

Temperature Controlled Logistics

Optimising Strategy Formulation and Cost-Balancing in Temperature Controlled Supply Chains

Talking Heads

In the mission to further refine a pharmaceutical's path to market: Risk conduct, compliance and cost balancing are three key pillars to be optimised in any temperature controlled logistics strategy.

When increasing the understanding of a certain route and the ability to navigate its risks, the application of both continuous monitoring and lane validation is a key tactic for robust lane qualification.

Risk assessments also need to establish transparency on the network of professionals who support the product through the cold chain. Jim Bacon, Cold Chain IQ columnist, illustrated an exercise which embodied this that was implemented in his time at Grifols. The Mock Shipment Call was a method used to eliminate risk and qualify the lane by having every single stakeholder on that lane present to clarify and run through their role in the chain. He commented: "All too often, an excursion can be attributed to some form of human error and more often than not this occurs during a transfer or hand-off from one service provider to another. I have addressed this issue in many presentations over the past many years, referring to it as "the weakest link."

Shippers that improve these handoffs through robust and disciplined process steps and improved agreements with providers have mitigated their risk by securing "stock throughput coverage" insurance which provides continuity coverage for shipments. This however does not eliminate the risk, so extra steps and a continuous loop of review is required.

"More recently, due to increased regulatory scrutiny, shippers have engaged in lane qualification, serving to document the process, test and approve with live data. Through collaboration with our cold chain partners, we have taken it a step further and engaged in a process we call "The Mock Shipment Call". This is a tele-conference call we engage in before agreeing to execute a live shipment for a new shipping lane."

Another area highlighted by industry commentators that needs increased use within the cold chain – is stability budgets to calculate the permissible Time Out Of Storage within the manufacture and distribution of the pharmaceutical. TOS will impact the product's shelf life, so this time used needs to be measured and balanced. Hazards within transportation represent larger threats to the cold chain with the prospects of physical contact, handovers and unforeseen delays, so the TOS can be useful in managing temperature excursions.

Dr Rafik Bishara, Ph.D, Technical Advisor, Retired Director, Quality Knowledge Management and Technical Support, Eli Lilly and Company noted that to shirk the use of a stability budget could be perceived as an indicator that professional is not following modern industry best practices. Regulators are likely to enquire about stability and the protocol deployed to generate the data and the implementation of a stability budget. Rafik stresses that to avoid implementing a stability budget is in fact taking on a risk – dependent on the inspector they are allocated and whether that inspector decides to focus on the stability budget.

Industry figures have called for increased market consensus on the risk assessments a lane qualification should contain. Dr. Bishara has stressed the need for an industry task team for lane qualification – with the benefit being that standards can be outlined to specify required handling, storage and distribution to

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to the patient. However, many have noted that these standards would need to be flexible to allow approaches to be tailored to specific scenarios. Standalone cases would require the end user to invest in analysis to assess the most effective method for transit and temperature profile.

Looking at streamlining financially through the cold chain, one hotspot to assess is packaging and the consolidation of volumes. Both active and hybrid shipping systems quite often demand less distribution flexibility due to their reusability which requires a closed distribution loop. One cost reduction tactic to apply in planning phases is to evaluate the payload volumetric efficiency – leveraging innovative techniques and metric calculations to maximise container utilisation. This involves the identification of where moves can be consolidated and packaging can be downsized. This will reduce the cost per unit based on packaging spend and also in freight savings as less space is occupied. 1

Deploying a selection matrix can compare and analyse attributes which are critical to your firm's projects to verify decision making – which is integral especially for leased solutions.

Categorisations made through generating data internally can consider the following:

Temperature accuracy: Active shippers have the highest temperature accuracy in comparison to hybrid and passive shippers. They also provide the best flexibility when exposed to a temperature profile that does not match the qualification profile.

Size availability: When compared to passive shippers, active and hybrid shippers, due to their increased complexity and cost, have a narrower selection of payload sizes, which can cause complications in packaging efficiency. This demands added planning to ensure the availability of the container is well timed. Bulk passive units provide

the benefits of no power source dependence and 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.

Ease of use: Active and hybrid shippers are easy to set up, but may need maintenance in transit, depending on the length of the shipment.

Cost: The increased size, weight and complexity of active and hybrid shippers make them typically very costly. This cost translates through to extended freight payments.



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. 5

A note to the carrier or freight forwarder: 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. If you believe there is no advantage to this collaboration because you may be shrinking your invoicing, you may be soon in a RFP process for carriers or freight forwarders. You want a healthy and organic revenue that comes from the collaboration of the supply chain links.

Hazard: Active shippers may use lithium batteries. 2

Eco-impact – Consider the footprint active solutions are likely to produce. Alongside being compliant and controlling costs, life science companies are expected to reduce the environmental impact of their cold chain.

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.

Cold Chain IQ spoke to a selection of temperature controlled logistics experts to gain insight on the latest strategies and cost balancing techniques in the industry.

How is new technology and increasing data availability affecting QMS strategies and risk analysis in the industry?

Patrick: “It’s a good thing to [acquire] more data and more visibility on the whole of the logistics chain. Our risk analysis gets more and more thorough, based on the historical data, the availability of current data and even sometimes real-time data, so it helps a lot actually. The only issue is that you need to apply appropriate filters because you do not need all of the data that is coming in.

“ It’s very good to see that the technology is advancing for example: Real-time data, GPS tracking, cloud solutions for data storage and access to data almost everywhere and anytime.”

Frank: “Well, I think the availability of much more tracking as real time tracking data gives us a much better [analysis] of what is really happening during the shipments and to really pinpoint the most problematic stages much more precisely.”

Considering the tight margins involved with temperatures control logistics, especially in regards ambient and controlled room temperature products. How is the industry looking to drive down costs? Have you ever seen the application of any of the following?:

- Payload volumetric efficiency with packaging leveraging innovative techniques and metric calculations to maximise container utilisation.
- Multi-cell trailers—refrigerated trailers in which insulated curtains are hung at intervals to create different temperature zones.

Speaker Panel

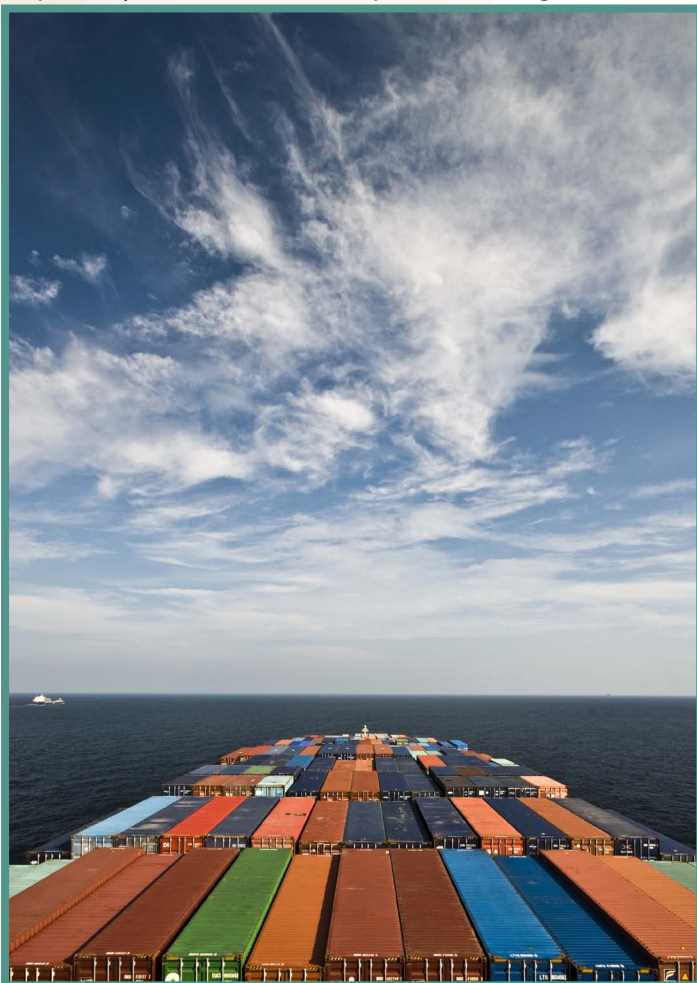
Patrick Pichler,
Director, Head of Distribution Quality
Merck Biopharma | Quality

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

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

- Collaboration with peer firms on shipments and lanes instead of having vacant space that is wasted due to packaging size constraints.

Patrick: “What we are working on at the moment is efficiency in packaging so that we do not ship too much air and we also try to get the maximum out of one pallet in terms of volume and weight. We also use these multi-cell trailers, so we have refrigerated and non-refrigerated goods on one trailer. We are also checking for different transport solutions, especially for the room temperature range



can be sure that it is transported within the 15 and 25 temperature range. This is quite difficult because the industry provides a lot of things between two and eight but for 15–25, it seems to be difficult to get something really reliable and sustainable.”

Frank: “I think the collaboration strategy has a lot of potential. In the end, when you realise that between different pharmaceutical companies, we don’t compete in that area at all. We should be able to work together - If we are using the same lanes, to combine our shipments and achieve a [higher level of] efficiency. Often you will find that manufacturing plants are somehow located in clusters and if you look at different companies that there are a lot of common shipping lanes. So this [method] has huge potential and it doesn’t even involve any technical change to the shipment itself, it’s just in the forefront, finding the right partners and collaborating to coordinate shipments, which has become much easier now that everything is handled digitally.

“The payload volumetric efficiency, I think there is still some progress that can be made when it comes to passive temperature solutions. There is a lot of interesting technology being developed, like phase change materials. I’ve recently seen one company that uses lamb wool to insulate shipments. There have been some really interesting advancements that make passive cooling solutions much more efficient in terms of volume use and being more cost effective.

“Multi-celled trailers. I think most shipments are either in the 2°-8° or 15°- 25° brackets. It’s an interesting solution to combine both in one trailer, but often you will find that one company really has just one class of products to ship at one time. But nevertheless, I think this technology also has its applications.”

Do risk strategies change when it comes to controlled room temperature profiles?

Patrick: “Well, the risk strategies do

not really change. There are different rules that need to be applied, yes. We still face the issue that we have customs warehouses, even in ambient temperatures, that can run out of control: In winter - too cold and summer - too hot. What changes are the requirements in individual countries. So more countries are [getting stricter] with temperature requirements and you [may] have a gap between the infrastructure that [is] available and the [country] requirements.

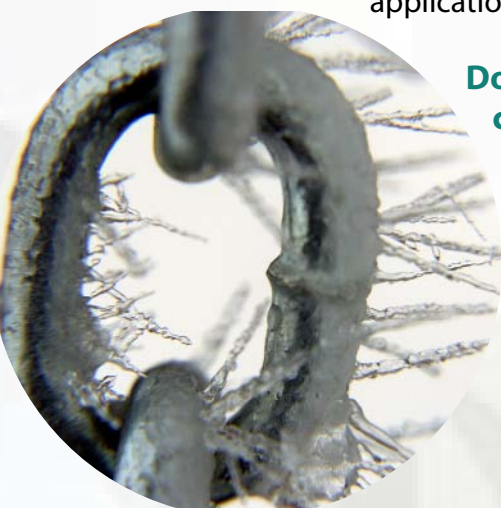
“We even face cases where we have strict requirements from the health authority and then customs refuses to set up any infrastructure, so we need to come up with our own solutions at the airport. For example, to mount the container that is temperature controlled and so on, it’s really, in many cases, an issue of infrastructure more or less.”

Frank: “I think if we go to risk strategies, there would be a huge benefit generally in having stability data available. That really allows the company to make risk based assessments of which kind of excursions are permissible and which not. So a scientific basis is certainly good and necessary. Often [with] the stability data, there is more available for the 2°-8° [products] than the 15°- 25°, but I think there are benefits to applying this to the controlled room temperature shipment as well, very clearly.

“I think what’s important for CRT shipments is that you really [examine] each loading and unloading point, the shipping routes and [what] happens at the airports. I think CRT shipments are more at risk of being left for longer times on the tarmac than the 2°-8° shipments. There is not necessarily the same awareness by shipment [handlers] that you need to stay within the 15°- 25°. So I think you need to have a very close look at the entire shipping process end to end.”

In assessing productivity inefficiencies, what areas of the supply chain tend to cause the most issues in delays?

Patrick: “Well, there are two things: Its product release time - as one of the first parts of supply chain. The second is the individual lead times during the individual journeys due to flight delays, cancellations, [or not getting] pallets on board because a plane is overbooked and so on.



In some cases, not even our global forwarders can help because it's up to the airlines and sea lines to decide what they want to take on board"

Frank: "I think you still see a lot... a surprising lot of paper based processes, even in air freight. I think there's very good initiatives underway of IATA to... and from airlines to really have electronic airway bills on that. I think paper based documentation, that is an inefficiency that is problematic but that's... where I see there are some good initiatives underway to address it."

What are the hotspots of the supply chain that tend to cause the most issues with excursions?

Patrick: "It's more or less during customs clearance and in the last mile from customs to the final destination. If we depart from a European airport then it seems to be more under control. If we depart from a Latin airport or Indian airport then we [tend to] have issues there."

Walter: "We are mainly working with passive storage solutions. So when it comes to delays, it may be necessary that the shipment has to be stored in a cool area or dry ice has to be refilled during the delay. Such a situation can cause excursions especially when control of the shipment is out of the hands of the forwarder and e.g. under the supervision of an airport. This situation can sometimes lead to problems."

Frank: "I think one of the biggest risks is loading in the airports when the pallets are brought to the tarmac and then left standing for quite a long time. Especially for products that are shipped under time temperature sensitive conditions, if [it] can be planned much more tightly [so the shipment is] on the tarmac just in time for loading, I think that would go a long way to improve the situation."

The best management strategies for culture

change within temperature controlled logistics?

Frank: "Well, I think it's important to create an environment where the current processes are frequently reviewed and people are allowed to speak their minds: What they think could be improved, what they think are the issues. I think it's about continuously measuring the results and having then some really focused workshops and saying: 'Okay, we have seen some troubles with this in this process.' And look to bring people, also operational teams, together to [search] for improvements. With performance metrics and management objectives [should] really foster that. It should become normal for people to challenge what is being done and look for improvements."

Patrick: "We ran a project this year - called Right First Time. This is not new for the industry but we actually have a joint objective for the individual departments like quality, SNO, planning, manufacturing and so on, to do things right first time with clear KPIs and [metrics]. In addition to that, we rolled out this project through our forwarders. We saw a quite good improvement over the year. At the beginning, it was a little bit difficult, but now it's actually going quite well and forwarders and suppliers actually understand why and they really try to [fulfil their] responsibilities. We see that in terms of responsiveness; temperature deviations getting better."

What are the trailblazers in the market are doing differently when it comes to cost balancing?

Patrick: "[In terms of what we did] it was a time of hard negotiation with our service providers, in terms of costs. We totally understand that they also need to run their business but they also need to understand [the same for us]. On the first run, it was more or less: 'If you are not compliant we are going to punish you by not paying, or you pay some additional fees. But overtime it changed into a good



collaboration. One example could be: your forwarder [could approach you] and say: 'We have a new product and we would like you to be the first one testing this product within our shipping lines that we have established for you. If this is something you want to work with, then we are happy to provide it for free for the first year and to see if it fits for you.' It's more in terms of [a healthier] collaboration and with this you definitely reduce costs because two companies with a different aim work towards the same goal."

Name a rising challenge within the industry, looking at strategies aiming to streamline time, resource and monetary burdens? What are the consequences if this obstacle isn't addressed sufficiently?

Walter: "Do it right the first time and don't have deviations is the greatest challenge especially in an environment with continuous rising requirements. To achieve this it is essential to choose the right supplier or the right forwarder. There are many different companies in the market that try to convince you that they are up to the task and are able to provide the service you require throughout the whole route from the pick up till the delivery. The challenge is to find the right partner, develop together a SLA, that assures that the shipment is carried out the way you expect it to."

Patrick: "On the one hand, as I said already, it's the regulations. On the other hand, it's the mindsets, especially in countries that aren't too highly regulated the infrastructure. I found out at various conferences that some companies are willing to pay for infrastructure if it's available."

"The total cost of quality is everything that you didn't do right the first time. If you evaluate your supply chain [in light of this phrase], you immediately see where the issues are. The global market is quite diverse. There are countries that can provide quite good infrastructure and can be

entered quite easily and [there are those with no infrastructure] that you can enter quite easily."

"This is what we are facing, I'm not talking only about Europe because Europe is quite harmonised and [simple] compared to other countries in Latin America or Africa or even Asia. The upcoming track and trace systems, which are not harmonised could really place a burden, in terms of manufacturing and also for the supply chain. It reduces the flexibility that we have as a company to have shared packs for more than one country. This is definitely something, we need to overcome."

Frank: "Yes, I think the challenge is a strongly increased scrutiny by authorities especially on controlled room temperature shipments. As an industry we have to find smart and scientific based ways to ensure and prove that we have things under control. For example, say I want to use [an expensive supplier] everywhere for an air shipment, then that would drive costs for many companies and would be a real issue in terms of the logistics costs. So we have to develop a risk based approach to prove that we have things under control and that the product integrity is maintained even under the real life conditions of the shipments."

What are the biggest transit issues to navigate when using the following modes of travel:

Sea freight

Patrick: "Sea freight works out well. The main drawback is the loading and unloading of containers. The loading seems to be more under control than the unloading phase, in our experience. Another burden in sea freight is if you have multiple stops."

Frank: "With sea freight it's important to work with a forwarder who has really reliable processes to make sure that the containers will always be maintained in the right temperature conditions."

STRATEGY

Timing could be an issue, but overall, this has to be really handled by somebody who understands the requirements of the pharma industry very well."

Air freight

Patrick: "It really depends on the airline, the airport and the hub. Also, it depends on the individuals - if they have the correct mindset and are trained a little bit in pharmaceutical handling, then it's fine. If you do not have that then you are absolutely lost - you have no visibility of what is going on with your goods. You just see it when your goods arrive or are cleared after customs. Sometimes even forwarders can say 'okay, we know your products are sitting in front of the customs warehouse, but we simply cannot do anything. There is nobody who can touch the product at that point of time.' So you get this message and you know your product is rotten so you immediately start with a new campaign to avoid a stock-out situation."

Frank: "With air freight there are so many different companies and people who touch the products: Load it, unload it, move it and so on. This has to be really well integrated, so there needs to be somebody on the ground who will link all the [processes] together."

Train freight

Patrick: "At the moment, we do not use train, but this is something we are currently evaluating because we see this as a quite good opportunity instead of long distance trucking or even for air freight."

Frank: "With train I would say it's, at least



in many parts of Europe, it's the reliability of the schedule and the time it can take for a train, I think. I have a lot of sympathy for train, for using trains for freight, but in many instances the train industry needs to up their game and be more focused on our needs."

Truck freight

Walter: "When we are using trucks, for us a main issue is to make sure the truck we are using is technically on an up to date level. The truck needs to have a cooling system that runs on gasoline even when the truck is parking and we need to be sure that the temperature control system of the truck works accurate. So that for a temperature-controlled shipment we can be sure that the temperature shown by the trucks control unit is equal to what we measure on our data loggers that go with each shipment."

Frank: "For trucks, I have heard of several cases of unexpected delays. For example, [on] driving to Calais and to take the ferry there with the refugee situation there are real issues. I've [heard of] cases where people have broken the seals of the truck and entered the truck with pharmaceutical goods in the hope of using that truck for illegal entry into the UK. So there are many risks today that didn't exist just a few years ago. The world has really changed in that respect."



Are there any aspects of temperature controlled packaging that could benefit from more standardisation across the industry?

Patrick: "Well, for the temperature controlled packaging, if we're talking about transport solutions, there are already some standards in place, naturally given by pallet sizes, heights

and so on. What we could perhaps work on [as an industry] is the standardisation of secondary and primary packaging. I have heard of some ideas of putting temperature controlled products into a certain kind of secondary pack that can hold a temperature easily without a tertiary and a quarterly pack around it. Especially if we consider vaccines in countries that really lack infrastructure like the allocation of warehouses with cold rooms. So this would definitely help tremendously if we could have some kind of industry standard. This would be something where we, as an industry, can approach the health authorities and say: 'This is what we are going to apply. Do you have a better idea? If not, then this is what we can offer.' If you [try] to do that as a single company then you will fail."

Frank: "The packaging providers are doing good stuff overall, but they could be [doing] even more so in a sense to provide packaging that has been validated for temperature profiles that are easy

for the industry to recognise [and apply]. I always hope that the [burden of] significant work [to] validate shipments can be eased by pre-work from packaging providers. A lot has been done already, but more could be done [through] collaboration with the industry."

Top tip for addressing regulatory compliance challenges in the regional and global market?

Frank: "For a supply chain professional in the pharma industry it's very important to keep-in close contact with the regulatory team. They should be the ones who gather the information on the trends, but you also need to educate yourself, know what are the trends in the region. If you work on a global level, then it's probably important to orient your work on the regions that are the most demanding in terms of GDP."



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.



Resources

1. <http://www.coldchainiq.com/packaging-shipping-systems/columns/validated-passive-packaging-weighing-the-costs-and>
2. <http://www.coldchainiq.com/packaging-shipping-systems/columns/an-insulated-shipping-packaging-solution-perfectly>
3. <http://www.lifescienceslogistics.com/logistics/temp-control-packaging/three-life-science-cold-chain-trends-watch-2016>
4. <http://www.coldchainiq.com/supply-chain-security/articles/anti-counterfeit-countermeasures-tactics-evolving>
5. <http://www.coldchainiq.com/quality-management/white-papers/lane-qualification-vs-continuous-monitoring-2015-r>
6. <http://www.coldchainiq.com/transportation-logistics/columns/the-human-side-of-lane-qualification-the-mock-ship>

