humidity).
4. Equipment IQ/OQ/PQ for refrigeration system such as freezer, environmental chamber, air conditioners, thermal containers.
5. Temperature mapping for the shipping route, shipping route qualification and qualification of monitoring systems like thermometers to advanced real time data recorders and alarms.
6. Cold chain track and trace system with sensors-based technologies like RFID and cloud connectivity for real-time data analysis.





Cold Storage

Preparing for Pre-Shipment Conditions

An effective cold chain solution accounts for not only the varying conditions of the distribution environment, but also pre-shipment conditions. Regardless of the active or passive cold chain system, the packages need to be conditioned to ensure optimum temperature control throughout the transport.

Depending on the load prepared for the shipment, it may take anywhere from a few hours to several days before a product is shipped.

Cold storage options include either freezers (for temperatures below 0 °C), refrigerators (for temperature from 0 °C to 15°C) or environmental chambers which can maintain ambient or room temperatures. The validation of these chambers as a stand-alone piece of equipment or as a part of cold chain logistics are of paramount importance since this is the last step before the product is shipped out of the facility.





Solutions to Maintain Temperature Range



Passive Temperature Control Solutions

Passive temperature control solutions do not have a continuous cooling mechanism to maintain temperature at or within predetermined temperature range. The temperature is maintained by multiple insulating layers and the starting temperature is kept as cool as possible within the temperature range. Therefore, passive cold chain solutions are mainly used for products shipped through expeditious channels (e.g. overnight shipment, single parcel shipment, priority shipments, etc.). Preconditioning of these shipments are of paramount importance to achieve maximum shipping duration.



Active Temperature Control Solutions

Active temperature control solutions have a continuous cooling mechanism to maintain the temperature at or within a predetermined temperature range. Continuous cooling is achieved over longer periods of time using coolant material and electrical supply or both during the distribution cycle. Active temperature control solutions are typically suitable for larger loads in shipping container and temperature-controlled trucks and ships.

Monitoring: Critical Quality Control and System Performance Indicators

Monitoring of the temperature-controlled system to ensure that the product temperature limits were maintained and to capture any deviation is critical to cold chain logistics. Monitoring not only provides quality control but is an important indicator for determining how well the overall system performs.

Another important use of monitoring is to ensure any systemic issues are captured and resolved before it impacts patient safety and cause business risk. This also helps identify anomalies and enable root cause investigation, specifically when products are exchanged between CMOs and 2PL/3PL vendors.



Conclusion

Ensuring Integrity of the Product

With advances in cold chain research and technology, paired with the economic need for increased shipping of products due to COVID-19, cold chain logistics has been increasing in value for many leading companies.

Because of its increasing value, it is also more important than ever to get cold chain logistics right the first time. Involving experienced and knowledgeable packaging engineers from the early stages of product development means there will always be someone keeping an eye on the big picture and planning each stage of a cold chain packaging solution to complement the careful work done in the other stages.

This holistic approach to cold chain packaging ensures the integrity of the product and helps brand owners avoid costly rework and product recalls down the road. With proven expertise and experience with cold chain package development, working with external vendors and design to market support, Adept Group can be a valuable partner to bring your products to market competitively.

Learn more: adeptpackaging.com

