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Managing Cold Chain Risk Through Appropriate Packaging: **One-Size Doesn't Fit All**

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Managing Cold Chain Risk Through Appropriate Packaging: **One-Size Doesn't Fit All**

Companies that match Controlled Room Temperature packaging to their products' specific supply chain risks will come out ahead.

Fear should not drive executive thinking about pharmaceutical Controlled Room Temperature (CRT) packaging solutions – effective risk management should.

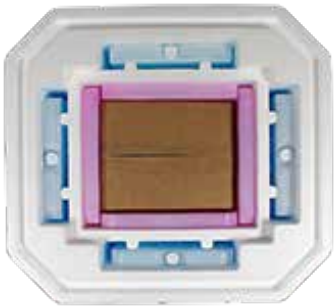
Evaluating and differentiating the cold chain packaging of life sciences and drug products can fine-tune packaging solutions to reduce risk, because appropriate packaging improves efficiency and control costs while building in safety margins. Managing risk smartly up front matches the right package to the right product and lane, preventing dangerous supply chain breakdowns, improving worker productivity, halting product loss and reducing waste. Those who handle cold chain risk through focused packaging solutions can increase their products' competitive advantage and drive business success in today's increasingly crowded drug spaces. (*See sidebar, "How To Save Big On Packaging."*)

However, corporate risk-management teams often fail to realize these advantages. Pharma companies typically consider worst-case risk scenarios when choosing CRT packaging – which consequently leads to implementation of unnecessarily costly solutions. In managing high-value products, they overspend in the pursuit of seemingly breakdown-proof supply chains. Rather than evaluate and mitigate real-world risk, risk management leaders opt for excessively engineered, inefficient and wasteful CRT solutions.

Today's pharma products move along very complex global cold chains, and by failing to tune packaging to each drug's complex supply chain, companies actually increase their costs substantially and, in some instances, add a layer of unwarranted handling and packaging intricacies, raising the risk for supply chain breakdown.

Understanding Cold (Chain) Realities

As the pharmaceutical and life sciences industries have moved rapidly and decisively into complex, high-value therapeutic products, unsubstantiated fear of decreased revenue and safety concerns have combined often to blind companies to the advantages best practices in packaging can deliver. The boom in biological, gene and cell therapy; rare disease; and immunotherapy product development and sales over the past two decades reflects the relative lower cost of their evolution, higher likelihood of their approval, and potential greater profitability of a marketed therapy, as well as the promise of lengthy patent protection.



Inmark packaging engineering and design studies have shown that companies can potentially save millions of dollars annually in a drug product's packaging and transport costs by matching the right solution to the right product.

However, these spaces where products once faced little or no competition have seen a flood of new medicines in development or coming to the market, and pricing pressures from insurers and regulatory bodies have reduced reimbursement rates. Along with these challenges, the emergence of so-called biosimilars – generic biological agents – means that successful drugs that seemed protected from generic competitors through their complex manufacturing processes are eventually almost certain to face lower-cost competition.

With competition comes the need for greater business efficiencies. When company leaders consider their strategic horizon, competitive advantages, including the impact of packaging costs on their cold chains, cannot be overlooked. Smart packaging aligned with supply chain can emerge as a key differentiator in the cost of goods.

From raw material sourcing to manufacturing to fill and finish to distribution, a single product's cold chain often involves myriad steps in different configurations involving globalized suppliers; fill, label and packaging houses; warehouses and regional distributors.

The mode of product transport has also grown more complex. According to 2016 data from Seabury Consulting, although most pharma trade by weight shipped globally via ocean, the scale tipped heavily by value to air freight. By weight, about 91% of pharma products moved by ship, while just 9% traveled by air; however, air cargo comprised 70% of the total value of all pharma global trade. (*See: http://www.flypharmaconference.com/wp-content/uploads/2015/09/170605-JPM-FlyPharma-presentation.pdf.*) And air traffic in pharma continues to grow, expanding at a 4.7% CAGR from 2000 to 2016, with cold chain within air freight increasing at an even faster clip. The rapid growth in pharma air cold chain derives primarily from high-value products (>$150/kg, e.g., enzymes, vaccines and advanced biological therapies), whereas lower-value products (<$15/kg, e.g., vitamins and other bulk pills) constitute the majority of ocean freight.

Shipments among developed nations account for the bulk of global pharma trade, but increasingly drugs are traveling by air to the developing world and other regions with rapidly changing demographics, such as the BRIC nations. In fact, Seabury analysts point to Asia as the destination creating much of the recent growth in pharma's global air cargo, a region where cold chain conditions and handling may be at great variance from export sources, primarily the US and Europe. In addition, non-governmental organizations are driving augmented distribution of Western pharmaceuticals to treat diseases of poverty in Africa, Indonesia, and other less-developed locations. Packaging engineered for particular temperatures and duration within cold chains is essential for the product to move through its supply chain life cycle without undue handling, and unnecessary waste and cost.

As a result of these involved, multifactor supply chains, a typical drug may be manufactured using raw materials from multinational suppliers and then pass through fill/finish houses, warehouses, and on through multiple channels to regional distribution hubs. From there, product parcels get pushed out to end users in enormously varied locales, transported in vehicles with significant differences, from a refrigerated truck

By weight, about

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9%

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70%

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to a box on the back of a motorcycle. A vaccine bound for a hospital in Japan versus a clinic in Brazil faces dramatically different temperature and duration challenges. In addition, advanced cell therapies sometimes require two-way traffic from patient to laboratory and back.

Further, cargo packaging needs to be globally harmonized to reflect the realities of transnational logistics and all necessary regulations, including those of the:

- United Nations (UN)
- International Air Transport Agency (IATA)
- Agreement on Dangerous Goods by Road (ADR)
- Regulations Concerning the International Transport of Dangerous Goods by Rail (RID)
- International Maritime Dangerous Goods (IMDG)

In combination, all these factors have driven the cost of risk up dramatically. Fear of supply chain breakdowns has led supply chain executives to overspend rather than *manage* cold chain risk. Team leaders must think through at a granular level the specific risks their products will face moving along the global cold chain, and develop data to address those risks with a sufficient safety margin for maintaining critical temperature control for the realities of their supply chain. But most current industry packaging standards do not align with those realities.

Developing A Risk Profile

Simply issuing a packaging RFP (Request for Proposal) won't identify the proper CRT packaging solution. Inmark, a packaging solutions company, advises pharma businesses to instead partner with a firm such as itself, to evaluate and differentiate their product's cold chain risk profile. Analyzing each product's cold chain life cycle is a first step in identifying the appropriately tuned packaging solution to mitigate the real-world risks the product will face.

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An accurate, comprehensive risk profile includes supply chain logistics, production constraints, in-house budget considerations, and internal, supplier and distributor organizational philosophies, as well as the many external forces that put products at risk. These may include temperature variation along the supply chain, multiple sourcing of a drug's incipient and excipient components, and constraints in production and warehouse operations. Also to be factored are the mode, duration and destination of shipments including the time freight sits in bulk shippers and on tarmacs; regional differences in CRT regulatory requirements; potential for loss, breakage and theft; and the need for two-way shipments. Holistic thinking about a product's cold chain from the start – even during preclinical stages – will account for the many elements that can put a cold chain at risk and thwart those risks with the most effective solutions.

Packaging solutions should offer multiple configurations where it makes sense, while enabling each touch along the cold chain to take place in the simplest, most cost- and time-efficient and least materially wasteful manner. Along with managing safety and security risks, packaging should not become a stumbling block for low-skill fillers, packers and handlers. The right CRT solution will make their work as efficient and simple as possible.

Fit-For-Use Packaging

Identifying the right solution to package and transport globally distributed pharmaceutical, biotechnical and other life sciences products should not be left to the last minute. Inmark's analytic studies show that inefficient CRT packaging solutions add millions annually in unnecessary costs to products. As therapeutics become ever more sophisticated, the need to assure cold-chain compliance, while optimizing efficient handling practices, safety and security, has grown. Achieving consistent storage, transport and handling all along the cold chain demands knowledge of global shipping lanes, company cold chain constraints, and local and hub temperature and storage duration to globally harmonize procedures. To serve these intricately connected needs, solution providers must offer efficient, multifunctional, off-the-shelf, customizable, scalable, and two-way CRT packaging solutions and pallet and container systems.

Innovative solutions rely increasingly upon systems that are SKU-efficient to simplify scaling up and down shipment size. Integrated packing unit, data logger, GPS tracker, an IT platform for temperature control and monitoring visibility and quality management are also components of an effective solution. Enabling a combination of these elements as dictated by company philosophy, existing contracts, budgets and supplier quality standards is mandatory.

Off-the-shelf packaging should enable the simplest handling procedures possible throughout the cold chain while meeting adequate safety margins for the risks the product will face. Features most multifaceted, complete solutions should include are:

- Qualification/Validation to ambient temperature profiles representative of the lane(s) being considered
- Multiple durations/temperature ranges

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- Design for reusability
- Modular design pallets for scale up or down to payload
- Correct material for product compatibility
- Flexible product line for pharma product variety and batch size

Leveraging data and building in margin to account for cold chain realities allows packaging providers to arrive at a solution that is truly fit-for-use. Fit-for-use does not mean the most expensive and highest performance system. Rather, a fit-for-use solution combines the right mix of characteristics and attributes based on data and metrics used to define the clients' real-world risk-mitigation goals. The pharma company and its CRT vendor should arrive together at a realistic expression of risk based on those goals.

However, sometimes products need customized solutions to mitigate the realities of their unique cold chain risks.

Thinking Beyond The Box

Occasionally, life sciences product companies have unique cold chain requirements that, if not solved through proper CRT packaging, can add significant costs, create handling challenges and result in unnecessary waste, for example, transporting both ambient and frozen biological substance Category B (diagnostic specimen) materials while maintaining critical, proper temperature control for the duration of shipment and handling.

A pharma company's researchers may often ship their systems back to the lab at the same time, using separate shippers. A packaging solution might include developing a combination system (frozen/ambient in the same shipper solution) that could help reduce redundant shipments. The vendor partner's engineers would use their expertise to ensure that the ambient specimen would not freeze as a result of being in the same packaging system with dry ice.

Decreasing the size and weight of the initial packaging in the custom combination system could be another part of a solution for this client.

The right solution for one product will rarely be the same as for another. Pharma companies need to develop real-world risk profiles for their products' cold chains that account for all of the internal and external forces that can negatively impact the prime directive for any pharma professional: delivering life-saving therapies to patients when and where they need them, maintaining safety and efficacy, and fulfilling compliance requirements.

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How To Save Big On Packaging

What if a company could save anywhere from $1.7 million to as much as $6 million while delivering its products safely and efficiently? These are examples of the savings in cold chain costs that Inmark study models show a typical small-to-midsize biopharmaceutical company might achieve in just a year by matching the appropriate packaging to its products.

The model assumes the company sells about 556,000 vials of three liquid drugs, through a complex, multi-step global supply chain, from fill/finish to regional distribution. Both manufacturing and fill/finish take place in single plants located in the Western US and EU, from which bright stock vials are pushed out as they are produced, without commingling different lots and products. After traveling to three label-and-pack facilities in the Eastern US, EU and Asia-Pacific, the boxed-and-labeled drug cartons travel to regional distributors and wholesalers, with the addition of some product that goes directly to hospitals in the US and EU.

Inmark compared scenarios in which the drugs in cartons get shipped as they are produced in single passive shippers versus a variety of different, fit-to-use shippers. Then, after labeling and packing, the drugs travel in active containers, single passive containers, or multiple-size passive containers.

By going from one parcel box size to multiple shippers, Inmark data show the company saves in the first instance nearly $6 million. By moving from a single active pallet system to multiple passive pallet shipper designs, the company will save an additional $1.7 million. Of course, every cold chain is unique and has specific risks that determine the packaging solution

that is fit-for-use. Smart, granular analysis of the cold chain will tune the CRT packaging solution to the product's real-world risks.

To view the data and other factors in this model, contact: **information@inmarkinc.com**

Inmark's Life Science Division core business provides prevalidated, cost-effective, globally harmonized, simplified solutions for individualized packaging needs and it utilizes a state-of-the-art thermal validation lab for testing. The division specializes in Temperature Controlled, Specimen Transport and Used Medical Device Return packaging, along with individual and corporate Dangerous Goods Compliance Training Options. Inmark offers a wide range of controlled room temperature, refrigerated and frozen shippers, shipping accessories and a variety of customizable packaging solutions.

To view Inmark's fit-for-use packaging solutions, go to: **http://inmarklifescience.com/products-services/temperature-controlled-packaging/**

To learn how Inmark engineers solve packaging challenges, contact: **information@inmarkinc.com**

With over 40 years in business, Inmark has become a recognized leader offering both standardized transportation shipping systems, and customized solutions designed to meet the most demanding payload requirements. Our solutions are used by entities ranging from governments, pharmaceuticals & medical device manufactures, universities, clinical laboratories to small physician office laboratories.

Our global footprint includes offices strategically placed in North America, Asia, Europe and South America, positioning ourselves to quickly and affordably deliver clients a wide spectrum shipping solutions. These solutions are designed for the Life Sciences which include solutions for Cold Chain (Temperature Controlled), Used Medical Devices, Class 6.2 Infectious Materials and Dangerous Goods.

Inmark's success ties our core values: Innovation and being Customer centric. Not only do our system engineers design and develop solutions to serve our clients' specific needs, our training is designed to further our client's understanding of how global regulations may impact the packaging and transport of their valuable cargo.

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