[Challenges Associated with Controlled Room Temperature Logistics](http://blog.fisherbioservices.com/challenges-associated-with-controlled-room-temperature-logistics)

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The shipping and data monitoring of [cold chain logistics](http://www.fisherbioservices.com/services/distributiontransport) is a hot topic within our industry. When your products leave your care, the data you receive helps to ensure your peace of mind by validating the products’ integrity throughout the chain of custody process. As our world becomes more focused on data to support efficiency it is becoming increasingly important to monitor if product integrity has been impacted by environmental problems. But at what cost?

In the past, we've discussed some of the [concerns](http://blog.fisherbioservices.com/bid/337378/10-Things-You-Should-Know-About-Dry-Shippers-Before-Shipping-High-Value-Biologics-Part-I), [considerations](http://blog.fisherbioservices.com/bid/339094/10-Things-You-Should-Know-About-Dry-Shippers-Before-Shipping-High-Value-Biologics-Part-II), and [best practices](http://blog.fisherbioservices.com/best-practices-for-managing-cold-chain-shipments)associated with [ultra cold chain logistics](http://blog.fisherbioservices.com/bid/334770/Cell-Therapy-Webinar-Ultra-Cold-Chain-Logistical-Challenges) of high value biologics and biosamples. However, there are many challenges associated with controlled room temperature (CRT) logistics as well. Recently, I had the opportunity to discuss these challenges with some of our internal experts who deal with these types of shipments frequently, and have summarized them intosix basic points below!

**1. Defining Controlled Room Temperature**

The definition of CRT includes a range allowance that is entirely dependent on the product being shipped, which can make the shipment quite complicated to arrange. Therefore, obtaining a clear understanding of what the product’s true storage and shipping temperature range is paramount to the stability of that product. This information can be gathered from the manufacturer and depending on the product’s qualification, there may be a lot (or a little) variability in temperature.

**2. Location,**[**Transportation**](http://blog.fisherbioservices.com/bid/317150/Controlled-Rate-Freezing-of-Cells-During-Ultra-Cold-Transit)**, and Duration of the Product’s Journey**

Where is the product being shipped?  How is it going to get there? How long is going to take? These are three questions that must be answered prior to packaging your CRT product. If a product is being shipped internationally by air transport over 2 or more days, [the packaging requirements](http://blog.fisherbioservices.com/top-10-concerns-and-considerations-in-cold-chain-logistics) would be quite different than if it were shipped domestically using a same or next day delivery service.

**3. Product Preparation**

Before a product departs the facility it must be prepared for the shipment and packaged properly. The shipping container (box, dry shipper, or otherwise) is directly dependent on the product’s definition of CRT. To maintain the temperature, the shipment would require room temperature gels to help achieve the temperature ranges needed and increase the hold time. The gel configuration impacts the size of the container required and the weight, which has a direct impact on cost.

**4. Impact on Operations**

When monitoring the temperature of CRT product, there is an increase in the number of steps involved across all aspects of the process from preparation, to storage, to shipment.  This impacts operations; particularly the resources and supplies needed to meet the volume of shipments that are distributed on a daily basis. Additionally, the operations team doesn’t always know the number of scheduled shipments ahead of time so it is very important that the necessary supplies are readily accessible to fulfill the shipments.  This will likely require an increase in labor to assist with operations. Additionally, the increased need for infrastructure such as refrigerators, bricks, dry shippers, and data loggers take up valuable square footage which impacts the space allotted for storage.

**5. Impact on Cost**

As mentioned above, the impact on operations results in an increased need for supplies, labor, storage space, and infrastructure, all of which have a direct impact on the bottom line - cost. Some of these costs would be one-time expenses and others, such as labor and supplies, would be on-going. This is mainly due to ensuring the necessary equipment and supplies are readily available to keep shipments on schedule.

**6. Chain of Custody Gap**

During transport, controlled room temperature shipments are at risk of temperature extremes.  There are cold excursion risks in winter and warm excursion risks in summer.  These risks are not singular for international shipments.  That is, international shipments can be exposed to both cold and warm temperatures.  Cold risks occur during air transport regardless of the season shipped.  In addition, both cold and warm excursions can occur when shipping from a northern to a southern hemisphere.  The chain of product stability custody is only as strong as its weakest link.  Transport is a weak link for products improperly packed.

As an industry driven by data, the challenges associated with cold chain logistics, particularly controlled room temperature shipments, are becoming increasingly prevalent.  Despite these challenges, it is of utmost importance that the products’ integrity is maintained prior to administration to a patient to ensure it as effective as possible.