Tip of The Iceberg

Total Cost Approach to Temperature-Controlled Life Sciences Supply chain

Tips to finding risk in your cold chain and addressing it head on
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Product loss is just the beginning

With the changing nature of pharmaceutical products, the rules, regulations and guidelines adhering to good distribution practices (GDP) requirements for them, are also being revised and adopted globally. These expanding compliance requirements, particularly for temperature-controlled products, are straining supply chain operations as well as budgets. This necessitates development of a more cost-effective temperature-controlled life science supply chain. The issue, however, is

Traditionally, logistics, QA, and packaging teams could look simply at product loss to determine its effect on the bottom line. Times have changed though, and in the age of cloud computing and sensor-based logistics, it’s not just the immediate replacement costs that are needing to be evaluated.

The total cost approach to cold chain risk management

With rising costs and budget constraints, smarter cost management is a necessity. To drive down total costs, the entire supply chain, including customers, vendors and partners are finding benefits from working together. Pharma manufacturers and their logistics partners have to move to a total cost of ownership (TCO)

Jean Bedard, VP of Operations at Mesa Labs explains, “Although the purchase price is an important and easily identifiable factor, the life cycle analysis of an insulated package reveals that other associated costs can have a sizeable effect on the total cost of a product: Load time, mode of transport, weight, etc.” He adds, “In the case of the temperature-controlled life sciences supply chain, Total Cost Optimization includes everything from patient safety to product and market share losses to brand risk. TCO must include the real costs
According to Robert Menard, Certified Purchasing Professional, Total Cost of Ownership (TCO) is the single most important principle in all of supply chain management. It quantifies and measures costs. The principle of TCO has impacted commercial negotiations by expanding the narrow confines of price to a vast field of opportunities for attaining win-win results. Anyone can get a lower price. The object of good business is to attain the lowest TCO.¹

TCO is defined as the compilation of direct and indirect costs associated with a purchase, transaction, or activity. Direct costs, such as the invoice value of a service, are typically visible to the supply chain part of the organization and represent only a fraction of the total cost.² In essence, the purchase price only

Recently an infographic from DHL (see above diagram)³ was used to clearly identify the issues related to total cost when related to your supply chain.

Similar to an iceberg, it is what you can’t see that should be concerning. Direct costs are those that you can see, like the invoice value. Indirect costs are hidden costs that are difficult to identify and consolidate because they are tracked and accounted for under different heads of the organization. These indirect costs have a long term effect on your bottom line.
TCO for Packaging and Monitoring in the Life Sciences Supply Chain

Traditional MBA programs talk about risk management in four distinct areas: credit risk, market risk, operational risk and asset-liability. The challenge is that your role in logistics, finance, quality or other position may not have visibility into these areas. The same goes for other department heads as well. This creates silos that don’t add value to your company versus the huge cost of maintaining those silos.

Identifying and calculating these hidden costs, and factoring them into a business decision or operating plan, is not easy. "Within large pharmaceutical organizations, costs often are spread across various departments, further hindering a strategic approach to cost management," says Angelos Orfanos, President, DHL Life Sciences & Healthcare. "A damaged or lost product is one cost line, the cost of packaging is in a different line, transportation is in yet another line, and so on."

Therefore, managing an efficient, optimized supply chain requires us to understand where risk occurs and where opportunities can be found to mitigate those risks. The way this happens is by looking at the bigger picture.

How do you economize the temperature-controlled supply chain without factoring

Short answer is, you can’t. Marketing executives, insurance analysts and financial groups alike can testify that data is king. Without it, you can’t make effective, objective decisions. According to Liberty Mutual’s Debbie Michel video and article on taking control of risk by focusing on TCO.

“In general, losses account for 85% of a business’ total cost of risk, while the remaining 15% goes to excess premiums and claims-handling charges. Focusing on the 85% by reducing or preventing losses, and delivering superior outcomes when bad things happen, are two of the best ways of bringing down TCOR. But how should a business do that?”
4 areas to find risk in your temperature-controlled supply chain

If tangible loss only scratches the surface of the total cost of loss, then how do you look for and resolve the other factors?

1. Prioritize the costliest elements first

Start by prioritizing the costliest factors affecting profitability, and pick the top 3-4, then decide if you can quantify the results. Below are some components of TCO that constitute indirect costs for life sciences.

- Cost of packaging
- Time management – product launch delays
- Unplanned down time
- Lack of product efficiency / product quality cost
- Back office invoicing
- Brand risk / customer perception
- Visibility

- Patient safety
- Product loss and recovery
- Regulatory gaps
- Scrap cost
- Warranty & insurance costs
- Currency fluctuation
- Inspection cost
- Training & education
- Environmental impact

Source: Adapted from 1) Elements of the Total Cost Approach Iceberg² and the TCO (total cost of ownership) of an insulated shipping packaging solution³

Any one of the above factors could be a show stopper for your company. Take for example, the cost of a temperature excursion in your supply chain and let’s take out the actual cost of replacing the product. Recovery, inspection and disposal of the expired drug have time and shipping costs involved. There is also the lost time it takes to repackage a replacement product, reship that package, and log issues.

Now look at the long term effects regarding your brand. Big pharma has traditionally kept their heads down when it comes to umbrella branding techniques. But, in today’s age of direct-to-consumer marketing and political fallout related to recalls, it is no wonder. The Vioxx recall made Merck a household name. Claims that OxyContin is potentially addictive have done the same for Purdue Pharma. Customer perception of your brand is your brand. Keeping bad news out of the narrative is and should be a primary focus of risk management. As a packaging and logistics team, there is an implied, not stated value in your
2. Look at your existing systems for issues

Look at your existing systems for reporting and determine if there are standard deviations that match an external change (i.e., did the time of excursion happen during a shift change, handoffs from carriers, dock delivery, etc.). This may require meeting with others in your organization to collect data on insurance claims (insurance agent/finance), temperature monitoring platforms (QA/Logistics), and others may all provide this insight. You may also want to look at customer satisfaction surveys from your marketing department to see if customer loyalty has been affected or even mentioned. It is not a bad idea to set aside budget to conduct data cleansing and optimization that will inevitably eat time and costs in the short run, but result in savings in the long run. Relational data (comparing information from two disparate systems) can reveal gaps and trends not

As an ERM (Enterprise Risk Management) approach today’s temperature monitoring platforms, like those from Mesa Labs, will often times integrate compliance factors (such as data logger calibration, excursion alerts, audit trail logging) with staffing and training issues. For example, if a refrigerator door is left open for too long while looking for products, you can determine if the risk of exposure happened in your own facility versus the customer’s site. This may trigger either a training issue, product labeling issue, an issue with your carrier, or an issue related to your refrigeration system.

As a developer of cloud-based solutions, we know it is not a new software platform that you want, it is the data, in an organized way that enables good decision making. Without well organized, complete data, the cloud is just another file server, another trash can for information you don’t need. So what does this mean to a manufacturer of hardware and cloud-based services? Remote monitoring platforms establish checkpoints of visibility that align to your SOPs and compliance requirements in order to enable proactive controls. If audit or intervention should be required, you have the audit trail needed to resolve the situation.

The cloud-based systems of today provide easier integration than ever before. Integrating these systems over a mixture of risk platforms provides sustainable reductions in both capital and operating expenses.

3. Identify workflow factors in your SOPs

Identify workflow factors in your SOPs and systems that are lacking detail. Standard Operating Procedures (aka SOPs) are a set of step-by-step instructions documented and tested to help employees carry out routine operations. The purpose is to ensure the integrity of and quality of your product by creating efficient uniform performance outputs. It also reduces communication gaps and related failures.
Your SOPs should be reviewed regularly to look for gaps. Matching data from the above systems can identify when and where the issues are happening. **As a certified ISO 9001 company**, Mesa Labs is not only required to determine processes (documented as standard operating procedures) for our own manufacturing process but the company offers consulting, writing and training of any type of Cold Chain Management and GMP SOPs that may affect product quality and integrity.

4. Test your distribution environment

Conduct shipping studies by testing the distribution environment of your packaging. Shipping studies are designed to assess the external conditions to which your products will be exposed during the shipping process, evaluate the ability of your packing materials to maintain a stable environment, ensure products are being shipped within their stated stability parameters and then recommend solutions to address issues identified during the shipping study. This study may also include a transport process assessment and compliance gap analysis to collect data not otherwise accessible and identify actions to take.

You may also want to model and stress test your packaging at a certified ISTA lab to determine if it is appropriate for the amount of risk you are willing to absorb. For new packaging systems, stress testing and shipping studies will identify the optimal packaging configuration for your needs that will effectively protect your products from both typical and extreme temperature conditions across your distribution system. This will also ensure that your packaging solutions are cost effective and compliant with all regulations.

This level of testing will also help provide the data you need for additional analysis and evaluation of both your end to end supply chain and provide an assessment of your carriers as well.

Where to go from here

Not as easy as it sounds. It takes time and focus to make these data points come together. Sometimes consulting projects like these can take on a life of their own, having a cost associated initially and then become a cost savings in the end.

Start with evaluating your risk, look for trends in your data, prioritize those risks and cost factors that will most affect patient safety, your brand, and your bottom line. Then present a compelling view as to which will make the biggest impact.
If you are not a senior member of your organization, look for an executive sponsor to support your project. Once you have the support, engage with your vendors, customers, partners and other departments to build your plan. The result is well worth the effort.

**Finding risk in your cold chain and addressing it head on.**

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**About Mesa Laboratories, Inc.**

*Mesa Laboratories, Inc. (Nasdaq: MLAB)* is a growing, highly profitable public company based in Denver, CO. Mesa develops, manufactures and markets, high-quality process validation and monitoring instruments and consumables. From

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**About TempTrust Qualified Packaging**

Mesa Labs, formerly Infitrak, is a leader in providing of cold chain packaging solutions and related cold chain packaging services for the life sciences market. The Mesa Labs packaging line, called TempTrust, helps clients to assure their pharmaceuticals, blood, tissue, and other products remain in compliance with regulatory guidelines and are stored or transported under ideal conditions. TempTrust cold chain packaging

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http://prescription-drug.addictionblog.org/is-oxycodone-addictive/

This paper was written by Kevin Kohleriter, President of The MarketBurst Group and regular contributing writer to Mesa Labs. For more