# Q&A with Ardena Experts

# Strategies for Effective Cold Chain Packaging and Labelling

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***What are the special requirements in a clinical supply project for temperature-sensitive clinical trial material?***

Clinical trials often require the use of temperature-sensitive products, such as biologics and vaccines, which need to be stored and transported within narrow temperature ranges to maintain their stability and efficacy. Temperature excursions, even brief ones, can result in the degradation of the product, leading to incorrect results and affecting patient safety. As such, the main requirements for maintaining the stability of temperature-sensitive clinical trial material involve proper handling and storage to ensure that the products remain within the specified temperature range throughout the supply chain.

Before starting a clinical supply project, it is essential to generate stability data to determine the temperature ranges that are suitable for the storage, transportation, and handling of the clinical trial material, as well as the duration of time that this material can be stored outside these temperature ranges.

The supply chain for clinical trial material typically involves multiple distributors. For the end-to-end supply chain management of temperature-sensitive materials, it is essential that these distributors work together in a seamless and coordinated manner. To ensure that the stability of the clinical trial material is maintained throughout the entire supply chain, each of these distributors must have well-established best practices in cold chain management.

***How do you ensure that temperature sensitive clinical trial material is kept within the required temperatures during clinical supply?***

To keep temperature-sensitive clinical trial material within the required temperatures during clinical supply, a system must be established that can handle controlled temperature requirements. This system should monitor the environmental conditions continuously from the product's arrival until it leaves the company, ensuring that the temperature remains within the specified range.

One way to achieve this is to equip cold rooms with logging systems that can continuously monitor and record the temperature of the products. The data collected from the logging system can be analyzed

to identify any temperature deviations, and corrective actions can be taken immediately to ensure that the temperature remains within the specified range.

It is also important to have established processes that allow the storage conditions of temperature-sensitive products to be monitored and tracked from end-to-end. This process tracing can help prove that the stability of the temperature-sensitive clinical trial material was maintained during the supply chain.

The use of dedicated cold storage facilities, refrigerated containers, and temperature-controlled packaging can also help ensure that the temperature of the product remains within the specified range. Additionally, the use of temperature-monitoring devices such as data loggers, temperature indicators can also be used to monitor the temperature of the product during storage and transport.

***What are some examples of challenges you faced in clinical supply projects involving temperature-sensitive clinical trial material, and how did you overcome them?***

In one project, we faced a challenge where the cold chain could only be interrupted for a very short time. To ensure that the temperature-sensitive material remained stable during this time, we carefully evaluated our packaging, handling, and distribution strategy to minimize the time outside of the required temperature range.

In another project, we lacked stability data to justify any time out of the ideal storage conditions for the material. To address this, we conducted in-use studies that involved setting up freeze-thaw protocols. We subjected the material to extreme conditions, and after conducting three freeze-thaw cycles, we were able to prove that the storage of the material outside of the ideal storage conditions for a certain time was justifiable. Through process tracing, we were able to demonstrate that the stability of the temperature-sensitive clinical trial material was maintained throughout the supply chain.

***How did Ardena's integrated services platform add value to the project involving temperature-sensitive clinical trial material?***

The clinical trial material needs to be transported until they reach the patients participating in the study. The interruption of the cold chain during shipping can be a significant challenge. The more shipments are required, the greater the time out from the ideal storage conditions, and the higher the risk of problems. This risk is amplified when there are multiple providers involved in the supply chain. To mitigate these risks, the requirements for technology transfer for the distribution strategy are increasing.

This is where the Ardena services platform comes in. Ardena specializes in developing drug products with beneficial properties, including those that are temperature-sensitive. When Ardena is involved in the development of a drug product from the beginning, in-depth product insights are available. This allows for the creation of suitable stability plans and the development of an efficient strategy for packaging, handling, storage, and distribution.

In the case of the project that was just reported, Ardena's involvement in the drug product's development process from the beginning provided a thorough understanding of the product, which enabled the creation of appropriate stability plans. These plans were crucial in designing an effective strategy for packaging, handling, storage, and distribution of the clinical trial material. The development of a clinical supply program was facilitated by a dedicated team of global cold chain experts who worked collaboratively to ensure the product's stability throughout the supply chain. Additionally, strategic partnerships with established vendors for cold chain supply were leveraged to further reduce technical transfer efforts and simplify the overall supply chain process, ultimately contributing to risk mitigation.

***If you were the client, what factors would be important to consider when choosing a service provider for cold chain labelling and packaging?***

As a client seeking a service provider for cold chain labelling and packaging, it's important to find a partner who can provide end-to-end supply chain management solutions. This means a partner with a proven track record of delivering supply chain management for cold chain, and who has the necessary infrastructure in place to manage clinical trial material tracking and logistics.

In addition, it's crucial to avoid the need to engage with multiple providers who take over individual steps within the supply chain, which can add complexity and increase the risk of errors. By choosing a single provider who can manage the entire cold chain process, clients can benefit from greater efficiency, simplification, and ultimately, a lower risk of disruptions or delays in the supply chain.

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