Operating a Global Temperature Controlled Supply Chain

Cold Chain IQ Special Report

ColdChainIQ
Temperature Control Logistics & Quality Network

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Executive Summary

The size of the global pharmaceutical supply chain is growing rapidly. With the increase of outsourcing and offshoring there are now more players than ever before in the distribution chain.

Ensuring the safe storage and distribution of temperature sensitive materials remains a constant challenge for the pharmaceutical industry.

This report looks at the technologies and strategies the industry is employing to leverage partnerships and streamline processes in their supply chains of temperature sensitive products.

Over the past year Cold Chain IQ and Pharma IQ conducted individual interviews with over 100 experts from all stages of the pharmaceutical and medical devices distribution chain from logistics to quality assurance, regulators to manufacturers. In this report we share their daily challenges and how they are seeking to overcome these.

With an uncertain global economic landscape, key concerns for professionals included adhering to regulations, building value into the supply chain and implement cost-effective strategies and solutions.

Against this backdrop, Cold Chain IQ set out to examine the current challenges of operating a global pharmaceutical temperature controlled supply chain and where it is heading in 2020, with the following questions in mind:

-What is the biggest risk in establishing a logistical partnership?

-Which BRIC country represents the biggest opportunity?

- What place does horizontal collaboration have in the pharmaceutical supply chain?

-What steps are companies taking to improve service levels in their cold supply chain?

-Where is the most innovation taking place in the pharmaceutical supply chain?

During 2011Cold Chain IQ conducted several online surveys with the industry looking at investment levels in the temperature controlled supply chain and key challenges faced by professionals on which many of the findings in this report are based.

This report also incorporates the findings of the SCA live polling session conducted with 300+ logistics and QA professionals at IQPC's 11th Cool Chain Logistics Europe event.

Key Findings:

- 96% of respondents consider cold chain or temp control a core competency of their logistics provider
- BRIC in 5 years: China will present the greatest opportunity
- 63% said finding cost-effective solutions / products is their key challenge in the storage and distribution of CRT and ambient products
- 71% of professionals in pharmaceutical distribution planned to increase investment over the next 10 years.

Overview of Temperature Controlled Logistics in 2012

Background to the 11th Annual Cool Chain Logistics Europe survey

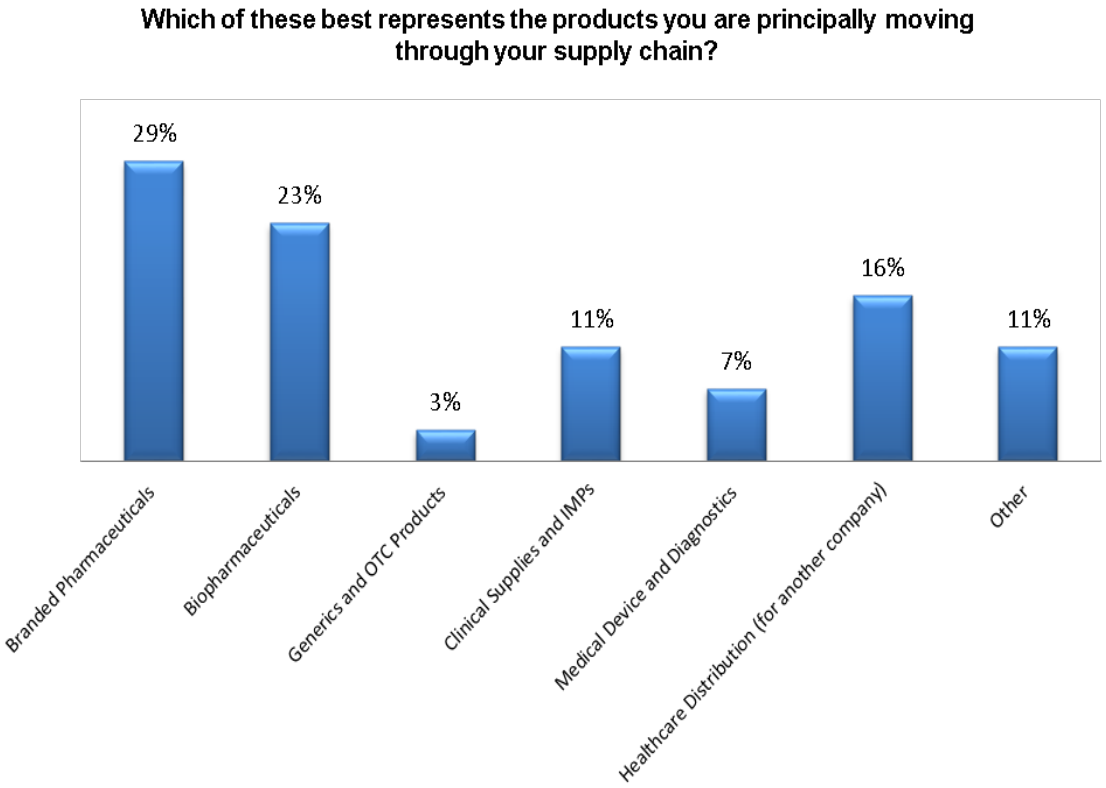
In February 2012 a live poll was carried out at IQPC's 11th Cool Chain Logistics Europe event attendees from the temperature controlled logistics and quality assurance community were invited to participate.

The poll's respondents represented all areas of the healthcare supply chain. The largest majority of respondents' products were branded pharmaceuticals 29%, followed by biopharmaceuticals 23%, healthcare distribution on behalf of another company 16%, clinical supplies and IMPs 11%, medical device and diagnostics 7% generics and OTC products at 3% respectively.

Priorities for the temperature assured supply chain

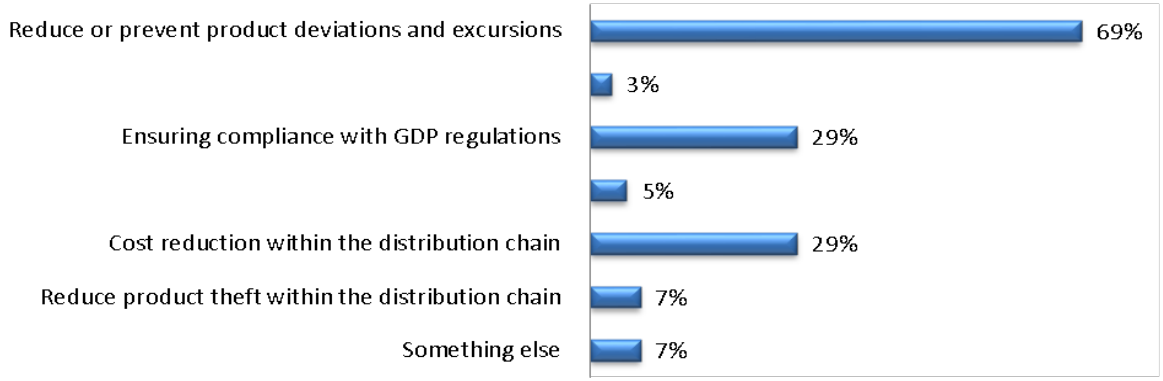
A majority of respondents 69% reported that reducing or preventing product deviations and excursions as one of their top three priorities in the temperature assured distribution supply chain.

As regulatory scrutiny increases and companies face increased cost pressures in the current economic climate other key priorities were ensuring compliance with good distribution practice (GDP) regulations and cost reduction within the supply chain, both with 29%.of respondents.



Featuring lower down the rank of core priorities where reducing product theft within the distribution chain 7%, the sustainability and environmental impact of the supply chain and moving toward the outsourcing model within the supply chain with just 3%.

What are the top three priorities in your temperature assured distribution supply chain?

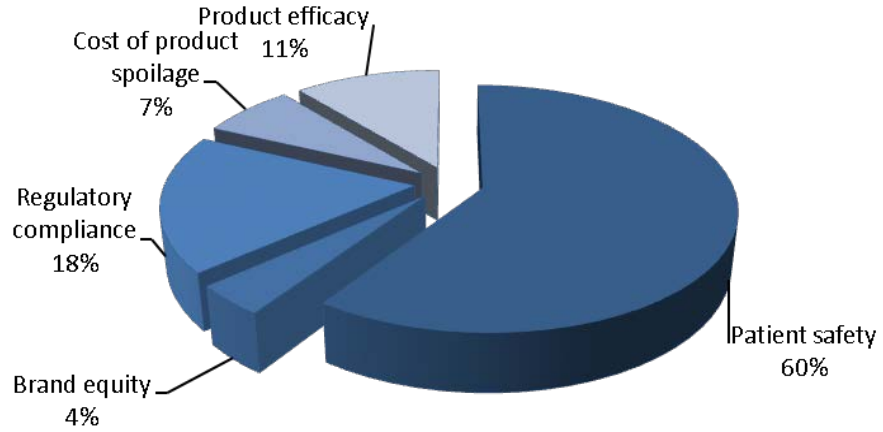


The Corporate Perspective

The pharmaceutical, biotech and medical device industries are under increasing pressure to ensure the effectiveness the cold chain and demonstrate measureable improvements to temperature controlled supply chain effectiveness.

For over half of the respondents, patient safety with 59% of the vote was the main business driver for ensuring an effective cold chain. Followed by regulatory compliance 18%, product efficacy 11%, cost of spoilage 7% and only 4% stating brand equity.

What is the main business driver within your business to ensure you have an effective cold chain



Opportunities and challenges: The BRIC economies

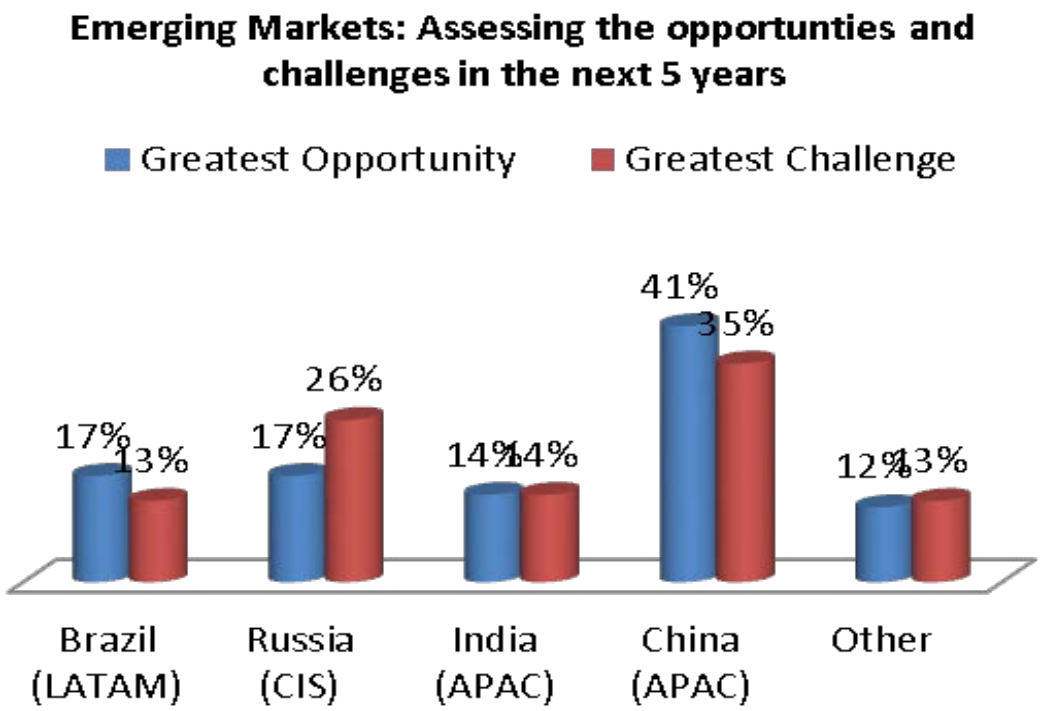
A significant number of the survey respondents – over 41% selected China as the BRIC economy which had the most opportunity for their business. Followed by Brazil and Russia both with 17% and India with 14%

However, China was also identified as the

BRIC economy that participants thought would present the greatest challenge in the next 5 years with 35% of respondents selecting the country.

Whilst many of these emerging economies have the domestic growth, many professionals are concerned that they do not yet have the infrastructure in place to support the logistic challenges of temperature sensitive storage and distribution

For many emerging markets improving the existing infrastructure is of key concern.



Focus on: Emerging Markets

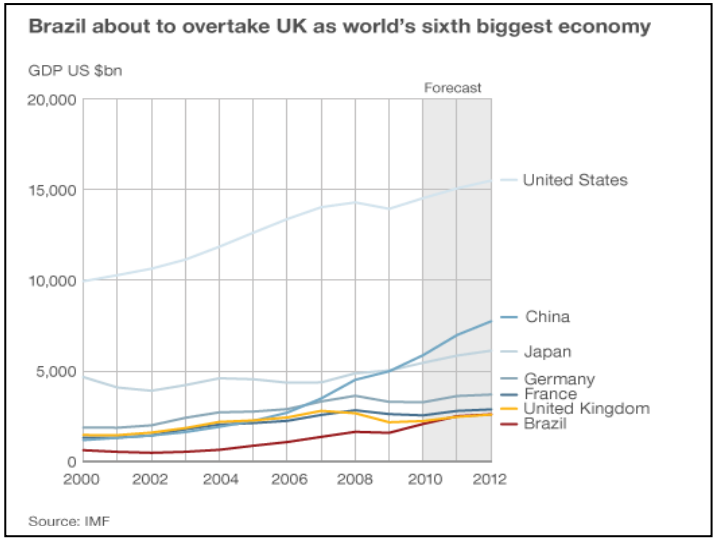
The emerging markets present perhaps the greatest opportunity and challenges for operating a global temperature controlled supply chain. Many of these countries economies are still growing at a healthy, sustainable event despite the global economic slow down and are proving to be an attractive global proposition for pharmaceutical companies looking to increase their global presence and invest in new areas.

Whilst wrapping up a visit to Latin America IMF Managing Director Christine Lagarde, spoke of the increasing role emerging markets will be play in solving global problems.

Brazil

In a press release she said: “As the balance of economic power shifts, emerging economies are a key part of the solution to the global problems. Brazil consistently presents an important voice to the world on behalf of the interests of emerging and developing economies.”

Brazil has recently overtaken the UK to become the sixth-biggest economy. The economy grew 2.7% last year, official figures show, more than the UK's 0.8% growth.



India

Fast-growing economies and large patient pools are attracting manufacturers to conduct more clinical trials in emerging markets. In turn this is increasing the demand on temperature-controlled storage and distribution of clinical supplies in high-growth regions. According to the “*BRIC Clinical Trials Report: Opportunities and Challenges*”, India is primed to become a hub for clinical research and clinical outsourcing activities, with over 53.5% identifying India as the BRIC country with the greatest opportunities for clinical trials.

“If pharmaceutical and biotech companies do not want to lose quality when accelerating clinical trials, it is important they remain aware of global standards among all stakeholders along the clinical supply chain. This requires more stringent monitoring and quality assurance activity, when quality cannot be assured the result is additional cost,” said the report.

The key concerns for manufacturers and distributors are accessibility, visibility and data. Local regulations and import and export issues

Ray Goff Director, Vaccine Production Pfizer, spoke to Pharma IQ about increased time spent implementing a clinical supply in the BRIC countries:

“In Brazil we are being asked to ensure that everything is monitored and that there is proof of monitoring. In the area of cool chain that’s going to require a little more diligence from us and we are seeing the timeline going much longer and any of the customs or logistics challenges need to be dialled into to all your estimates for supplies. At the same respect if that doesn’t happen, you end up getting more excursions which will require more supplies from you,” he said.

Pharmaceutical companies must assume responsibility for their product quality and safety and therefore need to ensure that the partners they work with in the supply chain comply with not only local but also globally recognised standards.

Russia

According to Frost and Sullivan the Russian pharma market expected to be worth $37.15bn in 2016. As the region prepares for a significant growth phase, the article "Russia: Needs to Invest in Cold Chain Infrastructure for Biopharma to Grow" examined the need for capitalise on this interest from big players within the pharmaceutical by investing in its cold chain infrastructure – an asset which will become ever more important as biopharmaceuticals develop.

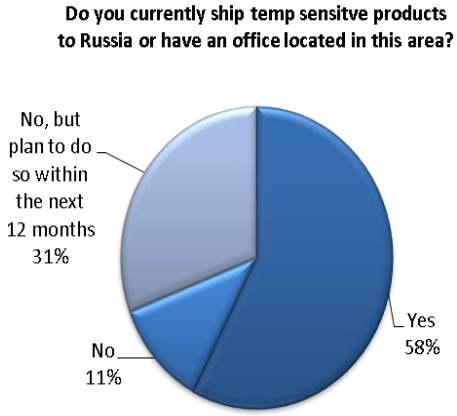
Deputy industry and trade minister Denis Manturov told the Moscow Times: "There's a lag in the technological development of facilities needed to manufacture competitive products in accordance with international standards."

Outgoing President Dmitry Medvedev has also previously declared modernisation of the pharma industry as one of his top 5 priorities.

Pharma IQ looked at how companies specialising in cold chain facilities for the pharmaceutical industry are now catching on to the demand for such infrastructure in Russia.

However, results from the Cool Chain Logistics survey conducted by Pharma IQ in October 2011 revealed that although authorities are making progress in boosting the appeal of their pharmaceutical market although not all are yet convinced about the cool chain infrastructure it has in place.

Some 58% of those polled said they currently have an office located in Russia or ship temperate-controlled shipments to the country, with a further 11% planning on doing so within the next 12 months. However, almost a third (31%) currently had no plans to start shipments to Russia in the future.



World Courier last year opened its temperature controlled distribution centre, boasting "validated storage areas for investigational drugs, diagnostic kits and medical devices", in Moscow. It is just the seventh such facility the company had opened worldwide.

Centralised depots can significantly reduce customs delays and improve regulatory permit process.

"This is particularly important in emerging markets where interest in conducting clinical trials is growing incrementally to advancements in the local infrastructure," said Wayne Heyland, president and chief executive office of Word Courier Group.

Just over one year later it announced it was increasing storage capacity at the Moscow facility, due to high customer demand.

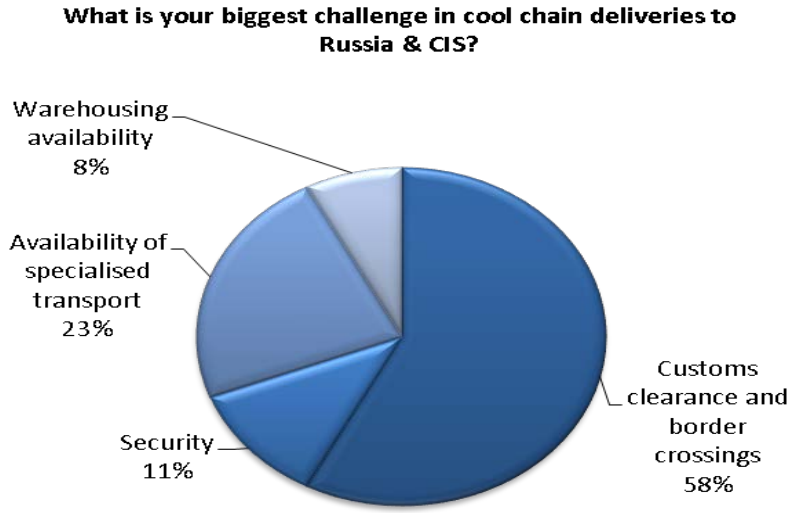
Source: Russia: Needs to Invest in Cold Chain Infrastructure for Biopharma to Grow

Looking deeper into the issue, problems start to emerge with the current cool chain provision in the country – the main one in an area where the government does have the power to improve the situation.

For those participants already shipping temperature sensitive products to Russia, customs clearance and border crossing were named as the biggest challenge in cool chain delivery by 57.7 percent of those surveyed.

produced pharmaceuticals over international imports, which has led to the signing of some lucrative deals.

Other issues raised in the Pharma IQ survey included the lack of availability of specialised transport, as mentioned by 23.1 percent of those polled, which is a particular issue given Russia's large size. Some 11.5 percent cited issues with the availability of warehousing, while 7.7 percent expressed concerns about security.



The issue could be connected with the decision by Russia to favour domestically

The Middle East

Viliam Kovac, Vice President Global Supply Chain Quality, Roche, spoke to Pharma IQ about reducing supply chain vulnerabilities and improving distribution operations across the Middle East. When asked what he thought were the three main challenges with regards to improving distribution operations across the region, he identified the cold chain first.

“I would say that a creation of a region related temperature profiles to implement adequate cold chain management controls, as a first one; then, having a specific and mutually agreed quality contracts of what need to be done as a second; and, finally, the last piece is the training, so people’s qualifications,” he said.

Mohamed Nasser, Managing Director, Eli Lilly, Saudi Arabia, also reiterated the significant business impact of the temperature controlled supply chain and the unique challenges that the Middle Eastern pharmaceutical market faces, with respect to the cold chain and temperature controlled distribution:

Nasser said: “The number one challenge we need to watch out for, is the climate in this part of the world is different from many other parts of the world, so if we are always concerned or careful about the product quality in different parts of the world, we need to be doubly careful about the quality of our product, post manufacturing, during handling and distribution

in this part of the world."

Nasser also noted distribution to remote areas based on the existing transportation systems and ensuring a closed chain even beyond the pharmacy, as key challenges for the Middle East.

One of biggest global challenges today for the pharmaceutical supply chain is ensuring supply chain integrity.

"Some studies show up to 10% of the medicines in the market are counterfeit, and again that's global percentage…. To ensure that distribution challenge is very well closed and very secure against, or circumvented against counterfeit penetration, is a significant challenge, and very, very important to make sure that quality medicine is reaching the patient."

The Business Perspective: Top Tips for Developing a Cold Chain in the Middle East

1: Look at the complementary supply chain

Before applying the pharmacy supply chain, you need to look at the distributor supply chain. Can the distributor supply in a short span of time, or in a longer span of time?

2: Be able to segment the type of business

How much the cold product represents of my total volume, and the process and the value of those cold products versus the total volume, because I need to invest correctly on the cold supply chain.

3: Maintain the security of that supply chain

How can you ensure that supply chain is very well monitored and the product coming in and coming out of the chain has the right log? By ensuring that the system in place is closed and secure.

(Source: Understanding the Importance of Cold Chain as Part of the Bigger Picture)

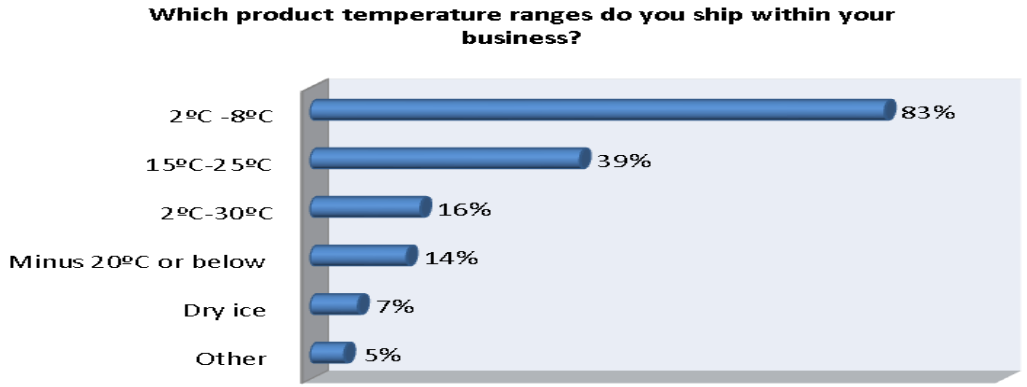
Controlled Room Temperature

Temperature control is a critical part of product integrity improper handling especially of temperature-sensitive pharmaceuticals can compromise the efficacy and safety of drugs and pose just as serious of implications to patients' safety.

With the number of temperature-sensitive drugs set to rise over the next few years. Controlled Room temperature (CRT) is becoming an important temperature range. Thermal deviations outside of the CRT envelope can comprise efficacy and patient safety.

As a result, regulators around the globe are paying closer attention to temperature controls and data results from shipments of CRT and "ambient" products. This attention has changed the industry discussion from cold-chain management to temperature controlled management for all ranges of product temperature sensitivity.

Whilst the majority of respondents of the 11th Annual Cool Chain Logistics Europe 2012 survey (83%), distributed products between 2ºC - 8ºC, the second most popular temperature range that respondents shipped their products in was 15-25ºC at 39%.



Gary Hutchinson, cold chain expert in thermal packaging engineering and controlled environment logistics for biotechnology and high risk product and President at Modality Solutions predicted that the CRT supply chain landscape was set to grow.

"I think that's going to be a huge market. I don't think the volume is necessarily increasing, but the stance that the regulators are taking and even internal quality people at each individual pharmaceutical company are really starting to ask some questions about at least our product at controlled room temperature and how do we maintain that temperature and show those controls in our distribution channels as well," he said.

Pharma IQ asked Jim Lucie, Senior Manager for Material Control at AMAG Pharmaceuticals, about what recent supply chain trends he had witnessed.

He said: "[The Industry] seems to be more focused now on the CRT portion of shipments as drugs come off 2ºC - 8ºC and they try to get a wider range for shipping and storage, which just makes it easier for the supply chain itself, from a drug standpoint, but it seems like there's a new focus on control room temp from the shippers, and a little bit closer look at that even from a regulatory standpoint."

According to the recent Pharma IQ study, Storage and Distribution of CRT and Ambient Products conducted earlier this year, increased regulatory scrutiny is being felt by the industry with respect to the handling of CRT products in the supply chain.

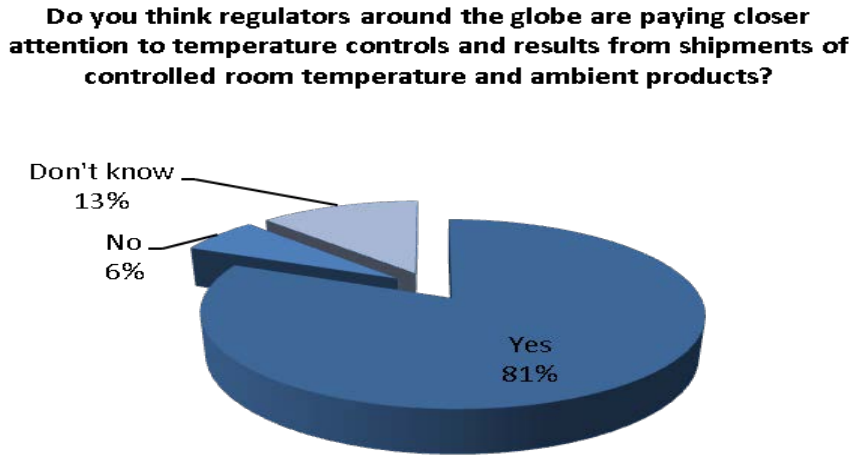
An overwhelming 81% of respondents think regulators around the globe are paying closer attention to temperature controls and results from shipments of controlled room temperature and ambient products.

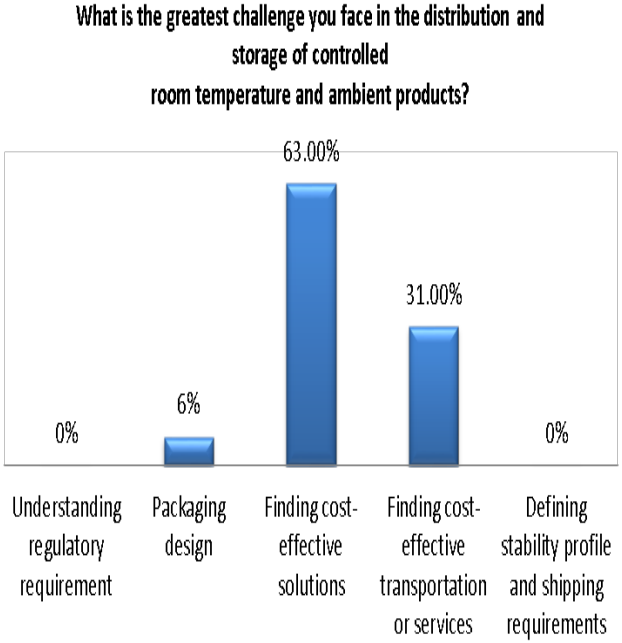
countries with variable climates and redesigning packaging and labels which are mainly for use at chill and frozen temperatures.

For the majority of survey respondents, cost was their greatest challenge. With finding cost effective solutions at 63% and finding cost effective transportation and services at 31%. Only a small number indicated packaging design at 6% as their greatest challenge when distributing and storing CRT products and none identified defining stability profile and understanding regulatory requirements.

products.

“A lot more questions over the control of these products are coming up for transit and there are several attempts to maintain this tight range especially for clinical items. I think manufacturers are better able to demonstrate robustness of these products for ambient shipping and should do that,” said English.





Collecting ambient data can be a time-consuming and expensive project. There are a number of challenges associated with determining temperature profiles for (15-25ºC) and (15-30ºC) regimes, distributing to

Michael English, Senior Product Engineer of Packaging Technologies at Merck, also highlighted the increased attention by the industry on distribution of ambient and CRT

Implementing a Quality Management System

As reducing the number of excursions and deviations in the supply chain is a key concern for the majority of temperature controlled logistics and quality management professionals. The 11th Annual Cool Chain Logistics Europe survey also looked at the current percentage of excursions and deviations of temperature sensitive product whilst in the distribution chain.

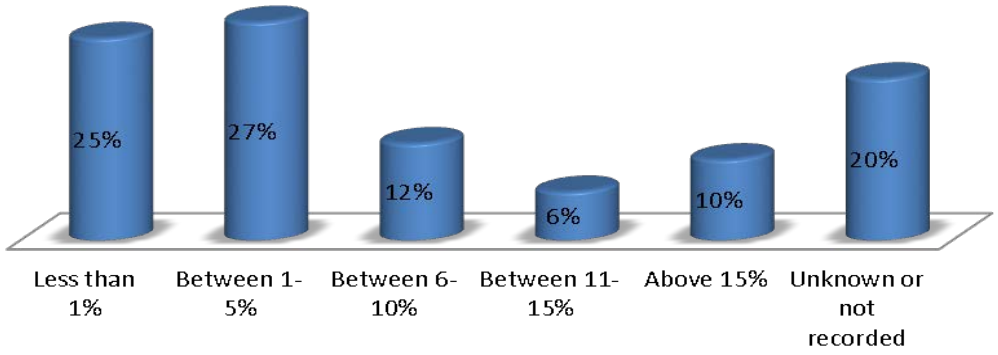
It found that at least 10% of respondents had recorded a deviation or excursion in above 15% of their temperature sensitive product whilst in the distribution chain.

One way that the industry is looking to overcome this challenge is implementing a quality management system (QMS).

A QMS can be expressed as the organisational structure, procedures, processes and resources needed to implement quality management. It encompasses all of the critical control points in delivering a high quality pharmaceutical customer to the end customer.

> A good Quality Management System should be in the DNA of a company - Tony Wright

Currently what percentage of temperature sensitive product shipped is recorded as having an excursion or deviation whilst in the distribution chain?



Implementing a QMS involves:

- **Understanding the requirements**
- **Putting procedures in place**
- **Understanding the risk**
- **Mitigating risk**

Implementation of a sound QMS within the temperature controlled logistics process is increasingly expected by the shippers and the regulators.

“We have heard that there have been many adverse reactions in related to product that has been delivered under unsuitable conditions,” said Dr. Mary Mazur-Melnyk to Cold Chain IQ.

Maintaining quality in the supply chain is essential to successful healthcare logistics. In a recent Pharma IQ interview industry expert Tony Wright, CEO of Exelsius Cold Chain Consultancy said: “A good Quality Management System should be in the DNA of a company.”

It is important to understand what a product can handle at each step to avoid product recalls and adverse reactions.

Quality should be built in from the beginning of the supply chain from R&D down to delivery to the end user.

Mazur-Melnyk said: “A Quality Management System is key. We have all heard, quality has to be built in to the process and product, it can’t be tested in.”

Speaking of the consequences of not following a quality management system, she said: “You can see a company that has not followed a quality management system is testing and testing and the costs are increasing and the stability programs are increasing, product losses are increasing”.

When implementing a QMS one of the key challenges companies face is how to define their quality management system and understanding what the mechanism is about.

> Quality has to be built in to the process and product it cannot be tested in - Dr. Mary Mazur-Melnyk.

Wright broke the quality management system down into three simple principles:

1. **Document what you do** put on record all the processes and procedures that are part of your business and your involvement in temperature sensitive logistics.
2. **Put into practice** some of the things you’ve written down as your process and procedures
3. **Use the system to prove what your system says** use the quality management approach as a way of improving what you do.

Many misconceptions still surround quality management systems, such as they increase cost or provide unnecessary complications. However as Wright highlighted not implementing a QMS can be more detrimental for a company:

“Quality seeks quality. Bio-pharma manufacturers will want to do business only with those service providers that operate a quality management system, so if you don’t have one, then don’t expect to be a preferred partner,” he said.

“I think companies not using a quality management system will typically be noted for having disjointed and inadequate procedures. They won’t, for example, have qualified their equipment to a high standard, and I think one other feature of companies that don’t have a quality management system is that they do spend a disproportionate amount of their time in the correction stage, correcting things that have gone wrong, and not using a quality management approach to take those learnings that have come out of the correction process back inside the business, and doing things right the first time,” he added.

All stakeholders in the temperature controlled supply chain need to have quality at their heart to ensure effective temperature assurance.

Ready to take the temperature of your QMS?

Here's a simple test with Pharna IQ columnist Jon Wetzel to see where your QMS really stands:

- **Go through your active SOPs and find any that are older than 1 year**
- **Take the SOP to the work area and watch the process. (Going to the Gemba)**
- **See how close the SOP is to the actual work being done**

Are you running a high QMS out of tolerance fever?

- **Don't freak out**
- **Don't point fingers or play the blame game**
- **Ask the workers what the best way is to get everything back up to speed**
- **Empower them to get everything back on target**

When you pay your staff to do a job with their hands you also pay them for their experience and intelligence. It's your job as a company to find a way to harness that. That's what it takes to be "Best in Class".

(Source: Putting the "Quality" back into Your QMS)

Just in Time and Multi-Use Packaging

Time is probably the most critical factor in the distribution of temp control clinical supplies.

Running clinical trials effectively can provide a company competitive advantage and clinical supply professionals have a unique understanding of just how important it is to ensure timely dosage of patients and keep to trial timelines.

Dan Holst Jakobsen, Systems Specialist & IT Coordinator and Abhijit Bendre Business Analyst CMC Clinical Supplies from Novo Nordisk, spoke to Pharma IQ about reducing risk in the clinical supply chain of temperature sensitive IMPs and materials by shortening the lead times between packaging and the patient.

They talked about the advantages of postponing packaging decisions as much as possible so that we can have more precise information about demand is at hand.

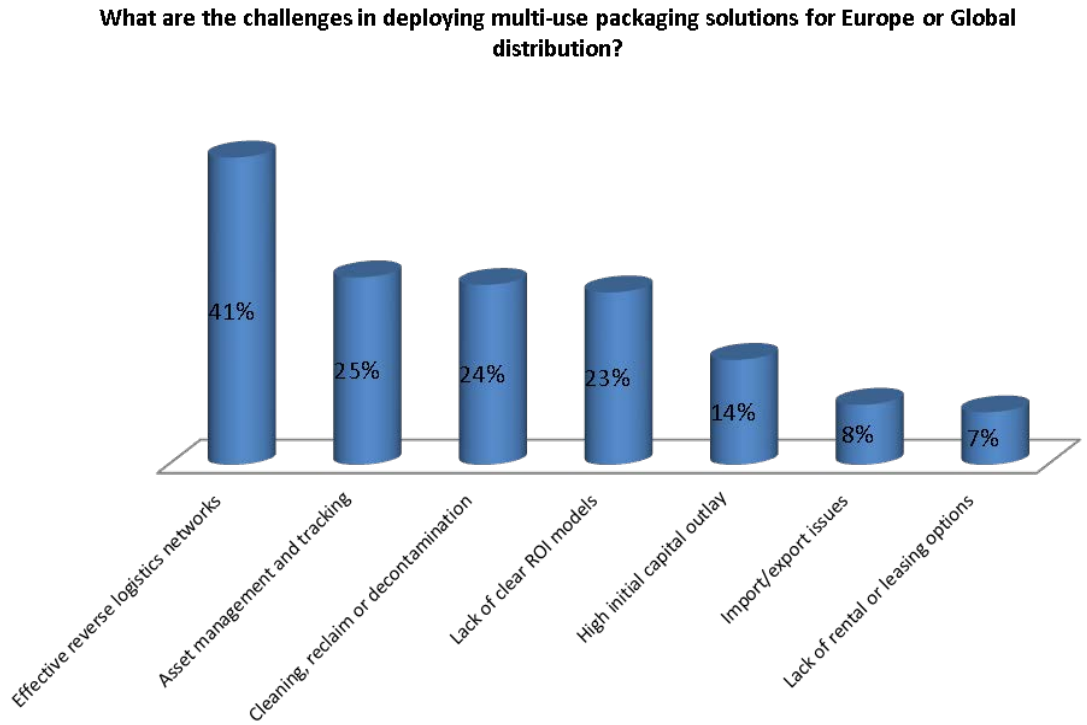
“Just in time printing and packaging would be a great way of reducing risk because you have less product in the supply chain,” said Jakobsen.

One of key challenges for temperature controlled clinical supply is reducing the amount of overages.

There are many challenges the pharmaceutical industry faces in deploying multi-use packaging solutions for European or Global distribution.

In the 11th Annual Cool Chain Logistics Europe survey, the majority of respondents 41% found effective reverse logistics networks a challenge.

at 25%, cleaning, reclaim or decontamination standards/methods to satisfy QA 24%, lack of clear ROI models 23%, high initial capital outlay 14%, import/export issues 8% and lack of rental or leasing options respectively.



Reverse Logistics

According to Martin Wegner, Vice President of DHL Solutions and Innovations (DSI), the key drivers for implementing a reusable shipping system are availability and cost.

> I believe with reusable systems we can reduce cost, which will meet the needs the of the pharmaceutical industry, especially looking at generics, where we see the need for alternative and low cost solutions - Martin Wegner

An integrated supply chain strategy that incorporates both forward and reverse logistics becomes increasingly important in an increasingly globalised and stretched supply chain management reality. Effective reverse logistics can help manufacturers reduce 40-60% costs by only 20% of the manufacturing effort. (Tan, A.W.K. and Hosie, P. 2010) Reverse logistics is all about setting metrics for cost saving and efficiency-boosting investments.

The main challenge is to devise a reusable system that will have lower cost than a one-way system.

Wenger spoke to Cold Chain IQ about the need for a smart solution to overcome this challenge: “The availability plays a big role in this, because in a lot of cases face imbalanced trade lanes so we have demand in one way, but no demand the way back, which this puts a challenge on the containers, because you would have to transport them back without any goods inside, which again increases the cost. “

In the next 2- 3 years Wenger believes we will see a big uptake in reusable systems due to cost pressure especially in the transportation of generics.

“I believe with reusable systems we can reduce cost, which will meet the needs the of the pharmaceutical industry, especially looking at generics, where we see the need for alternative and low cost solutions based on reusable systems., “ he said.

In contrast, some also question whether reverse logistics really save money, when further validation is always required to ensure temperature assurance and re-testing of equipment is required to make sure packaging is still reusable.

Gary Hutchinson, President at Modality Solutions commented: “I don’t think reusable packaging systems are going to get much of an uptake because I think the challenges are just really too great. “

He continued: “Because a lot of the reusable technologies, especially the vacuum panels, are fairly fragile in the sense that they can very quickly end up losing their effectiveness if they’re damaged in transit. So, you’re going to have to put some sort of inspection or requalification in place to make sure the equipment that you sent out is still viable.’”

It is crucial to build a robust quality assurance process to avoid costly delays.
For all companies their experience of forward logistics is greater than of their reverse logistics. “Everyone’s goal is to succeed and see their compound through regulatory approval and through to commercial success reversing the process distances you from this goal,” said Robert Bronstein, Director of Clinical Supply Operations, MacroGenics.

> Everyone’s goal is to succeed and see their compound through regulatory approval and through to commercial success reversing the process distances you from this goal - Robert Bronstein

The need to reduce risk in reverse logistics is just as important as for forward logistics. “Risk

mitigation for the reverse supply chain is difficult and requires planning for all possible outcomes. You must always have a plan ready to execute should it become necessary to reverse the clinical supply chain or recall a product or component," Bronstein said.

Bronstein shared example of one of the processes that MacroGenics have in place to bring supplies back.

When initiating a site they have the site fill out documentation with regards to their destruction capabilities. Should anything negative occur at the site, can they destroy product at the site or do they need to return? This enables MarcoGenics to plan a strategy in advance.

In order to measure the success of reverse logistics, goals must be set for customers and partners and evaluating your outsourcing partners' capabilities in reverse logistics.

There will also be an increased demand for visibility and tracking in transport logistics.

Green Initiatives

The pharmaceutical industry like many other industries around the world is facing pressure from the public and governments to reduce their environmental impact.

As focus shifts towards reducing carbon emissions, the pharmaceutical industry finds itself facing a dilemma in maintaining strict safety standards while improving its environmental credentials.

In "Cutting Waste in the Cold Chain" Geraint Thomas, Technical Director at Laminar Medica wrote: "The suppliers and users of temperature controlled packaging systems are under increasing pressure to reduce the environmental impact of cold chain shipping. The widespread introduction of formal corporate social responsibility policies, together with new customer expectations and more strict regulations, mean that developing a suitable packaging system is more challenging than ever."

But can a resource and energy intensive area like cold chain ever become truly sustainable?

The Cold Chain IQ article "Can the Cold Chain Ever Become Truly Sustainable?" addressed this challenge: "In many countries around the world the idea of an environmentally-friendly cold chain is just not viable. This does not represent a lack of commitment to green issues, but more the challenge of establishing even a basic cold chain in the first place," said the IQ.

Thomas explained the importance of considering how your temperature controlled packing system impacts on the environment, and suggested approaches for minimising both your waste and costs.

"While it might seem at first necessary to reduce the amount of packaging used, it is important to note that under packaging is usually far worse for the environment than over-packaging. Over-packaging by 10% means that 10% of the resources needed to produce the packaging are wasted, and extra fuel will be needed to distribute it. However, under-packaging that results in the product being spoilt or damaged wastes 100% of the resources used to produce both the contents and its packaging, and all the fuel used to distribute it," he said.

Mark Goh, Director of Industry Research, The Logistics Institute of Asia Pacific, told Cold Chain IQ, in order to 'go green' in the pharmaceutical cold chain, you must first identify the areas where you can green and which are going to be more amenable.

He said: "I think the low hanging fruit in this case would be the secondary packaging. And today the good news is there are smart astute service providers out there in the market place who are focusing very strongly on making sure that packaging is reusable and particularly in the area of secondary packaging."

Goh commented on the fact that we are already seeing investment by logistics providers in this area.

"Good service providers in logistics, such as UPS and DHL in fact have invested good money into this area. One example that UPS is doing, is to look at the end of life of products and packaging. If done correctly it goes along way to recapture much of we produce and not really consume directly."

"Today in the context of Asia, there are legislations that are driving the use for reusable packaging more so than the customers or the companies themselves, and that is a good sign," he continued.

However, there are still many doubts as to how green the pharmaceutical cold chain can be.

"Personally I doubt if we could have an entire green cold chain from source to point of supply. Certain links can certainly be greener than others. The biggest challenge would be to have green vehicles which often form at least 3

links in the chain," John Ackerman Chairman South African Refrigerated Distribution Association said to Pharma IQ.

The participants where asked to pinpoint the 3 main solutions in which their organisation was investing to improve the temperature controlled supply chain.

The balancing act of reducing the environmental impact of pharmaceutical cold chain distribution whilst reducing cost is growing in importance among all stakeholders.

Building a robust green pharmaceutical cold chain is not just about the packaging. Installation of renewable energy technology at the warehouse and utilising alternative fuels during distribution are also avenues being explored for reducing the supply chain's carbon footprint.

This exploration looks set to continue as companies seek to implement green strategies efficiently and that can ultimately reduce cost.

Today in the context of Asia, there are legislations that are driving the use for reusable packaging more so than the customers or the companies themselves at that is a good sign – Mark Goh

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Balancing Act

The range of packaging solutions and materials now available is greater than ever, presenting many new and exciting opportunities, but it is important to think about how the materials you choose will be disposed of, and the impact this will have on the environment. The waste hierarchy provides a useful framework with which to do this. By specifying the most efficient packaging solution available, you can reduce your waste, improve the sustainability of your business, and ultimately lower your operating costs.

(Source: Cutting Waste in the Cold Chain)

Working with a New Logistics Partner in the Supply Chain

Ensuring a robust temperature controlled supply chain is among the most pressing issues facing pharmaceutical and biotech manufacturers today and working with the right logistics providers is one of the keys to successful cost-effective distribution.

Outsourcing is now a fundamental part of drug development and distribution and the Pharmaceutical Distribution survey report conducted in 2011 found that 71% of professionals in pharmaceutical distribution planned to increase investment over the next 10 years.

The report on the Pharmaceutical Distribution survey examined the relationship between manufacturers and of third party organisations in the temperature assured supply chain.

"Partnerships between pharma and logistics firms must be based on mutual understanding and trust if supply chains are going to work, with product integrity intact throughout the journey from lab to end user," said the report.

Setting the evaluation criteria for new logistics provider can be a complex task when defining a global strategy for temperature assured pharmaceutical distribution and it is important to strike the right balance between global and local resource.

As part of the 11th Annual Cool Chain Logistics Europe survey, participants were asked to identify the most important capabilities they look for when selecting supply chain vendors to work with in your temperature assurance supply chain.

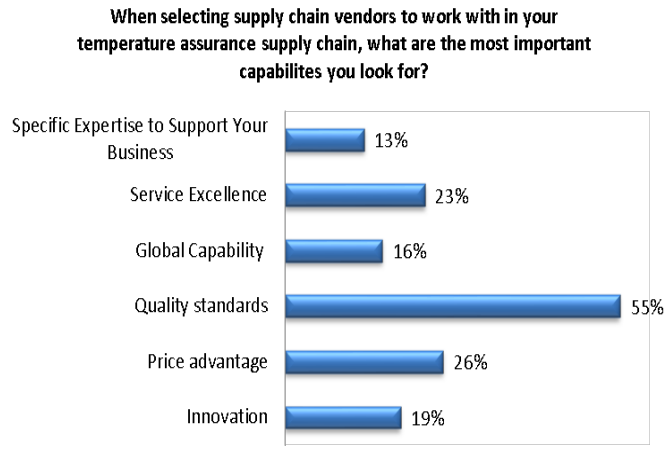
Over half of the respondents, 55% said quality standards. Followed by 26% price advantage, 23% service excellence, 19% innovation and 13% specific expertise to support their business.

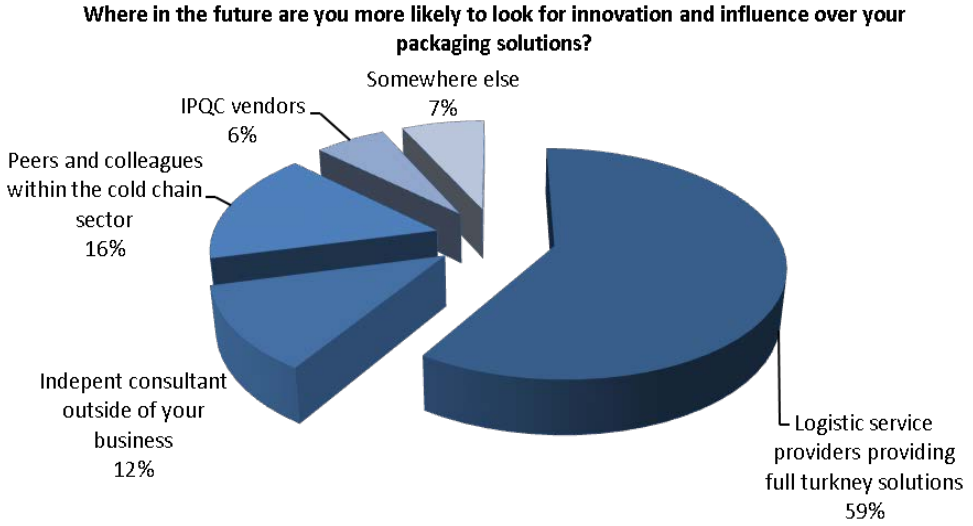
Therefore it is critical to select a partner who has as good track record of adhering to quality standards and maintaining supply chain integrity.

As the healthcare industry focuses on core competencies, and the supply chain dynamics change, nearly 60% of participants said they were likely to for innovation and influence over their packaging solutions from logistics service providers who can provide full turnkey solutions. Whilst 16% of respondents said they were more likely to look for influence and innovation from their peers and colleagues within the cold chain sector.

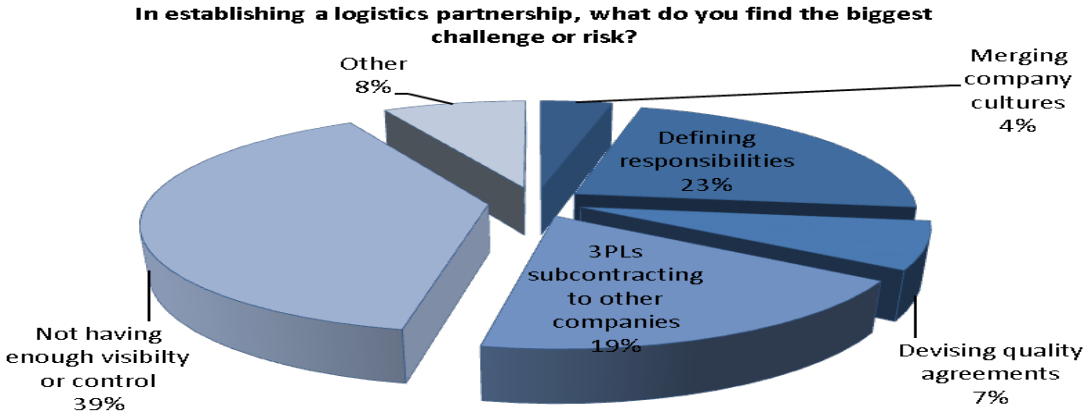
> Partnerships between pharma and logistics firms must be based on mutual understanding and trust if supply chains are going to work, with product integrity intact throughout the journey from lab to end use – Pharma IQ

Pharmaceutical and biotech companies are taking various steps to improve their service levels in their cold chain supply, from investing in new technology and infrastructure to increasing the number of partnerships with service providers.





As part of the Cool Chain Logistics survey, respondents were asked what they found was the biggest challenge or risk in establishing a logistics partnership. For 39% of respondents not having enough control or visibility was the biggest risk. This was followed by defining responsibilities 23% and 3PLs subcontracting to other companies 19%, devising quality agreements 7% respectively. Merging company cultures was only big risk for 4% of respondents. For 96% of respondents, cold chain or temperature control was a core competency of their logistic service provider.



Summary

In summary a global reach and local market expertise is essential for ensuring seamless distribution of temperature sensitive pharmaceuticals on a global level. Manufacturers and distributors alike must address global and local challenges together to ensure a temperature assured supply chain. Investment in new technologies and infrastructure alongside robust partnerships can reduce cost, maintain quality and increase efficiency.

As the number of temperature sensitive drugs increases in the pharmaceutical pipeline – are you ready for this explosive growth?

Interested in Finding Out More?

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New Look, New Format, New Ideas - Sign up Today at **www.coldchainiq.com.**

The ideas presented in the white paper will be discussed in further detail at our Global Series of Cold Chain and Temperature Controlled Distribution events. Hear from leading experts as to how they are ensuring the integrity of their temperature controlled logistics. To find our more or to sign up for an event, please visit www.coldchainiq.com or contact our customer services team on customerservice@coldchainiq.com.

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About Cold Chain IQ

Free Pharma & Biopharm Industry Best Practice Information at Cold Chain IQ

An international resource centre for the temperature control life science professional, Cold Chain IQ delivers insightful, unbiased information about today's 'hot topics'.

Members benefit by reading expert analysis, trend-setting articles, listening to podcast interviews, watching video features and top-rated presentations from IQPC's global temp control supply chain event series.

Cold Chain IQ focuses on all areas of temperature controlled logistics, distribution and quality in pharmaceuticals and biotechnology.

Cold Chain IQ, part of IQPC, maintains the largest cool chain pharmaceutical international database, offering strategic partners, members and contributors an unparalleled opportunity to network, share ideas and disseminate best practice information across the globe with peers.

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Appendix

Focus on: Emerging Markets

BRIC Clinical Trials Report: Opportunities and Challenges

http://www.pharma-iq.com/clinical/white-papers/bric-clinical-trial-report-clinical-trials-opportu/

An Interview with Ray Goff, Director, Vaccine Production, Pfizer - Clinical Trial Supply Trends and Challenges

http://www.pharma-iq.com/clinical-supply/videos/an-interview-with-ray-goff-director-vaccine-produc/

Viliam Kovac: Mitigating Risk in the Global Pharmaceutical Supply Chain

http://www.coldchainiq.com/supply-chain-security/articles/viliam-kovac-mitigating-risk-in-the-global-pharma/

Mohamed Nasser, MD, Eli Lilly (Saudi Arabia): The Business Impact of Cold Chain Supply

http://www.coldchainiq.com/supply-chain-security/podcasts/mohamed-nasser-md-eli-lilly-saudi-arabia-the-busin/

Controlled Room Temperature

Gary Hutchinson: My Do's and Don'ts for Integrating Cold Chain Management Systems

http://www.coldchainiq.com/supply-chain-security/podcasts/gary-hutchinson-my-do-s-and-don-ts-for-integrating/

How are Temperature Restrictions for Ambient Temperatures Affecting Packaging Design?

http://www.coldchainiq.com/beyond-2-8c-crt-and-ambient/articles/how-are-temperature-restrictions-for-ambient-tempe/

Implementing a Quality Management System

What is a Quality Management System?

http://www.coldchainiq.com/quality-management/podcasts/what-is-a-quality-management-system/

Tony Wright on The Importance of having a Quality Management System

http://www.coldchainiq.com/quality-management/articles/the-importance-of-having-a-quality-management-sys/

Putting the “Quality” back into Your QMS

http://www.pharma-iq.com/pre-clinical-discovery-and-development/columns/putting-quality-back-into-your-qms/

Just in Time and Multi-Use Packaging

Challenges in Cold Chain Logistics and Just in Time Packaging

http://www.coldchainiq.com/clinical-supply/articles/challenges-in-cold-chain-logistics-and-just-in-tim/

Reverse Logistics

REWIND: Reverse Logistics in Clinical Trial Supply

http://www.coldchainiq.com/clinical-supply/podcasts/rewind-reverse-logistics-in-clinical-trial-supply/

DHL's Martin Wegner: Implementing Cost-Effective Reusable Shipping Systems

http://www.coldchainiq.com/packaging-shipping-systems/videos/dhl-s-martin-wegner-reusauble-shipping-systems/

Gary Hutchinson on the Three Rs of Logistics: Reusable, Reverse & Requalification

http://www.coldchainiq.com/transportation-logistics/articles/gary-hutchinson-on-the-three-

rs-of-logistics-reusa/

Green Initiatives

Cutting Waste in the Cold Chain - Geraint Thomas, Laminar Medica

http://www.coldchainiq.com/packaging-shipping-systems/articles/cutting-waste-in-the-cold-chain/

Can the Cold Chain Ever Become Truly Sustainable?

http://www.coldchainiq.com/packaging-shipping-systems/articles/can-the-cold-chain-ever-become-truly-sustainable/

Is Your Pharmaceutical Packaging Solution about to Fail?

http://www.coldchainiq.com/packaging-shipping-systems/articles/can-the-cold-chain-ever-become-truly-sustainable/?

Finding the Optimal Route for Cold Chain

http://www.coldchainiq.com/supply-chain-security/articles/finding-the-optimal-route-for-cold-chain/