By 2016, world sales of cold-chain drugs and biologics such as vaccines and blood plasma products will near $240 billion. The increase has led to a surge in discussion about how to protect these products throughout the transportation logistics cycle.

Industry experts are recommending that the term “cold chain” be eliminated from rules, guidance and best-practice documents. “Cold chain” now includes a broader spectrum of temperature ranges, such as controlled room temperature (CRT).

**CRT doesn’t mean ambient**

Not long ago, CRT, ambient and room temperature products were synonymous and considered by many to not require thermal protection. CRT products, however, do require temperature control protection as they move through the supply chain. There is, however, currently no industry-defined temperature standard for CRT transportation. And there are few guidelines for packaging and protecting CRT products. Some product labels for example recommend 15-30°C, while others state 20-25°C.

The transportation of temperature-sensitive medical products via general cargo may no longer meet future regulatory environments.

**Moving forward, the healthcare industry must:**

- Define CRT.
- Develop packaging appropriate for all temperature ranges, including CRT.
- Partner with providers who can develop processes to protect temperature-sensitive products.

This eBook—the first in a series of five—focuses on the initial steps required to establish a temperature-sensitive supply chain.

A 2008 study conducted by the UK-based Medicines and Healthcare Products Regulatory Agency (MHRA) revealed that 43 percent of critical and major product deficiencies are related to ineffective temperature control.

UPS’s 2011 Pain in the (Supply) Chain survey found product damage and spoilage was an issue of far greater concern in Asia and the U.S. than in Europe. 70 percent of Asian companies and 67 percent of U.S. companies reported concerns versus only 27 percent in Europe. The reasons for the disparities are unclear.

1 BioPharma Cold-Chain 2012 Sourcebook
ESTABLISHING
a temperature-sensitive supply chain
Establishing a temperature-sensitive supply chain

Addressing the Challenge

Compliance

The pharmaceutical and biologics industries have come a long way in their knowledge of the distribution environment. But there has never been an all-encompassing temperature-sensitive management resource for all supply chains, market needs and regulatory requirements. Instead there are many separate guidelines describing how to maintain temperature—some with very little detail.

Product protection

If you do not meet temperature regulatory requirements, then a product potentially could be placed on hold by the FDA or equivalent non-U.S. agency. Product could also be recalled, diminish in efficacy or, in the worst case, be deemed spoiled. Spoilage could occur when an accumulated range of temperature excursion reaches a level considered unacceptable by your quality assurance department, or by government agencies.

Protecting your brand

Your organization has invested a significant percentage of revenue into building brand awareness. Even one product quality issue can compromise patient health and public trust and adversely impact sales, brand image and shareholder confidence.

Defining Temperature Requirements

Mark Davis, Global Strategy Product Manager, UPS Healthcare Logistics, talks about defining temperature requirements and managing controlled-room temperature products.
APPROACH

Work with a transportation and distribution partner to not only help protect shipments, but also to document the conditions your product will encounter as it moves through the supply chain. This should help improve quality control, customer satisfaction and ultimately patient health.

Select a partner with expertise and experience and agree upon a transportation protocol for the movements of your shipments. Ensure your partner has quality control assurance in place to support compliance with regulations and guidelines.

For example, UPS offers UPS Temperature True® and PharmaPort™ 360 containers to protect the shipment of vital products and document actual conditions during transit. In addition, a trained staff supports shipments together with an independent, healthcare-dedicated QA group.
PLANNING PROCESS

Planning a successful temperature-sensitive supply chain helps maintain product integrity throughout transportation and meets the regulations and guidelines of relevant agencies. Planning should not only include your organization’s specific requirements, including service modes, and packaging and quality requirements, but should also take into account quantifiable value. The more information provided during the planning process, the more effective the solution that will be developed. New technologies, new services, and new strategies may enable you to accomplish your goals faster, compete better, and improve the overall performance of your supply chain.

Creating Shipping Solutions

Hear a few words about the importance of collaboration between manufacturers and shippers.
Establishing a temperature-sensitive supply chain

Transportation providers and life science companies may not automatically understand the transportation requirements of specific healthcare products. You and your logistics partner need to discuss these requirements, allowing the provider to design a supply chain that meets each product’s specific needs. Among other things, you need to agree on mode of transportation, temperature sensitivity, stability data and reporting of in-transit temperatures.
ESTABLISHING
a temperature-
sensitive supply chain

PRODUCT PROTECTION

Unsurpassed global network
UPS can help you protect products as they cross oceans and borders with reliability and flexibility:
- By UPS Temperature True for temp-sensitive movements
- Of any size — from packages to pallets to plane-loads
- Of any weight — from ounces to tons
- To almost anywhere — from Los Angeles, California to Laos

Keeping control
UPS has designed a supply-chain environment that, in conjunction with appropriate protective packaging can protect products regardless of outside conditions.

Planning ahead for product protection
UPS conducts seasonal temperature profile studies of our small package networks to help shippers define actual supply-chain conditions and create plans to help protect temperature-sensitive products throughout their journeys.

Our healthcare distribution facilities offer environments to help protect products with the following required temperatures:
- Controlled Room Temperature: 15 to 25°C
- Refrigerated: 2 to 8°C
- Frozen: -10 to -20°C
- Cryogenic/Deep Frozen: -150 to -190°C

Studies include:
- Ground temperatures at origin, transfer and destination airports
- High-altitude temperature changes in cargo aircraft
- Temperature ranges in UPS hubs and vehicles across climate zones, from south Florida to northern Alaska

*All services are subject to the standard UPS Terms and Conditions of Contract.
When the planning (including contingency planning, which will be discussed next) is completed, your logistics partner should work with you to implement a solution. This may include packaging options to suit environmental conditions between origin and destination, time-in-transit, product temperature specifications and value optimization.

The overall solution will define service levels, primary and backup air routings and documentation requirements. In addition, an experienced provider will establish standard operating procedures and quality agreements.
CONTINGENCY PLANNING

You and your transportation provider should collaborate to identify potential problems and alternate transportation plans should a shipment deviate from the standard operating plan. It is necessary to create pre-defined alternative flight routes, for example, in the case of weather delays. Typically, a primary route with an additional one or two alternative flight routings should be identified. The provider needs to understand the path of escalation if a shipment is at risk for a delay or a temperature excursion where the product could go out of the acceptable temperature range. In addition, if the shipment completely fails delivery specifications, contingencies must be implemented for the return and replacement of the compromised product to ensure it does not make its way back into the market—and to patients.

It’s a Patient, Not a Package®

This is the philosophy that drives UPS Healthcare. It guides and inspires an extensive strategy built on close collaboration with customers, the knowledge of teams of UPS experts, and the implementation of supporting technologies. These capabilities can get life-saving products to the right place at the right time and in the right condition to achieve the best possible patient outcome.
CONCLUSION

Regulatory agencies are constantly challenged to keep pace with the growing demand for temperature-sensitive therapies, including CRT and cold-chain products. Awareness of and compliance with legislation and guidelines regarding supply-chain services are essential, as are detailed specifications on temperature requirements and the permitted temperature excursions for each product.

We look forward to continuing this conversation on better ways to ensure product integrity.

In the meantime, you can visit UPS Solutions Healthcare to learn more about our products or contact UPS to discuss how UPS can help design distribution, transportation, packaging, and monitoring and intervention solutions to help protect your temperature-sensitive products.
Establishing a temperature-sensitive supply chain

**STEP 1**  
**Plan**
Planning is essential in maintaining product integrity throughout the transportation journey and meeting the guidance and requirements of regulatory agencies. A plan should include:
- The shipper’s specific requirements
- Service modes
- Quality requirements
- Quantifiable value
- Packaging requirements

**STEP 2**  
**Product Requirements**
Discuss product requirements with your shipping partner. You should agree on:
- Mode of transportation
- Temperature sensitivity
- Permitted excursions

**STEP 3**  
**Design Solution**
The solution will include a mix of packaging options to maintain balance between:
- Environmental conditions between origin and destination
- Time-in-transit
- Temperature specifications
- Value optimization
It will also define:
- Service levels
- Primary and backup air routings
- Documentation requirements
- Standard operating procedures and quality agreements

**STEP 4**  
**Contingency Plans**
Work with your transportation provider to identify potential problems and devise alternate transportation plans should a shipment deviate from the standard operating procedure.
- Define the path of escalation for shipments at risk of delay or temperature excursion
- Define a return and replacement plan for compromised products

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