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COLD CHAIN PASSIVE PACKAGING SAVINGS THROUGH REUSE

White Paper

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How a 'Green' Packaging Program Can Drive Supply Chain Savings

In today's marketplace, biopharmaceutical companies are seeking improvements that lead to reductions in overall supply chain costs. With the ever increasing dimensional weight pricing, companies are going to be looking even more closely at cost saving supply chain ideas. When it comes to the packaging solutions used to ship temperature-sensitive materials, biopharmaceutical companies are considering the implementataion of reusable packaging programs.

It is imperative that a reuse program not only protect the efficacy of the payload by ensuring the thermal integrity of the shipping solution, but that it also provides a program cost savings. Prior to a company initiating a reuse program, it is important to understand and analyze the full scope of the economic impact. With reuse, the expected reduction in the quantity of newly purchased shipping solutions required would seem to result in guaranteed procurement savings. This is an oversimplification and the decision process is much more complex.

The key to obtaining critical inter-organizational endorsement and approval is to ensure the quality of the packaging being reused is acceptable, that the cost savings are real and distinguishable and that the end recipents will comply. This can be accomplished by ensuring that the shipping solution selected has a strong standalone one-time-use value proposition, that the quality, thermal performance and original specifications of the shipper are maintained during reuse and that the program is simple.

A Reuse Program Can Be Properly Evaluated by Considering the Following:

1) What is the initial cost of the 'reusable' solution?

2) What are the procedures and the resulting effectiveness of the qualification testing that ensures the thermal integrity of the reused shipping solution?

3) What are the additional program costs?

4) How much experience does the provider have with a reuse program?

5) How will the end users react to a reuse program?

The Initial Cost of a Reusable Solution

The first consideration is the initial cost of a reusable solution. Costs for a given duration and payload size solution will vary depending on the supplier, manufacturer, insulation materials incorporated and the type of phase change materials used. When using a low cost expanded polystyrene (EPS) shipping solution, the cost of reuse is more than the shipping solution purchase price. Thus, reuse from a cost perspective does not make sense. Consequently, the materials used in the design of a typical reusable solution are polyurethane (PUR) or vacuum insulated panels (VIP). The reusable shipping solutions can have prices that range from $30 to $500. There are many variables to the cost of a shipping solution and a higher price does not always mean better performance. Some of these variables include: 1) identify reputable and experienced manufacturers of qualified cold chain packaging solutions and avoid those that are 'assemblers' of another manufacturer's product (to avoid the duplication of margins) 2) select manufacturers who have good quality systems and the potential for an optimized manufacturing cost structure and 3) select manufacturers with the geographical footprint to minimize inbound logistics cost. Depending on the cost of the reuse program, the destinations and the reprocessing locations, it may not make sense to reuse lower-priced solutions. Reuse for higher-price solutions is the logical alternative.

Don't Reuse Unless Re-qualified

Most shipping solution manufacturers that have reuse programs ignore the importance of shipping solution thermal re-qualification. This is a oversight that shippers and regulatory bodies have recognized as a serious gap. An insulated shipping solution that is re-entering the cold chain should be thermally sound to ensure it continues to be a qualified solution. The only means to ensure that temperature-sensitive materials are shipping in accordance with FDA's stringent regulations is through the thermal re-qualification of the shipping solution.

In addition to regulations, it is important to remember that each shipping solution must be uniquely qualified for its specific shipping scenario. Using a "general" guideline such as a number of times a shipping solution can be used, does not ensure quality. Some shipping solutions may be subjected to harsher conditions and handling than others during shipment and will therefore thermally deteriorate more quickly and not deliver the required performance.

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Thermal testing affords the performance data that enables shippers to confidently engage in a reuse program that provides the necessary certified compliance documentation required by regulators and company quality directors. Re-qualification provides the Peace of Mind® that products remain unadulterated during the shipment.

The CSafe REPAQ® Program

1. **Reclamation Center.** The shipper is returned to the CSafe reclamation center using the return label provided.

2. **Inspection and Repair.** Each shipping solution has individual serial numbers and once received, go through a visual inspection. Items that can be reused are cleaned in compliance with FDA 21 CFR 211 Subpart 94. Items that are damaged are properly disposed and replaced.

3. **Cleaning.** The interior and all components are cleaned with biocide.

4. **Thermal Re-qualification.** The thermal components of each shipping solution are thermally tested to ensure they meet the original performance specifications. Any thermal components not meeting original performance specifications are replaced with new, fully tested components.

5. **Reuse.** When inspection and re-qualification are completed, the shipping solution is reassembled, new corrugate is utilized, and the shipping solution is shipped to the customer to re-enter into distribution.

There is typically a minimum $15-$30 REPAQ fee each time the solution re-enters the re-qualification cycle. This fee and the return shipping costs to the reclamation center are the total costs associated for each thermally re-qualified solution. This can be a fraction of the cost to purchase of a new shipping solution. The resulting REPAQ shipper is thermally re-qualified to original specifications and, after receiving new corrugate, is visually identical.

About CSafe Global:
CSafe Global is the world's largest producer of actively controlled mobile refrigeration units for biopharmaceutical and healthcare companies, militaries, and international disaster relief agencies. CSafe Global brands include AcuTemp® passive packaging and hand-held mobile carriers ThermoCor® vacuum insulation and the CSafe® brand of active containers.

The active solution product assortment includes the CSafe RKN, which utilizes heating and compressor-driven cooling technology to eliminate the risks associated with extreme ambient conditions (-30 to +49) as well as the cost, aggravation and environmental challenges associated with dry ice transportation. CSafe Global's AcuTemp brand has provided more than 10,000 hand-held mobile management solutions since its founding more than 25 years ago. The passive solution assortment includes packaging for 2-8°C, CRT and frozen shipments with hold times from 12 to 240 hours and with payload volumes up to 50 liters.

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