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Temperature Controlled
Life Science Supply Chains

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CHANGE & COLLABORATION IN PHARMA LOGISTICS

UNLOCKING THE VALUE OF SUPPLY CHAIN COLLABORATION

Featuring insight from....



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Organizations change for a range of reasons: to close performance gaps, seize new opportunities, to accommodate for a new merger or perhaps abandon certain projects in favor of more successful ones.

Pharma is one of the most conservative industries –namely due to the fact that its products are high risk – very influential to the health, well-being and in some cases the survival of their consumers. Regulations must be met to ensure that medicine quality and patient safety is protected. Therefore any changes, be it to product or process, need to be controlled to ensure that these vital elements are not in anyway jeopardized.

This being said, many areas in pharmaceutical supply chains could be greatly enhanced by change to save time, money and resources. Real time monitoring and machine learning technologies in supply chains could enhance agility to prevent losses in the field due to temperature excursions. Standardized metrics would be revolutionary when comparing and verifying shipping containers. Blockchain integrated as an additional security layer into supply chains would allow stakeholders to manage the chain of custody via one source of truth.

Therefore, it can be worthwhile to endure the hurdles required to invoke change in pharma. Also, with more stress being placed on the bottom line and executives scanning for areas that will scoop up savings, pharma firms may not be able to afford the luxury of shirking the laboriousness of change.

The high cost of spoiled pharmaceutical products is one of the motives driving some manufacturers to switch to using Phase Change Materials (PCMs).

Case study

A medical firm based in Singapore wanted to transport bio-materials for 48 hours at -18°C. These materials included the likes of fresh frozen plasma, blood serum, protein, plasmids, DNA, RNA, anti sera samples and tissues on slides.

By switching to PCMs the firm eliminated the rejection of products due to exposure to low temperatures, which constituted to 15 per cent of the consignment annually.

By reducing the level of product rejections and simultaneously deploying OPEX measures, the firm saw over \$0.5 million in annual savings.

Why is collaboration important in change management

As mentioned by Nick Candito, Co-founder and CEO at Progressly “Companies that transform are always thinking about their organization’s vision and long-term trajectory. They see transformation as a journey, consisting of changes, that allows them to stay competitive and continue to grow.”

However, organizational change almost always requires the input and coordination of multiple parties.

Overcoming resistance is one of the biggest challenges to tackle on the road to change, especially with large scale transformation. Effected parties need to be unified with a common vision that is rationalized by the change’s benefits. Here, communication and collaboration is vital.

Craig Vermeyen, Senior Manager, Packaging Engineer at Kite Pharma pointed out that when the relevant groups are involved and working

together, changes can be completed much faster. Also, more innovative solutions within the transition can be reached when different perspectives on the change are coming in from different groups.

Why collaboration is important in pharma logistics?

Collaboration is integral to a pharmaceutical supply chain working sufficiently, with different stakeholders operating various legs of the chain.

Cold chain partnerships are largely a game of trust. With lives at stake and billions of dollars invested, communication, training, modern infrastructure and a good track record of safely delivered temperature-sensitive cargo are essential qualities of an effective cold chain partner.

Once cargo is handed to a forwarder or carrier, shippers must rely on partners to safely steward their temperature-sensitive products through the cold chain. One of the most efficient methods of monitoring shipments is a truly collaborative approach, whereby all stakeholders charged with moving temperature-sensitive cargo work together to develop and implement the required programs.

Even though it is integral to the operation of its supply chains, collaboration doesn't come easy to pharma. Many have ventured to state that the industry is far behind other sectors when it comes to collaboration.

In Pharma Logistics IQ's 2016 research, collaboration between manufacturers and suppliers was labelled as the biggest adherence sticking point for new EU clinical trial regulations. Then 2017's research saw a

large portion of the temperature controlled logistics respondents, 32%, admit they do not hold enough meetings to share information with supply chain stakeholders.

Stakeholders can be so preoccupied with their own individual results and pain points, that they fail to check on the consequences felt within the whole chain. Instead, stakeholders should integrate into each part of the complete supply chain, working collaboratively to achieve the group's objectives.

Alan Kennedy, Founder, Team-Up Global and collaboration program Poseidon said, "It is time for pharma-logistics to step outside its comfort zone and take a hard look at developments in other service sectors. Only by adopting a more collaborative approach to pharma logistics can the pharma industry extract the benefits that are being routinely achieved by more progressive sectors."

At the end of the day, lacking collaboration measures will result in a deteriorating partnership and product loss.

Collaboration and intelligence sharing between drug manufacturers could drastically improve the landscape for the general market. Progressive industry commentators have proposed the idea of peer shipments – where drug manufacturers collaborate on shipments, to reduce costs and avoid the prospect of paying to ship a lot of vacant space.

Fully standardized packaging vendor qualification requirements

When comparing models, many firms struggle to determine which packages they should invest in to transport their medicines; due to the lack of standardization in the qualification testing conducted by manufacturers.

The existing guidance on qualification testing is helpful, but the number of different thermal profiles and testing procedures used in the market (regarding product loads, preconditioning requirements, etc.), can create confusion when trying to directly compare containers.

Selecting the wrong container would be a significant waste of investment and risk the safety of high-value drugs as they travel through challenging climates.

Fully standardized packaging vendor qualification requirements would allow for quicker and more informed selection of packaging for drug manufacturers. Costs would be lowered as there would be less of a requirement for additional internal testing when buying an off-the-shelf solution. Tests could instead be run purely to simulate performance in worst-case scenarios or if a specific use case was tested to reduce the cost or weight of the package.

This change towards standardization would hinge on collaboration because if only a few suppliers move adhere to the requirements, manufacturers still can't draw direct comparisons across the whole market. Craig Vermeyen notes that it could take some time for the industry at large to convert.

This change is likely to have significant growing pains as it benefits end users the most, but asks the most change from the vendors. End users have limited control in sparking the change.

It's mainly the suppliers who are going to need to find a way to collaborate. Craig Vermeyen said "[Vendors will have to] work with their competitors which is definitely a unique challenge that won't be easy to achieve. But we need to find some way for them to all agree on

how to align with each other to find the best way to test in a standardized method that is easy for customers to understand."

Craig Vermeyen notes that users may need to collaborate to financially motivate suppliers to change how they are qualifying products and provide guidance on where the demand lies on the temperatures to test to, payload configurations etc.

He said: "If we are able to unite and say: 'We are more interested in buying solutions from vendors who have been able to change the way they present the data to make it easier for us.' This may act as an incentive for suppliers to change the way they are qualifying containers."



Entering a new emerging market

The daunting cultural learning curve involved with entering an emerging market is made achievable by collaborating with a trustworthy local expert. When selecting such a partner, shippers should consider whether their network is sufficient to meet market requirements. The partner should have a good reputation with local customs, health authorities and ground handling agents for sensitive items.

Guy Hoskens, Clinical Supply Chain Logistics Expert within Janssen, Pharmaceutical Companies of Johnson & Johnson warns: "It's important that the logistics considerations

and teams are involved early enough in the process when setting up a new region. If that is not happening early enough, then logistics executors will be confronted with challenges in set-up. Pharma firms should have good local contacts in place who can help them with understanding the local requirements that are set up as quickly and as efficiently as possible.”

Change of transport mode in a lane

Tarmac exposure time is a phrase that can instill fear into many pharma logistics professionals. Many perceive this as one of the biggest challenges when transporting medicines via airfreight.

Many in the industry have opted for sea freight over air-freight to transport medicines as it is cheaper and involves less touch points. The Seabury Group maintains that every year 0.5 million tonnes of pharmaceutical products are transported by air, compared to 3.5 million tonnes by sea.

Even though airfreight sees a lower volume of pharma traffic, the overall value of the pharma cargo moved is much higher than sea freight. David Bang, Global Head of DHL Temperature Management Solutions clarifies that when a swift supply is needed for medicines - air-freight comes into its own.

Also, although some flaws remain in transporting Controlled Room Temperature (CRT) drugs via air-freight, providers in the space are taking strides to make the air more viable for medical cargo.

When gearing up to collaborate with airfreight partners, Guy Hoskens notes: From an airport point of view the pharma side of the business is often only a small piece. It's a high value and high-end market, but indeed understanding

the niche needs is not usually a critical concern. Airports mostly work with industries where the big volumes are situated and that's not typically pharma.

“So make sure the providers in your chain have a good understanding of your requirements and apply the necessary measures to handle your product. For instance, ensure they understand criticality of making sure that your product is not left out on the tarmac for too long and stored temperature controlled as long and much as possible before and after the flight.”

Safeguarding change – Lost in translation effect

When initiating a change pharma firms need to beware they do not suffer from the lost in translation effect. Processes need to be documented correctly when changes are made to accurately represent what occurred. Big pharma firms are likely to have the processes in place to prevent the lost in translation effect occurring. Biotechs or smaller pharma entities are more at risk of the lost in translation effect. By preventing the lost in translation effect, firms are able to conduct various transfers or changes and avoid issues when validation is needed. For example, when a lab wishes to relocate internationally, the validation of the lab transfer will be greatly simplified and the risk of wasting time and money will be minimized, if the unit had a well-documented process.

Tonino Antonetti, Executive Director, Regulatory Affairs, Quality Management, Safety & Health at Roche Diagnostics believes the industry would greatly benefit from a standard on this matter, a guideline or whitepaper, which outlines expectations and best practices to maximize chances for success.

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- Improving internal and external collaboration with change management
- Maintaining temperature controlled products
- Implementing new tech/innovation while aligning processes to a customer centric approach
- Improving transport route efficiency with suppliers

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