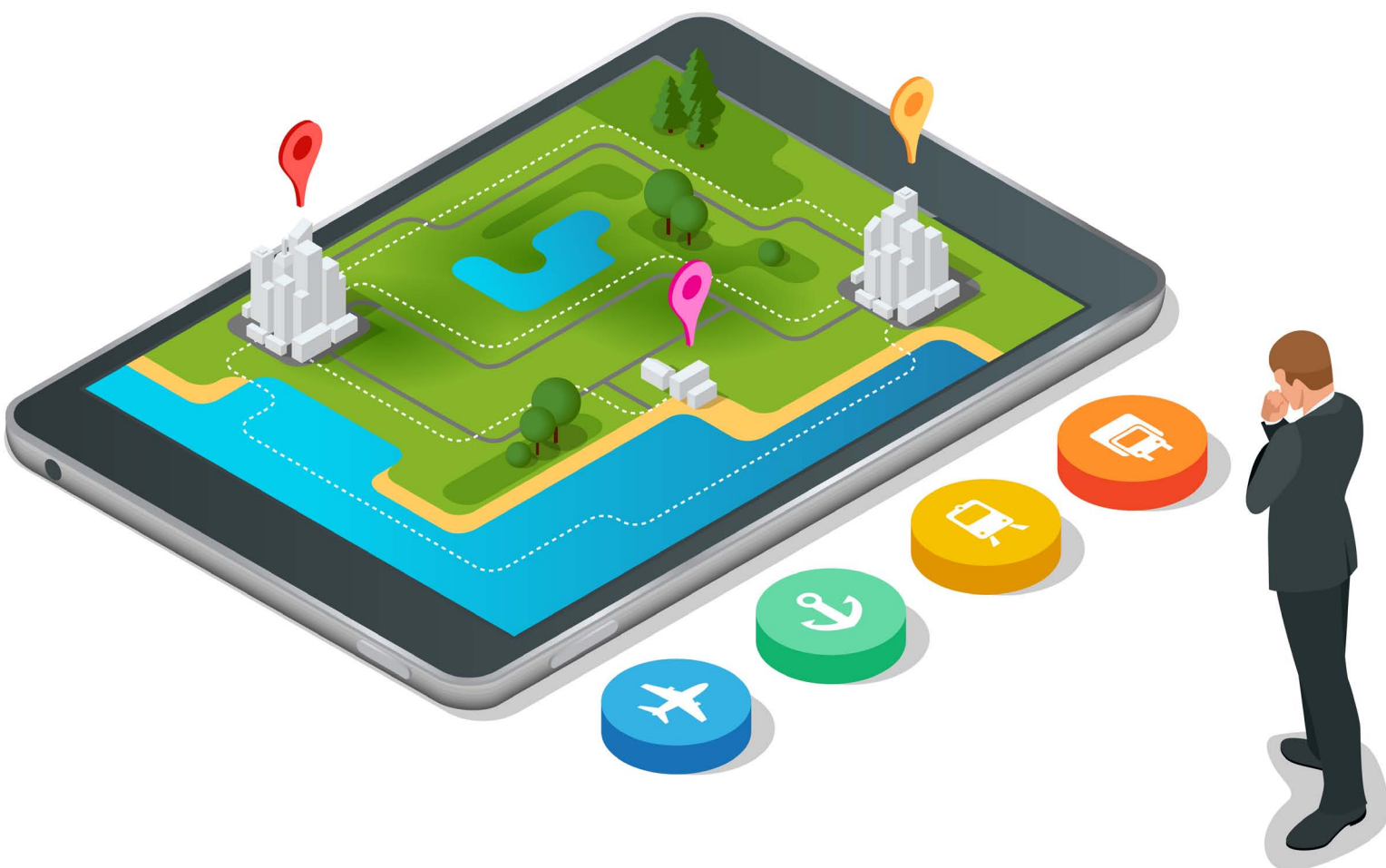


Brought to you by:

16TH ANNUAL COOL CHAIN

**TEMPERATURE
CONTROLLED
LOGISTICS**

The Supply Chain Owner's Guide to Planning



Pharma Logistics IQ

Temperature Controlled Logistics : Supply Chain Planning

In following the maturation of the temperature controlled logistics industry, the planning stages are vital to the continual enhancement and streamlining of the cold chain. There are multiple key areas within the supply chain that should be evaluated to assess whether improvements trim the fat and economical inefficiencies from the supply chain. To add to the discussion on continuous improvement within temperature controlled logistics, Cold Chain examines the notion of planning with a few key experts, more specifically in the areas of stability budgets, supply chain integration, temperature control with high value products, ambient ranges and oncoming trends to account for.

Speaker Panel

NOTE: The opinions expressed should not be assumed to represent those of the company an expert is associated with.

Stephen Mitchell,
E2E LP Quality Lead,
GlaxoSmithKline

Rubén Velázquez Treviño,
Change Manager - Transport
Services, Bayer

Val Petursson,
Senior Director,
Logistics Europe & PTC/PP
Teva

Brice Bellin,
Healthcare Director Europe,
Bollere Logistics

How can stability budgets be used to assist with cost saving in the implementation of temperature controlled management?

Ruben: "For one of the projects we went back to our temperature stability budgets and stability studies to see how much pressure and stress our products could withstand and then started to develop a transportation strategy based upon that. To revisit the original stability studies may give you more flexibility when planning difficult or challenging steps in your lane."

"The unloading/loading maneuvers, and handling at the distribution center or warehouse. These are key processes that can benefit from out of stability time that otherwise would be either too expensive or too complicated to manage."

Val: "I am not aware of companies doing this to be honest. We do not, but I'm pretty sure it could and should be applied. It acknowledges the responsibilities that companies have and also puts a focus on the costs involved. Not so many years ago, these freight costs were not recognised necessarily within the industry, but now it is not a matter of choice anymore."

"Also, it can be productive to organise spend on temperature control as part of a capex budget. So any improvements made to meet GDP standards aren't deemed as part of the operational budget but in fact the capex budget."

Stephen: "The only point I would make on this is that the stability budget should be built into the last mile. It is not something that people should be using to plan for their core distribution process centre. The principle is that you can't budget to include boost your stability budget in a normal supply chain process, I think that is quite important. At the end of the day, you do not know what your patient is going to do with the product once they have received it. The stability budget really is intended [for] that end of the supply chain."

Do you think temperature management for CRT/ambient products still stands as a large challenge within the industry. What are the best ways for firms to compliantly lower their outgoings?

Brice: "It still remains a very big challenge especially for freight forwarder. Many stakeholders are involved in transportation processes and products are passed

Temperature Controlled Logistics : Supply Chain Planning

through many different hands making a full control of these steps very complicated. This may set the integrity of products into risk. Therefore, a dedicated mindset for handling of Pharma shipments is mandatory. Assurance through risk assessments, transport plans and partnerships with qualified and audited stakeholders such as carrier, subcontractor, ground handling agents, warehouse companies and many others is mandatory for the most possible risk minimization. A high technical standardized Track & Trace system supports additionally and allows the immediate impact in case of deviations. Last but not least, the transport of ambient products still remaining the biggest challenge due to the fact that less transport solutions are available and implementation of them are cost intensive.

"A use of so called passive packaging solutions may be a key solution for many companies facing problems with ambient products and making transportation at the end cost effective compared to active solutions."

Ruben: "Well, ambient products have always been a challenge, probably a challenge we created ourselves because it is easier to set up sturdy processes to maintain and monitor 2-8 lanes than Controlled Room Temperature lanes, especially because there are no standard solutions for Controlled Room Temperature.

"Knowing your product will empower you to know which solutions available in the market that can cater to your needs. After studying this, consider your measuring principles: will performance be measured based on kinetic temperature or the real temperature as stated in the data loggers?

"There are pretty innovative and simple solutions out there that could be used instead of expensive traditional devices or shippers.

"So, know your product, how you are measuring your performance, and what solutions are available in the market that are not in your standard portfolio to help



you keep those temperatures within range without any additional costs."

Val: "You can of course end-up over investing and be supercompliant. We did that for many years, because we did not have the business intelligence to tell us where to invest and where we could go with minor measures.

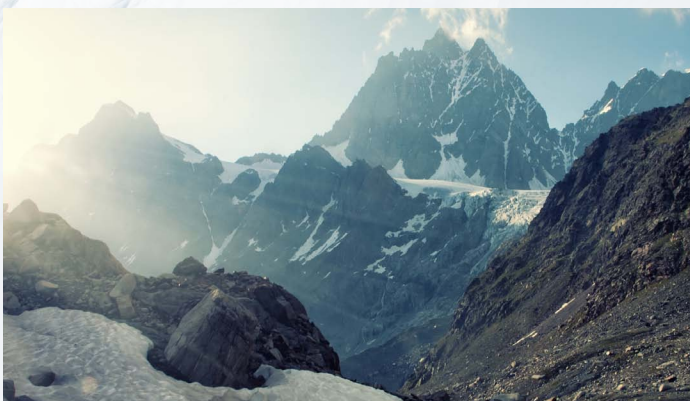
"The key here is to heat map your network. Companies use this technique to investigate where excursions occur, systematically track them, root cause them and place the right capex knowing which routes are risky. Also, as a result they know the products better.

"So, invest where needed and know where the risks are in your supply chain, to avoid overinvesting be sure to know where the risks are low. For example, companies don't need to move ambient products with active packaging. Some companies don't even need passive packers. It's fine to use blankets or even use the pharma services that are validated where companies have done the route mapping."

In regards to high value products – what is the best way to ship them, considering efficiencies as well as costs? With this in mind what are the pros and cons to: going by Air, Sea, Truck or Train?

Ruben: "So, this is a pretty interesting question with regards to the current trends in the industry, there is a tendency to lean towards lower price transportation modes – hence the movement from air to sea for example. However, especially in the pharmaceutical industry, it is difficult to assess what's the best way to handle your high value products, because the transport community has only recently started to offer tailored solutions for an industry that represents roughly 1% of their volume or less.

"When you have high value [products] cost is not your



Temperature Controlled Logistics : Supply Chain Planning

main driver, but quality. The rule of thumb is low volume-high value equals air freight and lower value-higher volume equals sea freight, with road somewhere in between. But that premise is being challenge, there are new sea freight services offered by both NVOCCs and regular carriers that provide reefer containers with enhanced monitoring. The main advantage being that you load everything, seal the container and, if there are no inspections along the way, you know no one is going to touch your cargo until it arrives at destination, which is something you could never have with airfreight. Volume is still an issue, but inter-company consolidation may just be the solution we're looking for, a joint approach can ensure that the quality requirements of the pharmaceutical industry (as heterogeneous as they may be) are being maintained while sharing the costs and container space. While we have joint ventures in other fronts, I don't believe we're there yet."

Stephen: "It depends on security arrangements and also the temperature requirements and value for those products, so it is really very product-specific. You have to bear in mind that some methods of shipment, for example ocean, [may] not take the high-value products because their insurance [may] not cover it. You really need to get into the detail on that to look at specific product requirements on what the supply chain provider is able to offer you. A lane risk assessment process is very helpful here. We musn't forget that at the end of our supply chain is a patient who is depending on the availability of our products."

Val: "You probably could cross off the train here, that is for sure not a good way to move high value products, and questionable in general."

"I think there is a contradiction here between compliance and time. Air shipments in general are not as safe as sea shipments if they are going correctly. Air is exposed



to flight delays and many more handling points than sea freight. So, in some ways sea freight is the safer option, however it could be more costly. in other ways

"Some products are of extremely high value, (millions). In such cases it becomes feasible to get the products to the destinations as fast as possible, because the freight cost is so small in comparison to the commercial gain from the product's sale.

[There] is almost a month time difference between shipping sea and air. So, for this reason, either high-value or extremely sensitive products are shipped by air.

"With intracontinental [travel] - we transport via truck. It makes no sense in my mind to use air within Europe. It takes the same time, involves more handling, it's more risky and it costs more. Just take a dedicated truck, but ensure the operators are trained and have agreed to your relevant documentation.

"[Also], set up and standardise your network - that is very important even if it is a little bit more costly.

"Effective custom procedures are very important to have in place. Especially in the US where there are extremely rigid import procedures. If procedures are not followed correctly, you are subject to FDA holds which opens up a window for excursions as well as added costs."

¹

Brice: "The choice of transport depends on the requirements of the customer, but especially of the product.



"A transport must be designed that way to meet expectations coming out from time and temperature sensibility. It also depends on the strategic distribution concept of a company which mode of transport may be the best. Indeed, road freight for local and regional distribution like in Europe is the safest and most cost effective way. Rail

Temperature Controlled Logistics : Supply Chain Planning

transport is today no option for temperature sensitive products and stays in no relation compared to air or ocean transports. As for the question, which mode of transport is the best for global transports, this indeed depends on the volumes, the value of products and their sensibility. There're many pros and cons for both air and ocean freight that need to be evaluated closely with the customer to decide for the best solution.

"In my opinion both will stay the main transportation modes. Ocean freight is indeed a cheap and quite reliable solution, but only accepted until a limited value and in case of damages, loses or deviation all products in a container may get needless. Don't forget, that transit times are often very long and this means an additional commercial impact on liquidity due to bounded capital. While airfreight seems to be a time and cost effective solutions for small packages such as for clinical trials and diagnostics and high value cargo is easier accepted the very high number of involved stakeholders increases risks and high transport costs for larger volumes need to be considered.

"Fortunately, the transport industry is moving forward and is establishing besides new solutions also new quality standards, as for example the IATA CEIV Certification process addressed to the airfreight industry. This will minimize in future stakeholders participating in Pharma transports, that don't invest in proper quality management systems to ensure high quality processes in transportation of pharmaceutical products."

What are the key areas to focus on when streamlining freight routes?

Stephen: "You have got to work with your LSP or service provider to try and make the efficiencies. They are the experts in this area and you need to work very closely with them on this. And again, cheapest is not necessarily best, so you need to look at risks involved in that supply chain - direct shipments via high temperature zones may not be a good thing. You may need to go a slightly more circuitous route to achieve your objectives or to transport overnight, for example.



"A lean supply chain, yes, everyone likes the idea but the patient comes first and you need to make sure that the products are adequately protected in that process."

How can your stakeholders support you to enhance your performance in the cold chain?

Stephen: "You have got to engage them, if necessary on a product-by-product basis and make sure that they are all involved in the discussion. Normally that is managed by your transport service provider, certainly the bigger ones should be able to provide that for you. They must also demonstrate good controls and an approval process for any subcontractors they engage and ensure compliance with local regulatory requirements."

Val: "In general, we need to align with the information from quality clarifying the product in question. It's information and stability data, the sensitivity of our product [being] grouped in the right risk segment and [having] good working procedures for excursions. Quality is the prime stakeholder here and the cross-functional partner that is most important to us.

"Manufacturing is an [important] stakeholder as well as planning. For instance, with the loading procedures, the packing and pre-cooling of the equipment and the awareness of risks that can occur on the sites.

"In our experience we had high-value shipments opened by customs in Romania, which is fine. However, the market had not communicated to them what kind of value was in the truck, so they left the truck

Temperature Controlled Logistics : Supply Chain Planning

open. [Therefore], during investigation they had contaminated the goods. There are all kinds of windows for miscommunication, like this, and these usually cause the worst excursions."

Ruben: "Enhanced communication lines and relationships between production planning, demand management, and warehousing & logistics are key for the transportation process. You cannot have reliable planning and stable transportation lanes and transit times if you do not have planning visibility."

"The interactions between the aforementioned SCM departments and Quality have to be aligned and properly documented to avoid delays and ensure a seamless cold-chain process."

How can the industry enhance its collaboration with partners to improve the delivery of product?

Brice: "A Partnership is a key for us in term of investment and expertise. It support our network where we do not have our own warehouses or cross docking structure, it helps growing our capabilities on all mode of transport, going further in term of Quality agreement, SOP, audits to provide the best follow and solutions for the shippers. Best example is our last collaboration with the Perishable Center at the Frankfurt Airport which includes solution on the tarmac and standard CEIV certification for both companies, working now on same Pharma standards."

"The way we need to progress is to work with our partner on the global standard certifications and processes. That's a start. Then tailor this specifically to road and ocean freight."

Val: "Deep partnerships are extremely important for the logistics in the supply chain, but also with compliance."

"We are building strategic partnerships and avoiding swapping partners without a very good reason, even if there is a cost element. The cost of change is usually quite high, especially with serious products."

"I can name a very good [case involving] a company called Controlant which has led the real-time data

logger solution for many years. We as stakeholders worked with them through the development and the pilot stage of their product to make absolutely sure that they understood the requirements of the business, why it was needed and we also gave them our projections on what the future landscape would be for a product like this."

"As a result, they brought on the market [what] I think [is] the leading product in terms of real-time data loggers. It is a preventive data logger. So with a shipment moving from A to B that is coming down to a critical temperature point. You can step in, call the driver or you can locate the product and mitigate [the incident]. This is extremely important on high-value products, oncology products. It is less important for the generics, but it is an enormous benefit for the entire organisation, not only for the logistics, but for sales and the business in total, because it literally mitigates stock-outs. So, that's my favourite type of collaboration."

Any changes in regulation that will be impacting the cold chain the industry should brace for?

Stephen: "In terms of audit trends, regulators are focussing much more on temperature requirements in the supply chain and supply chain security. Data integrity is another big area that needs to be looked at quite carefully now as well."

Ruben: "Of course GDP has been looming over us for a long time now. A huge challenge for the supply chain management departments across the board [will] be the implementation of serialisation. As it entails huge investments - in systems, packaging, and data maintenance - but also because different countries have different standards and you need to cater for every single one of them."

Any predictions on future trends within temperature controlled management planning over the next few years?

Brice: "I would consider several future trends which seems to me important. First one is the Security under TAPA levels which goes with control of the shipments on all mode of transport and structures. It is one of our main concerns."



Temperature Controlled Logistics : Supply Chain Planning



"It goes with Quality audit process and evaluations in port and airports within temperature controlled management planning.

"Other main trend is a Focus on e freight and digital documents to minimize custom process and transport documentation with air carriers to gain time and cost. Ocean LCL Pharma services into emergent regions such as Africa, is also considered.

"Last but not least real time sensors/loggers should be managed internally on IT platform in a near future"

"The parts I just mentioned are trends that should help gain the trust of the industry with a better understanding of the capabilities of the different mode of transport"

Stephen: "I think that if I was to point to any trend I would say that there is going to have to be detailed risk assessment of product and destination specific distribution lanes. It is going to be a case of matching products with distribution lanes depending on site origin and destination market.

"The other one I would say is that regulators will increase their expectations in terms of supply chain security, data management and GDP controls. We can expect more detailed scrutiny in terms of their audit assessment of what we do in distribution and how we do it."

Val: "It is absolutely clear to me that high-value and critical products will be mostly [accompanied] with real-time sensors in the future. There is a very fast trend towards that already. The cost element is now manageable and the solutions are now in the market. The producers of high-value and oncology products will invest in these monitoring devices.

"I expect that over the next few years there will be developments in the passive packaging arena with more eco-friendly [capabilities] and better return logistics. The problem with some of those solutions currently is that the return logistics are hard and [involve] a lot of waste. They break down too easily, every year we are throwing out hundreds of unusable units of passive packaging. I am sure this is now being developed in a better way, I [have] already seen a few solutions out there."

Ruben: "Things will continue to become more sophisticated in the sense that we now collect data as a routine process. Everyone is starting to make active use of integrated track and trace systems, temperature monitoring, and GPS devices in vehicles and containers. "When processed this data can give you an accurate idea of how your lane is behaving. This information can be used to take action and plan what processes, equipment and materials can be used to minimize risk, keep costs reasonable, and maintain high quality standards. We are going to see a more information-driven approach to temperature control, which in the past was more or less an educated guess.

"Freight forwarders have access to this data as well and are likely to become information aggregators as they are in a position to benchmark what is being done by their customers. An ideal situation would be to use this information to provide tailored services for an industry that is small, but growing. They already realized that they are dealing with an industry that has the means to pay for these additional services in order to safeguard product integrity."

● ● ● ● ● ● ● ● ● ● ● ● ● ● ● ●
 For further insight on temperature controlled supply chain planning, consider attending the upcoming temperature controlled logistics event in 2017 London.



30 January - 02 February, 2017 |
ExCeL London,
United Kingdom

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

Join us to:

- **'WHAT IF' ROUND TABLES – Are You Prepared For When Things Go Wrong??**
- **Developing Leaner and Meaner Temperature Controlled Supply Chains**
Julian Wann, Global Category Leader Freight & Logistics, AstraZeneca
- **The Sea Freight Working Group Present Their Updated Report**
Mark Edwards, Chairman, Pharma Ocean Freight Working Group
- **Quality Training Courses: Basic Principles of Stability Testing and a Systematic Approach to Stability Testing.**
- **Workshop: Essential GDP Compliance**
Tony Wright, CEO, Exelsius Cold Chain Management
- **Workshop: Switching to Sea Freight**
Mark Edwards, Chairman, Ocean Freight Working Group
- **Workshop Mapping Distribution Lanes in Worst Case Scenarios: Ensuring Supply Chain Quality and Integrity**

