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16TH ANNUAL COOL CHAIN TEMPERATURE CONTROLLED LOGISTICS EUROPE

Reusable vs Single-Use Containers

Pharma Logistics IQ

Reusable Vs Single-Use Containers in Temperature Controlled Logistics

Container selection for the distribution of temperature sensitive pharmaceuticals is highly influential not only on the success of the shipment but also on whether an overspend may be incurred.

The majority of Cold Chain IQ's 2015 survey respondents planned to increase investment in their CRT supply over the following 12-18 months. However, finding cost-effective packaging solutions, transportation and distribution services were pinpointed as key challenges. This compounded cost pressure to maintain overheads is of course connected to the lower margins attached to CRT products.

When evaluating your packaging approach, be sure to pay attention to the total cost - a low price does not guarantee a high quality of service. Also, the less expensive price per pound can often end up costing more in the long run through transportation costs, etc. [6] Vaccine vial size has been shown to have far reaching implications on supply chain costs. A study from the International Vaccine Access Center (IVAC) discovered that expanding the vaccine vial size decreased total costs by as much as US$0.25 per dose, which could win sizable savings if administered on a mass scale.

In deciding between reusable and single use containers, Andreas Seitz, Managing Director, DoKaSch Temperature Solutions GmbH explains that the best selection will become apparent on conducting a clear annual cost review - comparing the annual costs of the disposable unit to the yearly rental costs of reusable units.

In the face of various packaging modes, Pharma Logistics IQ explores the advantages and drawbacks that should be considered when making decisions on the application of reusable or disposable packaging solutions within the cold chain.

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Reusable Containers

Container Considerations Strengths And Limitations

- This packaging is more durable in structure so it can withstand multiple journeys.
- Semi-reusable solutions generally comprise a few recyclable parts.
- Available temperature modes for reusable containers include Active, Hybrid – dependant on an electrical source for compressors paired with dry ice or phase change materials - and Passive – which operate without external power.

Durability & Temp Stability: Reusable systems on the market are becoming more robust in regards to their exterior with hard shells now being deployed in comparison to the cardboard material structuring disposable solutions.

Andreas Seitz states with a high end reusable solution, like our active containers, then you can always plug it in and recharge it. So it can be used for long term [routes], even if it is hanging around in customs clearance. Whereas, with a simple passive insulation - after a few days it is over.
Durable Dewars & Non Hazardous Status

Carolyn Williamson Scientist II at Bristol-Myers Squibb noted said, "The advantage of using [dewars] is that you can ship with non hazardous status. You need to be able to maintain the temperature, but the paperwork and the difficulty of logistics [are both] reduced when you are able to say there is no liquid nitrogen present." She noted that dewar lifespan is highly dependent on handling: dents and rough care can severely shorten their duration so a maintenance programme is vital.

Sustainability: Reusable systems offer a quite substantial environmental profile, with the fact that the solution's components will be reused. More sustainable designs may even contain recyclable components or be made of renewable materials.[4] On the other hand, considerations must be made in regards to the carbon footprint for return shipments and the additional fuel bills.

Cost and Acquisition: As these containers are purchased on a lease or rental basis and will be used in multiple shipments this allows pharma firms

to invest more into financing the acquisition of a unit.

Although, they are more complicated to manufacture and further planning will be required in the application of reusable units in comparison to single use and more data needs to be shared with the service provider. As the situation may occur that they may not be enough containers available in the loop, Andreas Seitz explains: "It's not just [a case of] source it, buy it. You have to go one step deeper with your service provider to say: 'Okay, how many units do I in general need? How many units should I have on stock? And what is the total number of units I need to fulfil a constant flow?' That has to be evaluated together with the service provider."

Companies should choose to continue data collection after the initial purchase to track the performance and relevant costs for a container – including scheduling, repairs, cleaning etc, to clarify if there are sustainable cost benefits.[5]

Size: Reusable boxes tend to come in larger dimensions which is useful for driving down costs in relation to the amount of the cargo shipped per batch. Although, disposable solutions attract a lower initial price point than reusable containers, a compensation will need to be made for the larger volume of insulation material required. The lower level of insulation volume required by reusable systems means that more cargo can be moved per shipment.

There has been an expressed demand for larger passive units which are reusable. Bulk passive units are not power dependent and have a wider choice in payload volume sizes. These strengths allow pharma firms to be more efficient with the packing of shipments and avoid incurring over-spend from ill-fitting containers.

Validation and Risk Assessment: Jeroen Janssens, Senior Manager, Vaccine Distribution & Cold Chain, GSK Vaccines notes that an important point of attention is gaining assurance to confirm the container is still integer prior to the next use. These checks will clarify there are no cold breaches or any risk of possible contamination, which is not always that easy to confirm.

Airfreight Considerations: Containers need to be adapted to the size specifications of the air freight industry and not embody non-appropriate dimensions. This in some cases can cause pharma firms to have some lanes that ship a lot of air in the movement of product and other routes where products in the container are very optimised. Other costs to factor in are: optimising the container for the cargo hold of the aircraft, for example being lightweight, as well as providing good protection when the load is waiting on the tarmac.

Ocean Considerations: Reusable ocean freight containers often utilise refrigeration and air circulation systems using power from the ship – however these containers can on occassion encounter barriers with sourcing if there is high demand from other entities. at that time The high risk loading and unloading stages are hotspots for delays. Protection considerations for the container are required in regards to environmental exposure at the high risk loading and unloading stages.

The Price Tag Attached To Reverse Logistics: Jeroen Janssens noted that the reverse logistics attached to reusable containers acted as a large blockade for pharma firms moving more towards with the use of reusable systems. With closed loops being a necessity, in this regard reusable containers apply an additional cost and operational burden. In response to this effect on a pharma firm Jeroen Janssens reminds: "We are here to manufacture pharmaceutical products, not to organise logistics flows of empty containers."

With these greener packaging solutions on the rise in popularity, the suppliers of these packaging solutions, or even LSPs, have started to include the reverse logistics in the rental cost for the unit. Jeroen Janssens notes that with this improvement, today's reusable systems can compete with single use containers.

In the Spotlight with....

Over the last two decades, the DoKasch Group has grown to become one of Europe's leading manufacturers of high quality aviation solutions. Airlines who utilise DoKaSch Group's equipment include names such as Lufthansa, Etihad and US Airways.

"With our solution[s]- the high end active containers... you get an excellent insulation and temperature management system that is far better than any passive insulation and passive solution. "

The star of DoKaSch's climate control offering for temperature sensitive air cargo is its Opticooler, which is recognised for its excellent reliability and performance in protecting the efficacy of medicines through international transportation. Cathay Pacific Cargo recently signed a master rental agreement agreeing their use of these active containers.

Opticooler

This active container is not dependent on dry ice and instead is equipped with a large battery capacity, compressor technology and integrated CPU. The container can regulate temperatures from -30° to +50°. The desired temperature is retained at a homogenous level with fully charged batteries or supported by mains power. Battery charging time is only 4 – 6 hours.

Unicooler

Operated by dry ice, the Unicooler is a high quality container installed with continuous data monitoring capabilities of temperature levels. Alarms signals activate as doors are opened. The three temperature presets make the container preconditioning simple to operate temperature ranges include - +2°c to +8°, +15°c to +25°, -20°c to +30°c.

Icecooler

The user-friendly Icecooler sustains temperatures from -20° to +30° via dry ice, air circulation and battery power which needs a recharger.

Picture: DoKasch.com

Download Test Data

Single Use Containers

Container Considerations Strengths And Limitations

- A basic container that is disposed of after one use.
- Passive temperature control is used with this type of packaging.
- Some regional regulations depict that these single use containers need to be returned to the country of origin for their destruction due to various environmental regulations. 1

Costs & acquisition
These containers have a significantly lower upfront costs than a reusable solution in regards to the sourcing, purchasing of a unit and then the maintenance of stock levels. However, disposal costs should be considered also.

Collaboration between stakeholders in the supply chain will also be instrumental in ironing out packaging inefficiencies. For those in sourcing, understand that a cheaper container may provide savings in the material expenditure category but it may increase the shipping cost category. Work with the packaging expert to rank suppliers based on the impact to the logistics landed cost.

Ease of use: Open ended distribution: Operational burdens are eased with single use containers with the lack of need to ship the container back to its origin.

Environmental Considerations: In regards to the disposal of these containers and their insulation, pharma firms may be faced with environmental issues in regards to waste conduct. For example - are there dangerous goods involved or environmentally dangerous elements if it is burned or brought to a depot?

Size: Disposable units are harder to manufacture in bigger sizes at reasonable costs. Also, Andreas notes that disposable solutions tend to be paired with cheaper insulation material and this material can often require more volume. in comparison to the more expensive alternatives

Risk assessment:
Awareness on the lane of use and the handling of logistics providers and other stake holders are of course points of attention during packaging risk assessment. Andreas notes that a common mistake made in the qualification of packaging is to only conduct a theoretical approach in terms of ambient temperature. This results in shippers having a best case scenario process in mind, but in practice there will always be some process deviations that the container will need to endure. Andreas adds: "[Process deviations] appear definitely and that has to be taken into account. [This] is an issue if you use one way solutions, because one way solutions are more simple because they have to be cheap. [Then} if you have issues in your process, let's say time on tarmac, it's fine on paper [because] you have a perfect process. However, in practice there are deviations and then you [will encounter] problem[s]."

Kevin Kohleriter - President of The MarketBurst Group outlines the following best practices for packaging design to avoid loss through over engineering your temperature controlled packaging.

- During your packaging and design stages look for industry data that will help you optimize your spend on packaging. Technical reports, like those issued from the PDA can help save time evaluating shipping lanes (See Technical Report 58).
- With changes in weather patterns or when entering new markets, try conducting a

temperature profile study that evaluates seasonal changes and their effects on your products. This will also evaluate both the packaging and the carriers. Mode of transport – any allowable excursion.

•Determine the fiscal impact of packaging to the product itself. Over-engineering comes at price. Look at the transport process duration (24-hr; 48-hr), carrier type, container weight, packaging methods, insulated material, and shipping lanes as factors that can all be evaluated when determining the cost of the container.

• Have you tested for damage boundaries to understand what your product can withstand? If not, testing product stability can help determine where and when damage can occur so that you can use data recorders set to the right parameters or adjust packaging as needed.[3]

Airfreight considerations: Andreas notes that disposable units can incur slighly higher cargo rates than reusable units, in respect to price per product shipped, in cases where the cheaper insulation materials need to consume more space.

Ocean freight considerations: A note to carriers or freight forwarders: work to capture the difference between actual and dimensional weight. Report the shipping charges linked to these packaging inefficiencies and offer to collaborate with your client to find a packaging solution.

Preconditioning: As passive shippers and single use containers require pre-conditioning and specific assembly processes – look for systems that are user friendly in terms of the packing process they require. Alternatively look to train and re-train your system handlers to aid success.

Reusable and Single Use: Coolant Considerations

Preconditioning: Consider how the containers and their coolants will be received.

- Who is responsible for the cooling down of these materials - the manufacturing side, distribution department or the supplier?
- Also, will the coolants need to be preconditioned to the right temperature before shipping and will there be a lag time with this - so will it require being placed at ambient temperature prior to use.

Congruency in SKU management: SKU refrigerants which are compatible with a selection of passive solutions will reduce the need for the excessive management of SKUs at different levels – a resource drain that can translate into delays or potentially missed shipments. Although beneficial, this SKU congruency is hard to achieve as most passive systems are designed as unique entities

PCM Failures: Passive shippers have a lower amount of components liable to fail during transit in comparison to active systems. However, the awareness of potential failures with Phase Change Materials (PCM) will assist with qualification. These potential failures include:

Conditioning – Challenges and added costs can be encountered when the PCM being applied needs conditioning to the intended temperature range.

The permeation of packaging material – This can occur when there is a lack of compatibility with the phase change materials used. This in extreme cases escalate to the PCMs physically eroding neighbouring packaging materials.

Leaking – In regards to the manufacturing of PCMs they can be difficult to house in casing. They require more robust seal types in comparison to water based refrigerants as to avoid leaking

Custom sizings or off the shelf use. Pharma firms need to consider whether they opt for an shelf product or ask their supplier, due to high volumes, to customise the dimensions. Off-the-shelf container models leave the pharma firm with the demanding responsibility to abide by set dimensions but also maximise the volume of product shipped. Some companies use Euro type pallets, other companies use US type pallets. Alternatively, companies could choose to grouping boxes immediately inside a container without a pallet, so they will have some space to conduct payload optimisation inside a container.

For more information on optimising packaging considerations attend the upcoming Temperature Controlled Logistics Europe Conference in 2017.

16TH ANNUAL COOL CHAIN

TEMPERATURE CONTROLLED LOGISTICS EUROPE

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Europe's Biggest and Longest-Running Gathering of Life Sciences Logistics, Supply Chain & QA Professionals will yet again bring together 500+ professionals and 60+ exhibitors to start the big discussion. Built around "creating conversation" the whole programme focuses on what you can take home and implement when you get back to the office

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- Overcome the challenge of high value / low volume products: Hear the latest biologic and clinical case studies from the experts from UCB, GE healthcare and Pfizer.

- Audit expectations and regulatory experiences – Join the GDP regulatory panel to hear the top reasons for non compliance from the regulators themselves - hear from the USP and the Dutch Healthcare Inspectorate.

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- Utilise your temperature data to improve your logistics processes and meet GDP quality management requirements - Join our interactive pre–conference day workshops.

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Resources

1. http://www.towercoldchain.com/cold-chain-glossary.html
2. http://www.coldchainiq.com/packaging-shipping-systems/articles/cold-chain-packaging-systems-comparison-of-active
3. http://www.who.int/medicines/areas/quality_safety/quality_assurance/TS-pack-containers-reefer-trucks-final-sign-off-a.pdf
4. http://www.pharmtech.com/packaging-addresses-cold-chain-requirements
5. http://scholarworks.rit.edu/cgi/viewcontent.cgi?article=1032&context=theses
6. http://www.coldchainiq.com/beyond-2-8c-crt-and-ambient/white-papers/global-crt-logistics-industry-report-2015
7. http://www.coldchainiq.com/supply-chain-security/columns/optical-illusions-in-cold-chain-supply -
8. http://www.coldchaintech.com/assets/Cold-Chain-Technologies-PCM-White-Paper.pdf

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