Cold Conditions

The implementation of passive packaging systems could improve the cold chain requirements placed on pharmaceutical transit

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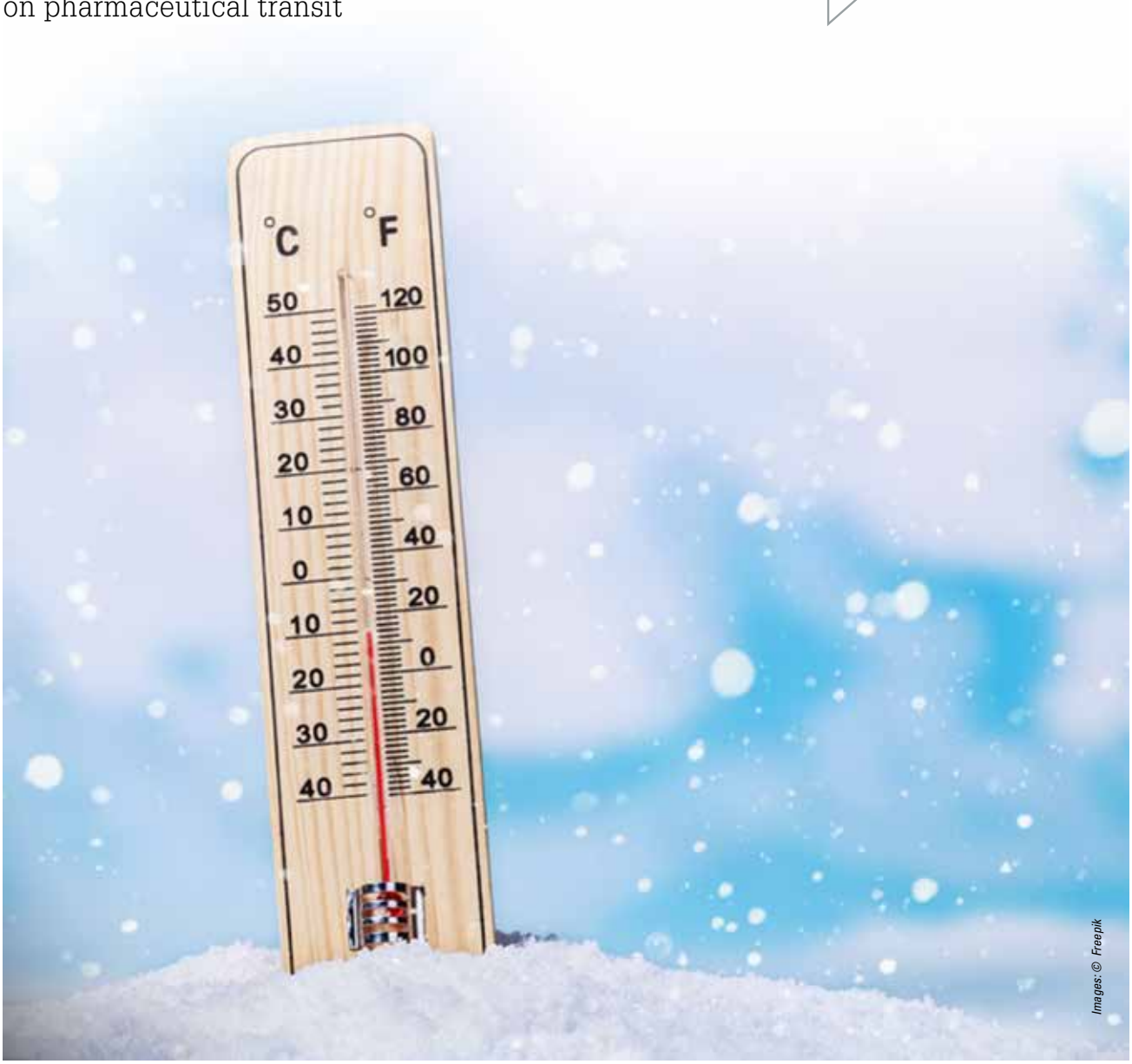

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The global pharmaceutical industry is continually striving to meet and exceed both their in-house and overarching regulatory cold chain requirements. To achieve this, pharma companies are constantly looking for innovative products and services that can help them cost-effectively maintain the cold chain for temperature-sensitive products in transit on both a global and local basis.

Regulatory Compliance

Pharma companies face many challenges when shipping temperature-sensitive products, one of which is to ensure compliance with the various regional regulatory bodies. The introduction of Good Distribution Practice (GDP) guidelines in recent years, which have been implemented in Europe, requires a business to transport their products at strict label claim temperatures. Conversely, the FDA in North America allows pharma companies to transport their products using stability data that permits a wider range of temperatures during shipment.

At first glance, the GDP guideline and FDA requirements may appear quite similar, but, in fact, a difference exists between the two. For example, in

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Europe, a pharmaceutical product with a label claim that states the storage temperature as being between 2-8°C must be transported strictly within the stated 'label claim' temperature range. However, when shipping in North America, that same item can use known stability data to widen the allowable temperature range. For example, this means the same product can now be transported between 1-25°C and still meet local regulatory compliance.

Additionally, companies now have to ensure temperature compliance during shipping for products that have a storage and transport requirement, commonly known as control room temperature (CRT). Historically, these CRT goods have been transported naked (unprotected) at fluctuating and uncontrolled ambient shipping temperatures. Regulators now require these products to be temperature-controlled during shipping within their defined temperature range. This is further complicated by the broad definition of CRT as the exact temperature range can vary from product to product. For example:

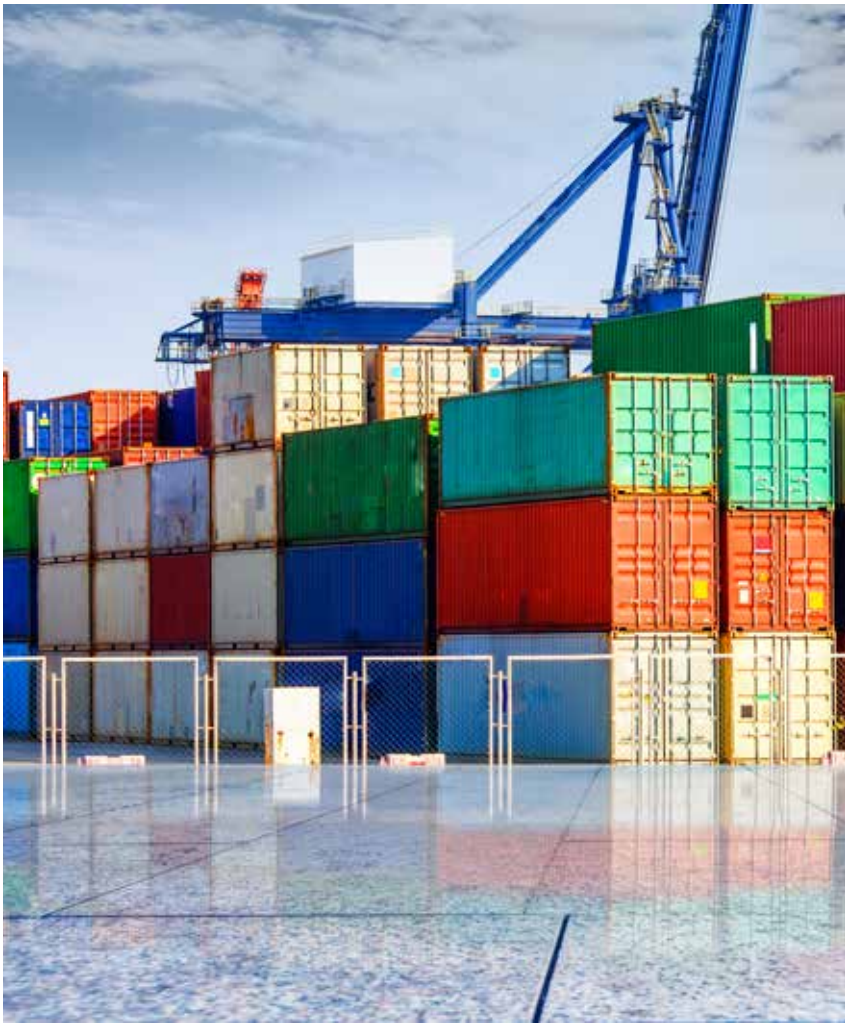
- 0-40°C
- 1-30°C
- 2-25°C
- 15-25°C
- Do not freeze
- Store below 25°C

The mentioned variances in regulatory demand can result in significant differences in the type of packaging systems required during shipping. The items also have a secondary cost-related impact associated with both the type of packaging required and the ultimate cost of shipping given that the materials needed to provide the necessary levels of protection during transport may have different costs, levels of performance, and shipping weights.

Global Supply Chain Continuity

While many companies operating globally are striving to standardise their temperature-control packaging (TCP) systems, many still operate at a local level, often sourcing potentially noncompliant TCP systems. Typically, these procedures are for in-country distribution and may fall outside globally approved standards. This is driving businesses to seek out global TCP vendors that can provide local supply and support. A key challenge here is finding cost-effective TCP systems that meet both local and global quality requirements.

On the face of it, this should be quite simple. A vendor is selected that has the products and services that satisfy the transportation and regulatory needs, and then the company must ensure that the vendor is capable of supplying TCP systems and/or services in the regions where they are required.



However, TCP vendors often have their own challenges to overcome when operating in a global market. Simply being able to source the correct raw materials to construct TCP systems or be able to source and deploy associated services to the pharma and life sciences industry is not easy.

A material that may be used within the construction of a TCP system may not be uniformly available in all regions of the world. Therefore, for the vendor to supply the packaging system to their global pharma customer, they may have to create variants of the product made from locally sourced materials to ensure that the client receives an item that is globally available, cost-effective, and satisfies the customer's regulatory requirements for temperature control.

It can also be difficult for those vendors that are supporting the global pharma and life sciences companies to keep pace with industry's new and emerging markets that require their products and services. Often, when a company starts to operate within a new region or market, positioning their products for distribution within the local market is necessary. Vendors are typically requested to provide warehousing or storage rather than local manufacture until they have a critical mass of business with the client to justify the investment needed to produce locally.

Environmental Considerations

Historically, many TCP systems used by the pharma industry have relied on the use of insulation materials constructed from expanded polystyrene and polyurethane foams, which, in themselves, are considered recyclable. However, the challenge has been to find local cost-effective recycling facilities.

Additionally, the term 'recycling' can be interpreted in different ways. Expanded polystyrene foams can be ground and re-processed into new polystyrene products, effectively recycling them. Alternatively, polyurethane products, such as panels, can be repurposed or upcycled into building materials. These recycling and upcycling programmes are not always readily available, leading to challenges in disposal, all of which can be further complicated by local environmental regulations. As such, many companies with committed sustainability initiatives are looking for greener alternatives that can be simply recycled at all locations. This drives the need for the use of new TCP systems that utilise environmentally friendly insulation materials. Such greener products often come with limited application due to lower insulation values.

At the opposite end of the spectrum, higher-performing TCP systems exist that make use of higher cost materials such as vacuum insulation panels and phase change materials, which are necessitating full reuse programmes to achieve sustainable cost-effectiveness.

Balancing Cost Reduction and Compliance

Pharma companies are challenged in reducing overall transportation cost and ensuring compliance with increasingly tighter regulations. Therefore, businesses need to look for new and innovative methods by which they can distribute their products.

Traditional TCP systems using expanded polystyrene and polyurethane foams have historically been designed for the simple 'ship and forget' distribution model. However, many companies are now turning to reuse models, which employ high-performance materials that offer consistent temperature control via rental programmes. Often, the challenge here is one of supply and demand given that many of the current range of reusable high-performance shippers are difficult to re-position after use, leading to high-cost service provision. As such, a requirement is emerging for cost-effective reusable shipping systems that can be made available on a global basis and can work in both controlled (pharma freight) and uncontrolled freight services.

The creation of TCP systems that help meet and exceed the cold chain requirements of the pharma and life sciences industries presents a complex picture, and only through close collaboration between the pharma manufacturer, TCP vendor and the freight provider can cost-effective maintenance of the cold chain for temperature-sensitive products be ensured in transit.

About the authors

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