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Temperature Control Logistics
& Quality Network

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Temperature Controlled Storage & Distribution in Emerging Markets

5 Local Insights from the Frontline








Produced in association with

14th Annual COOLCHAIN
Temperature Controlled Logistics Europe   

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Introduction

Pharmaceutical manufacturers face daily challenges during the storage, distribution and importation of their temperature-sensitive products. As the complexity of the global cold chain increases, it is more important than ever to have a reliable logistics partner, with local knowledge who is eager to adopt best practice and ready to invest time and effort into partnership development. Having a local partner allows access to knowledge of the market and cost-effective solutions.

In an increasingly complex global supply chain a one size fits all approach to temperature controlled logistics just won't work. *"Never say: "we are not doing this and that in the rest of the world". Be flexible and ready to address challenges due to local legislation,"* **said Mikhail Khazanchuk, Regulatory Affairs Project Manager, Novo Nordisk A/S.**

The emerging markets continue to be an attractive proposition for pharmaceutical and biotech manufacturers. However, in many emerging countries, there are unique challenges - whether regulatory, import law, cultural, financial or even perhaps political to overcome to ensure the time and temperature sensitive delivery of shipments.

"The greatest growth for pharmaceutical cold chain shipments will most likely come from emerging markets. Africa, Asia and Latin America signify key emerging markets for the pharmaceutical industry, but are also the main areas of challenge for time/temperature sensitive products," **said Saddam Huq QA Senior Manager, Global Logistics & Cold Chain, GSK Biologicals in a article for Cold Chain IQ.**

"Even though the world is getting smaller, the supply chain model for handling time/temperature sensitive drugs are getting overly complicated. This has resonated with more regulators now addressing their cold chain expectation for drugs entering their market and also setting standards for their local distribution requirements. Emerging markets like Saudi Arabia, Singapore, Malaysia and Brazil are among the countries that have made documentation of shipments of cold chain pharmaceuticals an entry requirement," he continued.

In this interactive eBook we speak to several experts from around the global about the storage and distribution of temperature-sensitive products in their region. They share their insights on market conditions, top tips for improving operations on the ground and successfully sourcing logistic partners in emerging markets.

Best regards

The Cold Chain IQ Team

14th Annual COOLCHAIN
Temperature Controlled
Logistics Europe 

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Spotlight on Russia



Mikhail Khazanchuk, Regulatory Affairs Project Manager, Novo Nordisk A/S

Mikhail Khazanchuk is a Regulatory Affairs and Supply Chain Quality professional with over ten years in the cosmetics and pharmaceuticals industries. His experience includes developing CMC documentation for biotech products and driving cross-countries projects on marketing authorization. Mikhail has broad experience in maintaining Quality Management Systems in accordance with ISO 9001 and GMPs and training co-workers on the same requirements.

Market Conditions

Russia faces lack of GMP implementation. We are at the beginning of a long road to setting GMP standards in practice while having clear understanding of the authorities' expectations.

The most promising opportunity is current development of a GDP guide in the Eurasian Economic Union which is represented by Russia, Belarus and Kazakhstan. It has been recently announced by the union officials that GDP rules will be adopted by October this year. Should the guide be set in force it will raise the regulatory bar and hopefully create a solid basis for compliance.

The main threat in temperature controlled logistics in Russia, is regulation is quite basic and currently insufficient to protect drug quality and safety during distribution.

What advice would you give to an outsider to the Russian market?

Do your utmost in ensuring compliance with the best practices. By doing this you'll give clear signal to both internal and external stakeholder regarding your commitment to compliance and patient safety.

How would you establish operations on the ground in Russia?

I would definitely do it through local partnership or presence. Firstly, define who is the ideal partner you are looking for. Consider which assets like skills, premises service etc. should be in place and what you are ready to develop together. Cultural differences might be absolute obstruction. Make a long list of potential partners and then try to benchmark whether similar companies or even competitors run business together with the ones from your list and what was the outcome. Industrial associations might be a valuable place to get required information. Invite the most promising partners for bidding and decide who you want to work with. Remember to consider and highlight mutual benefits of the partnership. Due to regulatory uncertainty the manufacturer has to put more efforts into finding reliable partners and developing a secured supply chain.

My top tip for overcoming customs & import challenges in Russia

Most ideally to work with a broker who has experience in customs clearance of the items you need to import or export. Otherwise you might be unprepared to respond to challenges addressed to you by the authorities.

Don't miss Workshop A Breaking Into and Optimising Operations in Emerging Markets

**Workshop Leader: Mikhail Khazanchuk, Regulatory Affairs
Project Manager, Novo Nordisk**

Monday 26th January 2015!

In this interactive session, discuss with several experts on different emerging markets what challenges are common, what unique issues have cropped up, and if they could launch all over again, what they would do differently!

- ▶ Doing the groundwork: Understanding the unique market conditions
- ▶ Setting up operations: Tips on how to get started
- ▶ Ensuring compliance: Factoring in any specific local regulatory (or legal) requirements
- ▶ Risk management: Avoiding the common pitfalls!

To find out more go to: www.coolchaineurope.com

Spotlight on Qatar



Moataz Mostafa, Procurement & Supply Chain Division Manager, Ebn Sina Medical –Doha Qatar

Moataz Mostafa, pharmacist by education, graduated from Alexandria University, Egypt with more than 8 years experience in the pharmaceutical field with multinational pharmaceutical companies. (Solvay, Eli Lilly & Novartis) Currently employed by ISO Certified Ebn Sina Medical Qatar, premiere pharmaceutical distributor for top multinational & regional pharmaceutical and medical equipment as Procurement & Supply Chain Division Manager where he managed with his team to pass successful audits by several multinational pharmaceutical firms.

Have been exposed to more than 150 certified training hours in various fields like GxP –WHO Guidelines, Cool Chain Management. Currently pursuing his certification from American Association for Operations Management (APICS) for CSCP.

Market Conditions

The pharmaceutical sector in Qatar is poised for growth over the next few years in line with the growth trend in Gulf Cooperation Council (GCC). A major driver to this will be the projected growth in the economy, especially after Qatar winning its bid for FIFA World cup 2022. This has accelerated growth in all areas, from population size to massive infrastructure projects. On the healthcare side, Qatar has well structured plans in place to promote leadership in this segment with regards to medical education.

Despite small size of the market, the pharmaceutical sector is expected to have bright future, with the recent availability of innovative therapeutics in the global market. On the regulatory side, recent legislation in early 2012 proposed by the Supreme Health Council towards deregulation of pharmaceutical imports to encourage free market competition, coupled with the most recent decision for GCC price unification, will bring down the high prices of chronic medication and increase the availability of affordable medications.

The GCC pharmaceutical market is projected to expand at a CAGR of 6%-8% between 2010 and 2020, with the pace of industry expansion in Qatar projected to outpace the regional growth. Increased domestic production, foreign investments and consumption of generics are likely to support the market's evolution.

Since almost the entire drug consumption in the State of Qatar is composed of imported products local manufacturing activities have been very limited so far. Relatively high market prices coupled with a strong ability to spend have made the country's consumers among the highest healthcare spenders in the MENA region.

Being an import dependent market, there have been developments in the supply chain with advanced distribution models adopted from partnerships with global pharmaceutical players. Yet for the global manufacturers it's not feasible to establish operations in a small market like Qatar. The preference being going to larger markets in terms of population like Saudi & UAE and managing distribution to other relatively small markets like Qatar, Bahrain, Oman through local distributors by selecting the platforms which apply the minimum accepted standards for the quality & supply chain department to ensure compliance with their global standards in addition to EU GDP guidelines.

What advice would you give to an outsider to Qatari market with regards to temperature-controlled storage and distribution?

Our advice to external manufacturers coming to this region is to always spend a good amount of time selecting and refining local partners. Clearly assess their capabilities, ensure 100% understanding for global guidelines in GxP. It is also vital to look for a partner with clear plans for investment in their own infrastructure like warehouse mapping, validation and reefer containers. They should have a well trained staff and a management team with the vision to ensure safe handling of valuable pharmaceutical products to the patient.

My last piece of advice for incoming and existing players is to deal with reputable third party logistics provider, with an understanding of cold chain management technology, especially in hot areas like GCC. They need to have a good reputation with local customs authorities, ground handling agents and local health authorities for handling sensitive items, and an outstanding track record in the industry. They will need to adhere with latest industry requirements and be covered with proper insurance either for marine logistics or for other facilities.

For the documentation part, to ensure safe shipping, storage and clearance as per manufacturer standards, you have to ensure proper shipping documents are in place as required by the local authorities. These need to be couriered to a local partner to give the green light to dispatch of goods safely to the destination port.

Spotlight on UAE



Narasimha Rao, Pharmacist in Charge, New Medical Centre Trading, UAE

Narasimha Rao is currently working as Warehouse Manager cum Pharmacist in Charge at New Medical Centre Trading LLC with responsibility for warehouse operations. He has been working for the last 21 years in NMC, and has good experience in the field of pharma logistics, including cold chain management.

Market Conditions

In this region the temperatures are very high during summer, so manufacturers, transporters and importers have to maintain and control the environment through the storage, handling, and transportation of temperature sensitive drugs, right from the origin warehouse to the final destination. Not many companies are producing cold chain products here in UAE, though it is picking up the pace. Most of the cold chain products are highly valued, highly priced and they are being imported. Currently the top 10 cold chain products are imported.

The main challenge is when we import and it takes about seven days to import (by air), release and come to our warehouse. Customs may not change their way of thinking and mode of operations, but we need to change. We have a responsibility to be aware of what customs actually do, what are their timing and processes etc. For example, during EID holidays, most of the service providers like customs may be closed and we can't release the shipments during EID, which is about nine days. It is a long time and if shipment comes from overseas and lands at the airport, it gets simply transferred to the cold storage, but what happens to the products which are in the passive shippers when the temperature starts deviating? So we better avoid receiving cold chain shipments during weekends and or national holidays.

What advice would you give to someone who was outside of the UAE market with regards to temperature controlled storage and distribution?

The relationship between the giver and the acceptor of the cold chain product is very important. They both are responsible in order to maintain the cold chain, from the time it leaves the warehouse to the airport and from the airport to the importing country. You have to work on a set of standard operating procedures and have quality assurance agreements (QAAs) in place. QAA plays a very important role that explains how the cold chain has to be maintained and what to do if there is a cold chain deviation nor breach.

Cold chain monitoring is very important and regular alerts and updates are needed just in case there is a cold chain breach so that a corrective reaction can be taken.

The cold chain is not simply a material problem. It is also a problem of the personnel. Unless the people who are in charge of storing and transporting the cold chain products are informed, You may be using the best refrigeration material and means of transportation, but the cold chain will be totally ineffective if the personnel does not take proper care of the vaccines. There has to be a responsible person nominated who ensures that the cold chain is maintained and that responsible person should be adequately qualified and experienced.

Spotlight on India



Ryan Viegas, VP, SupplyChain & Procurement, Watson Pharma

Ryan Viegas is Vice President – Supply Chain & Procurement at Watson Pharma based in Mumbai. Previously Ryan has been associated with companies like Teva, Bayer, Sandoz, Matrix (Mylan) and Lupin. He has also been a member of the Executive Committee of Indian Institute of Materials Management (IIMM) for several years. He is on the Academic Advisory Council and visiting faculty of management institutes for courses on Supply Chain & Logistics. He has initiated several innovative practices in Procurement & Supply Chain and received the “Supply Chain Officer of the Year – Pharma” award at the 6th Express, Logistics and Supply Chain Conclave in Sept 2012.

Market Conditions

Based on the area of the country and future demand there exist many opportunities for temperature controlled warehouses, transport and equipment. India is a growing economy with huge opportunities and for those who have the right approach success in the long-term is certain. We are also witnessing increased security measures, and monitoring is extremely important during both during storage and movement.

In terms of threats to the market, there is limited awareness and knowledge about temperature controlled logistics. With respect to logistics there are several bottlenecks, constraints like lack of sufficient cold storage space at airports, ports with limited infrastructure in terms of roads, and limited availability of compliant cold trucks. Being a large country the distances between the manufacturing to the ports / airport and local warehouses are significant.

One issue relating to dealing with Customs is that manufacturers may not be aware of updated customs’ internal standing orders that are not published.

How would you establish operations on the ground in India?

Select a local expert to guide and support operations, with on the ground knowledge, experience and the contacts to facilitate smooth movement of products.

My top takeaways for effective temperature controlled logistics in India

- 1.** You definitely require a local partner / expert to run the operations in India
- 2.** Do not expect a “copy paste” version of the Western world in India.
You need to operate in India as per the local environment.
- 3.** Maintain as much control as possible with all stake holders
- 4.** Do not take anything for granted
- 5.** Strict compliance with all local and international regulations

Spotlight on Brazil



Jair Calixto, GMP and Audits Manager, Sindusfarma

Jair Calixto is pharmacist graduated in 1985 at University of São Paulo in Pharmaceutical Sciences, in Industrial Administration – Escola Politécnica – University of São Paulo in 1992 and graduated in MBA – Master Business Administration at Fundação Getúlio Vargas in 2004.

He worked for Pharmaceutical companies in Brazil in Quality Assurance, Quality Control, Manufacturing and Product Development for 23 years. Before this, he worked in pharmacy during 13 years. Since 2008, he is Manager of Good Practices and Audits at the SINDUSFARMA – Association of the Pharmaceutical Industry in São Paulo State.

Market Conditions

Brazil is a big country in which the necessary structure for logistics is developing. It is a challenge to have strong control in a big country with extremes differences in terms of logistic structure and climatic zones. As a result, this emerging market is producing creative solutions for efficient and effective transportation and storage of temperature controlled products.

Another issue impacting the Brazilian temperature controlled supply chain is cost. Manufacturers are trying to reduce the operational costs and taxes, and these are the most important issues nowadays. Airport renewal has raised the bar for import and export products. Three main airports (for cargo purpose) in Brazil have been rebuilt, establishing a new and effective structure for logistics in general. Sindusfarma is currently finalizing a guide for temperature controlled products, especially in Brazil. The aim is to attend the needs of the market and give conditions to standardise storage and distribution of temperature sensitive products.

My top takeaways for effective temperature controlled logistics in Brazil

Develop best practices, technology and a good rapport among stakeholders in order to avoid temperature excursion during the entire process. Plus, the standardisation of procedures among all stakeholders and health authorities to facilitate import and export products.

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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Europe's biggest & best meeting place for life sciences logistics

Cool Chain & CRT Logistics Europe, the flagship pharmaceutical logistics event in Europe, will be taking place in **Frankfurt, Germany** on **27-28th January 2015**. With the most frequented railway station in Europe, direct access to both the Rhein and Main rivers, and the largest cargo airport on the European mainland shipping 2.2 million metric tons of freight in 2013, Frankfurt is the perfect location for CCE 2015.

Key highlights for the 2015 flagship forum include:

A practical look at GDP compliance

Never mind the guidance, how do we actually implement GDP – and cost-effectively?

CRT/Ambient Logistics

Thanks to the inclusion of CRT in the GDP guidelines, this has become a challenging (and often costly) challenge – how are others handling it?

Exclusive up-close site visit with Lufthansa

Visit Lufthansa's largest hub in Europe at Frankfurt Airport – an exclusive guided tour of a state-of-the-art logistics facility!

Transportation Modes: Air vs. Sea Freight

We know that sea freight has made a massive comeback in recent years, potentially saving manufacturers millions – how practical is it, and how will it impact air freight?

Lane Qualification and Mitigating Excursions

Doing test runs on every lane is often costly and impractical, much as we'd all like to – how can we get around this, and mitigate or plan for excursions?

It's Your Community



Cool Chain Europe brings together senior thinkers and doers, it's your chance to meet and learn from the industry's best.



"Very valuable. This year edition convinced me this is a yearly event I need to attend"

Sr Cold Chain & Specialty Logistics Analyst, Pfizer

"This was an extremely valuable event to attend and left with new ideas and thoughts on controlled room temperature logistics"

Head of Air Cargo, Metropolitan Washington Airports Authority



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