

What Would You Do?

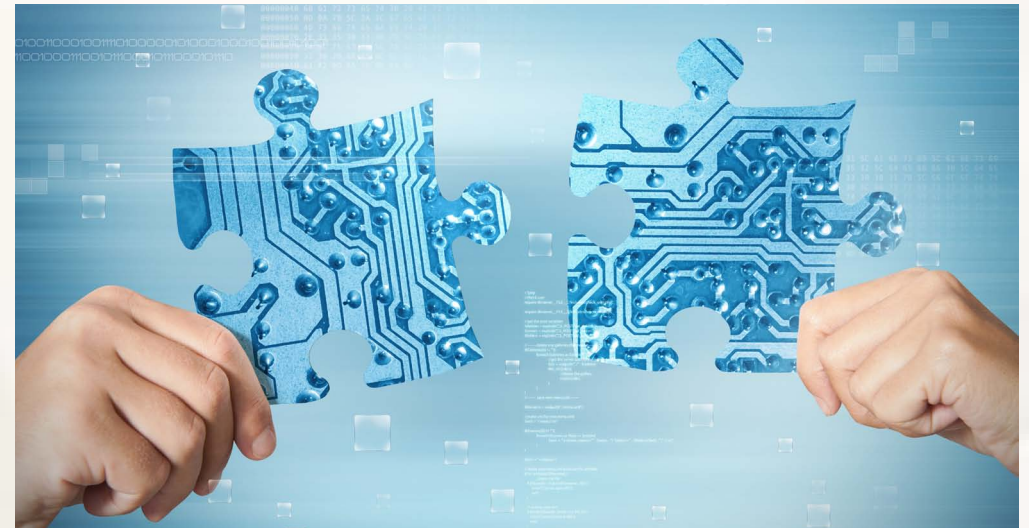
Decision
Making Agility:
Temperature
Controlled Logistics
Reactions

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Damage from disruptions in the supply chain can't be completely eradicated, however they can be mitigated. Disruptions could occur in the form of natural disasters, equipment/vehicle failure or unforeseen transport delays. Companies which apply –what if – scenarios are noted to be much better equipped and agile towards facing unforeseen occurrences in the supply chain. A wrong decision made within the temperature controlled transit of a pharmaceutical, may not only be costly in a financial sense but it also in terms of physical harm caused to patients in extreme cases.

There is an array of proactive planning tactics deployed in the cold chain such as shipment calls, lane validation and qualification that arm a pharma firm with oversight on how to manage and navigate risk prior to the initiation of the lane. For example, the increased level of data collected during temperature controlled shipments can be utilised to assess current practices and guide decision making. Data analytics can provide new alternatives to product distribution; help define the overall estimated costs and create potential scenarios. The combination of supply chain data analytics and risk management has the ability to create solutions that visualize the weak-points along the entire value chain, assesses them and helps develop new approaches and strategies. Understanding and identifying the specific risks along a given shipping lane is absolutely critical in order for a company to establish appropriate and effective contingency plans that their logistics and transportation service providers are responsible for carrying out. An innovative study has recently assessed the use of eLearning programs to develop expertise and train those handling temperature sensitive pharmaceuticals through the supply chain.

This dedication towards proactive planning should sharpen a firm's reactive abilities. It's important to move towards real-time decision making as a shipment moves through the supply chain as opposed to basing decisions on historical data. The most valuable piece of ROI from investing big data into the supply chain is the enhanced visibility which will facilitate targeted interception to adapt situations before hazards translate into damage. (5). Additionally, optimised visibility will allow supply chain costs



to be streamlined, very important with with cost- efficiency being a prime consideration in the transport of generics and ambient products. With a view to assist pharma firms with proactively improving their agility and reactions for accurate decision making in temperature controlled logistics, Pharma Logistics IQ examines a selection of scenarios and invites leading experts in the field to provide insight on possible best practise measures in the face of these circumstances.

Speaker Panel

Patrick Pichler,
Director, Head of Distribution Quality
Biopharma | Quality

Frank Binder,
VP Global Supply Chain Santen Pharmaceuticals Co.Ltd

Walter Mühlecker, Ph.D.
Vice President, Head Global Supply Chain, Bachem AG,

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Extreme Weather Conditions

You receive reports of a natural disaster involving extreme weather conditions is due to hit an active lane of yours transmitting temperature controlled pharmaceuticals. How do you react?

In ensuring the pharmaceutical supply chain during a natural disaster one key tactic is to agree unique identifiers for supply chains in reactive disaster planning especially with the formulation of community-centric and catastrophe-specific formularies to measure potential damage on product supply and how this should be navigated. Industry commentators have noted it is important to prioritise high-risk subpopulations and the drugs that will be in high demand. When passing through regions of extreme temperatures ideal routes are those with minimise the amount of times doors must be opened.

Anna Hallgren Senior Logistics Specialist, Vitrolife Sweden AB noted that in the 2010 volcanic ash cloud incident in Europe highlighted the supply chain's vulnerability – in always relying on with just in time delivery and that flexibility and backup plans need to be on hand for these situations. In this scenario relief was obtained through switching from courier transport to road transport in Europe and they managed to obtain customers through this reactive change.

Packaging Failure

On the report of a near-failure of a container being used for the transit



of an investigational medicinal product in an emerging market like Africa. What would your corrective steps in this situation be?

Frank: "Well, I think the most important [thing] is to make a fact based decision of whether the goods are still usable or not. So on the one hand, you need to get as much data on the actual temperature as you can and investigate with your quality function what the actual product stability data is. Then there will be a judgment call [to be decide] whether the product still has maintained its integrity and can be used or if you cannot be sure of the product integrity, in which case of course it would be discarded."

Walter: "Assuming it is a near-failure and we are still within defined shipment conditions, I would look at the route - at the time the container was on the road, the transit mode (air, truck...) and make a thorough evaluation of the problem. Was it a problem with the container, the route or some unforeseen, unexpected problem? [Once we know this] we [can] then act accordingly and set corrective and preventive actions. So, if it turns out– [for example]– average transit time is 80 hours instead of 70 hours, then I would change the cooling solution. A different type of packaging may be necessary, re-icing or recharging of the cooling elements."

Managing Culture Change

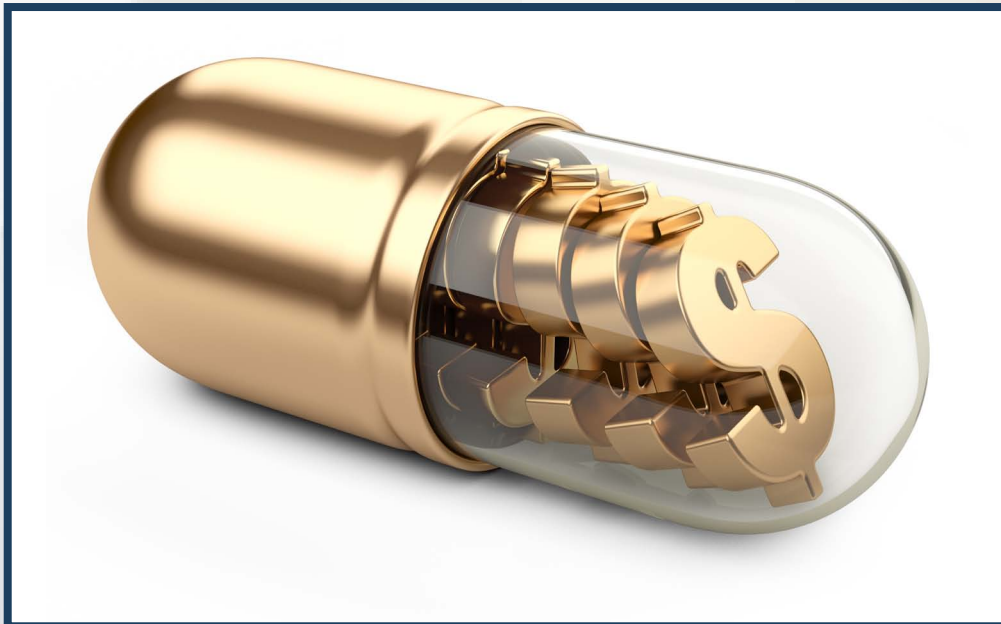
On the discovery that an efficiency change that should have been implemented a few weeks earlier by a supplier still isn't being applied, what are the first corrective steps you'd take?

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Patrick: “Yes, actually we have [experienced] that already and what we did in this case was we referred to the technical agreement that we have, with the technical supplier and we said: ‘okay, the deadline was missed by two months now. So looking at the next shipment if this is then out of range again then we will not release the shipment anymore. We will scrap it. You will not be paid for that and you need to pay the fees.’ The implementation was then done within one week. So that was good.

“Then we had a good conversation with them after this case and we tried to ask them to evaluate why it took so long and to provide us with the root cause. They came up quite quickly with the root cause and it was just two individuals that were not compliant to even their own company rules. This was more or less, the reason why not only our company was affected but multiple others as well.”

Frank: “Quickly understand what is the blocking factor. If there are technical issues that were not addressed or if it is that people don’t



understand the importance of this change. Depending on what the root cause is, quickly fix that. So quite a basic management approach.”

The Bottom Line

You had to save \$100,000 from current outgoings in temperature controlled packaging and freight spend, what are the best areas to examine to make these savings?

Frank: I would ask can international, intercontinental freight be moved from air to sea. However, it is important that the company understands the drawback, longer lead times and higher working process of working capital bonds. Also, looking at consolidating shipments even more – less trucks, but better filled trucks, that can go a long way.”

When assessing the operation of a new lane through challenging territories, in terms of risk assessment and evaluation, what are the most important steps for success?

Patrick: “The most important step that we’ve found out is that the risk assessment for an emerging market or challenging territory can only be done if you have someone from this territory in the risk assessment team. You need to local people either from your subsidiary, affiliate or agent, that you invite to participate in this risk assessment and give insight on what is going on. And make sure that this person is reliable. If you look at some Arabic countries, they never have issues, but if you then go there you see that they [do] have issues. So you need to tell them that [there] is something they need to address.

“The second part of the risk assessment: You take your conclusion on the validation steps and involve the local players. What we did for validations we did recently for emerging markets, is that we included the agents of our customs clearance, the forwarders that we use from the airport to the final destination and so on. They all got the validation plan; read the validation

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plan and they almost all signed [it] besides customs because the authorities said, no, we don't have to sign that. On the other hand, they were quite happy to receive this [plan] because they then said 'We [now] know what we need to do'. This was also something very enlightening for us because if customs does not know what they should do with the goods or how to handle them, then it's clear that we [will] always face issues there. "This was a very good thing to have in the validation approach - to include all parties that have the goods in their hands at the one point in time. It took some time until the validation protocol was ready at that point of time but it helped a lot and it's still, it's still working quite well on the lane [in question]."

Audit

What are the first measures that should be taken if there is an audit was approaching for an authorised product or for a lane's going through an emerging country?

Patrick: "Well, for the audit, first of all, definitely ask what they want to audit, what they want to see and prepare that accordingly in terms of regulation and requirements within the European Union, as most of our products leave from here, and connect [this] to the requirements of the [other] country [featured in the lane]. So what we would need is perhaps a little bit more insight into the requirements of the country or of this health authority, which will do the audit. Then you can see any gaps in the preparation phase and provide a cover plan or if [there is no] gap; we are still better to do more than they require."

To further strengthen your reactive decision making within temperature controlled logistics, visit the temperature controlled logistics leaders forum later this year."

Resources

1. <http://www.coldchainiq.com/supply-chain-security/interviews/gaining-an-advantage-by-applying-data-analytics-to>

2. <http://www.coldchainiq.com/supply-chain-security/articles/what-s-the-impact-of-big-data-in-the-cold-chain>
3. <http://www.coldchainiq.com/supply-chain-security/interviews/eric-newman-vp-for-loss-prevention-on-effective-ri>
4. <http://www.coldchainiq.com/transportation-logistics/columns/risk-management-and-quality-in-the-cold-chain-air>
5. <http://www.sdexec.com/article/12225837/risk-mitigation-should-be-part-of-a-healthy-supply-chain>
6. <http://www.coldchainiq.com/transportation-logistics/white-papers/turning-oh-no-into-no-problem-new-10-tips-for-cont>
7. <http://www.inboundlogistics.com/cms/article/temperature-controlled-logistics-cool-under-pressure/>
8. <http://www.coldchainiq.com/supply-chain-security/articles/is-the-weather-wreaking-havoc-on-your-supply-chain>
9. <http://www.coldchainiq.com/transportation-logistics/videos/anna-hallgren>



TEMPERATURE CONTROLLED LOGISTICS **LEADERS FORUM** DACH

October 25-27
Switzerland

The Temperature Controlled Logistics Leaders Forum will be bringing together industry leaders from across logistics, quality, supply chain and distribution. The forum will take a hard look at core challenges and best practices to take your TCL strategy to the next level!

Reasons to Attend:

- **Utilise risk management strategies to improve your business processes and increase ROI** - become more responsive to emerging markets and your customers
- **Benchmark your team's experience** to drive more innovative thinking and enable you to improve your temperature management approach
- **Reduce cost within your supply chain through cost-benefit and SWOT analysis of air, sea, rail and road.**
- Hear first-hand how other leaders such as Abbott, Merck, Shire and Amgen are **balancing compliance, cost and quality to build competitiveness**
- **Enhance your knowledge of the latest regulatory changes** relating to temperature management and using data to ensure you remain a step ahead.

