



**CASE STUDIES: CHINA**

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“The Chinese government remains determined to transform the industry from a generic drug-focused sector to an innovation-driven drug development powerhouse. Securing pharmaceutical supply lines, funding research, eliminating bottlenecks in distribution and making drug quality compatible with global standards remain essential targets for China.

Over the next few decades, China has the potential to become as one of the leaders in the pharmaceutical world. With every big company in the sector focusing on this region as a source of growth, the country is likely to play an increasingly significant role in the way drugs are invented, tested and perhaps even regulated.”

Source: China’s Pharmaceutical Industry—poised for the giant leap Source: KPMG 2011

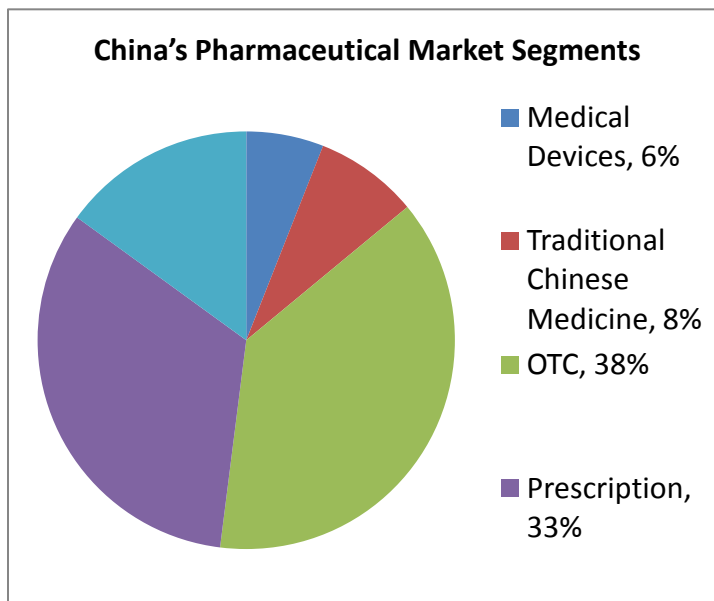
LifeConEx has identified the challenges for China in the transportation of temperature-sensitive products. We have experienced ourselves some of these challenges. The following case studies will present to you the challenges we faced and which actions LifeConEx took to obtain positive results.

### China Pharmaceutical Market Challenges



- ▶ Rolling out the healthcare reforms and increasing investment by foreign and domestic companies will be the primary growth drivers for the industry in the coming year, especially in the OTC market
- ▶ Forecasting of China to be the world's third largest pharmaceuticals market in 2011, with a value above USD 50 billion
- ▶ Increase of 28% during the first six months of 2010 in the value of import and export trade of medicine and healthcare products in China, compared to the same period in 2009
- ▶ Export value of Active Pharmaceutical Ingredients (API) is USD 10 billion, growth rate 31%, accounting for 53% of exported pharmaceuticals

Source: 2009 Information Explorer Ltd. (BMI)



### Case Study 1: Lack of Integrated Door-to-Door Management of all Key Partners

#### BACKGROUND:

A customer had shipped a total of four (4) active cool containers to China. Two (2) of the four (4) active cool containers were not loaded on the aircraft on the day of the scheduled departure because they would cause an imbalance in the weight of the aircraft. The aircraft had exceeded its allowable weight. A cargo plane has three compartments for storing cargo: front, center, and rear. Each compartment has different limits on both weight and space. Furthermore, the weight of the cargo in the respective compartments must be the same proportion of that compartment's weight capacity to maintain the balance of the plane.

As a result, the shipment was split and only half of the products would be departing to China as planned. The containers that were left behind were taken to a warehouse where ground handlers would store them until the containers would be loaded on the next flight. During the wait, the containers started to indicate a rising temperature and a decrease in the battery voltages. The airline, ground handler, nor forwarder staff had the necessary access to dry ice or batteries; it was a national holiday. It was imperative that someone take action to replenish the two!

#### APPROACH:

LifeConEx life science cold chain specialists were able to intervene and proceed with the pre-established contingency plan. The situation was analyzed and a calculation was performed to assess the risk associated with the amount of dry ice that was left in the container. Not satisfied with the results, the team arranged for the two containers to be flown to the closest airport where they are replenished with batteries and dry ice.

#### RESULT:

The two containers finished the journey successfully! The customers were continuously informed of the status and health of their product every step of the way.

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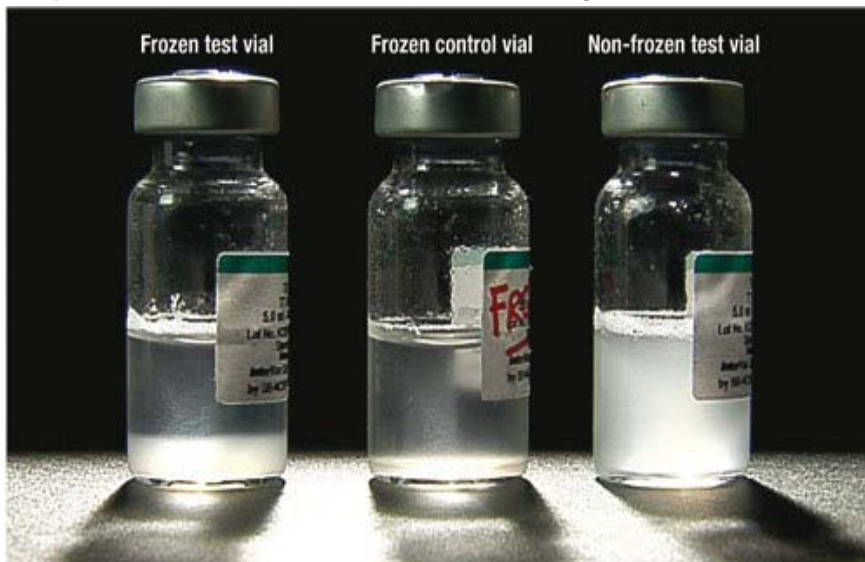
## Case Study 2: Inconsistent Standards and Infrastructure Across Climate Zones

### BACKGROUND:

After unloading the passive container from an aircraft, a ground handling agent at destination identified that the product temperature label which read “+2°C to + 8° C”. The agent confidently proceeded to store the container in a +2°C to + 8° C environment immediately. Unfortunately, according to the packaging validation, it was too early to store the container into the cool room. As a result, storing the product too early into the temperature controlled room caused the product to reach a dangerously low temperature, near freezing point. This incident is quite common and the World Health Organization has performed some studies to understand the implications of product freezing.

“Good temperature control during the storage and transport of vaccines is critical to ensure their potency and safety. Liquid formulations of aluminum-based vaccines against diphtheria, pertussis, tetanus, hepatitis B and *Haemophilus influenzae* type b, alone or in combination (adsorbed vaccines), should not be frozen.

Between 14% and 35% of refrigerators or transport shipments were found to have exposed vaccines to freezing temperatures, while in studies that examined all segments of the distribution chain, between 75% and 100% of the



vaccine shipments were exposed. More rigorous study designs were associated with higher levels of exposure to freezing.

When a vaccine is damaged by freezing, the potency lost can never be restored – the damage is permanent. Freeze-damaged vaccines have lower immunogenicity and are more likely to cause local reactions, such as sterile abscesses.”

Source: WHO Validation of the shake test for detecting freeze damage to adsorbed vaccines by Ümit Kivanc

Source WHO [Detecting freeze damage to adsorbed vaccines](#) Ümit Kivanc 09 February 2010

### APPROACH:

LifeConEx life science cold chain specialists proactively discovered the mistake in the handling of the container and instructed the ground handler agent to move the shipment into an ambient warehouse as addressed in the packaging protocol.

### RESULT:

The product temperature was stabilized and brought back to an acceptable temperature range. This avoided a potential loss of product to the client. Product integrity was achieved!

## Case Study 3: Uncertain Transfer of Accountability at Each Key Milestone

### BACKGROUND:

Sometimes, things happen, no matter how much planning is done. In the morning the product was scheduled to depart, the airline which would be responsible to take hold of the goods at the point of transit declared a strike. The cargo had to be booked with a different carrier as per the contingency plan. Due to the last minute booking, the airline failed to accurately reflect the piece count in the customs system. The Chinese broker was unable to clear customs and this would cause an extensive delay in the delivery of the product.

### Savage Chickens

by Doug Savage



### Approach:

LifeConEx life science cold chain specialists proactively contacted the airline at the transit point. This action enabled for the piece count to be corrected in the customs system.

### Result:

The broker was able to process customs clearance without any delay in the shipment transit time.

### Case Study 4: Lack of Temperature Monitoring and Documented Temperature Excursions

#### BACKGROUND:

A shipper's warehouse staff forgot to include data loggers within the packaging of the product. The oversight was discovered at the consignee's site (China) which prevented the release of the product.

Data loggers are important because they provide the data required by industry, federal, and international regulators in an event of an audit or for the verification and release of a product into a market. From the moment raw materials are perceived to final product delivery, it's crucial to ensure that factors such as temperature remain within acceptable limits.

#### APPROACH:

Upon review of the temperature data collected, LifeConEx supported with a detailed investigation consolidating all data collected and associated comments obtained during the transit of the product.

#### RESULT:

The client was able to provide validation of temperature and compliance with LifeConEx's documentation which resulted in release of the product into the market.



### Case Study 5: Inconsistent Documentation of Cargo Handling Through Transportation

#### BACKGROUND:


Proper control and handling of cargo documentation is essential for successful importation/exportation of goods. Each country has its own procedures which everyone needs to follow; industry specific requirements apply. It is the responsibility of each party to know how to process all documentation. Improper documentation will not only cause customs clearance delays but potential mishandling of goods.

For temperature-sensitive products, this document is critical because it identifies at which temperature the cargo needs to be stored in. Airline and ground handlers reference the master airway bill for cargo handling.

We experienced an instance in which the master airway bill stated that the temperature of the goods was +2°C to +8°C. This was an error, as the goods could only be stored at a temperature of +15 °C to +30° C”.

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sample

Shipment Air Waybill		ORIGIN	DESTINATION CODE
<b>1 Payer account number and insurance details</b> Charge to <input checked="" type="checkbox"/> Shipper <input type="checkbox"/> Receiver <input type="checkbox"/> 3rd party <input type="checkbox"/> Cash <input type="checkbox"/> Cheque <input type="checkbox"/> Credit Card Payer Account No. _____ Shipment insurance see reverse <input checked="" type="checkbox"/> Yes insured value (in local currency) _____ <small>Not all countries accept air waybills as evidence of value.</small>			
<b>2 From (Shipper)</b> Shipper's account number _____ Contact name _____ Shipper's reference (up to 32 characters but only first 12 will be shown on invoice) _____ Company name _____ Address _____ Postcode/Zip Code (required) _____ Phone, Fax or E-mail (required) _____			
<b>3 To (Receiver)</b> Company name _____ Delivery address _____ Postcode/Zip Code (required) _____ Country _____ Contact person _____ Phone, Fax or E-mail (required) _____		<b>4 Services</b> <input type="checkbox"/> Customs Document <input type="checkbox"/> Non-Document <input type="checkbox"/> Express <input type="checkbox"/> Express 12 <input type="checkbox"/> Express 12 to the USA <input type="checkbox"/> Express 12 Worldwide <input type="checkbox"/> Express 5-workday <input type="checkbox"/> Other _____ <input type="checkbox"/> Optional Service advantages (see reverse) <input type="checkbox"/> Security Delivery <input type="checkbox"/> Special Pick-Up <input type="checkbox"/> Delivery Notification <input type="checkbox"/> Other _____ <input type="checkbox"/> 2nd class flight <input type="checkbox"/> 2nd class <input type="checkbox"/> 2nd class <input type="checkbox"/> Other _____ DIMENSIONAL/CHANGABLE WEIGHT kg _____ * _____ gr _____	
<b>4 Shipment details</b> Total number of packages _____ Total Weight _____ Reces _____ Dimensions in cm: Length _____ Width _____ Height _____		<b>5 Full description of contents</b> Give content and quantity: _____	
<b>6 Non-Document Shipments Only (Customs Requirement)</b> Attach the original and four copies of a Proforma or Commercial invoice Shipper's VAT/GST number _____ Receiver's VAT/GST or Shipper's EIN/SSN _____ Declared Value for Customs (see on commercial/proforma invoice) _____ Harmonized Commodity Code if applicable _____ TYPE OF EXPORT <input type="checkbox"/> Permanent <input type="checkbox"/> Repair / Return <input type="checkbox"/> Temporary Destination duties/taxes if left blank receiver pays duties/taxes <input type="checkbox"/> Receiver <input type="checkbox"/> Shipper <input type="checkbox"/> Other _____ (see approved address form)		CHARGES Services _____ Insurance _____ VAT _____ CURRENCY TOTAL _____ TRANSPORT COLLECT STICKER No. _____ RETURN DETAILS (Cheque, Card No.) No. : _____ Type Expires _____ Picked up by _____ Route No. _____ Time Date _____	
<b>7 Shipper's agreement (Signature required)</b> <small>Unless otherwise agreed in writing, the shipper and the carrier accept the Conditions of Carriage and the terms of the contract between them and the carrier, and (2) such Terms and Conditions apply, where applicable, the Warsaw Convention and/or exclude the carrier's liability for loss, damage or delay and (3) the shipment does not contain sea or dangerous goods (see reverse).</small> Signature _____ Date / / _____			

How does a Master Airway Bill Work? Source IATA Manifest System Introduction

**IMPORT** Inbound manifests should be transferred to customs in advance. → Customs verify the inbound manifests → Customs clearance manifests → Analyze manifests → Master Airway bill report for all the inbound cargos → Compare master airway bill report with inbound manifest → Apply to customs → Import cargos arrival reports for master airway bill → Cargos clearance reports for house airway bills → Compare cargos clearance reports for house airway bill with house airway bill manifests → Apply for custom paper work procedure.

The major data of inbound manifests should be transferred to customs 4 hours in advance before the flight arrived at the first destination in China if the flight duration is over 4 hours. The rest data of original manifest should be transferred before flight arrival.

**EXPORT** Estimated manifests should be transferred to customs in advance → Customs accept the applications of export cargos → supply reports of house airway bill once cargos arrived → Customs check cargos and release procedure → The reports for arrival cargos on the master airway bills → on load cargo as per manifests → transportation allow to leave → Reports of master airway bills → Reports of house airway bills → Compare the reports of master airway bill and house airway bills with cargos arrival reports → Finalize customs paper work

Airlines or ground handling agencies should supply final export manifest to customs through system by the time dictated by customs after aircraft fly out of China.



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### APPROACH:

When the mistake was discovered by a LifeConEx cold chain specialist, it was immediately communicated to the trucking company on route to the airport. The driver was instructed to raise the set point of the truck. In addition, the booking of the cargo was corrected to reflect the proper temperature range, and LifeConEx confirmed the product was stored in the appropriate temperature condition upon arrival.

### RESULT:

By being proactive, LifeConEx was able to intervene and take the necessary actions to correct the inconsistent documentation. Because the error was caught in advance, the goods were not delayed or stored in the incorrect temperature storage.

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### ABOUT LifeConEx

*LifeConEx offers peace of mind as the only industry-specific, end-to-end cold chain management solutions provider for the life science industry worldwide. With oversight of the entire global landscape, LifeConEx designs and orchestrates the shipment process end-to-end proactively and reactively, assuring the integrity of your product's desired condition. You experience shorter cycle times, a reduction in temperature excursions, and far fewer damages than typically experienced by shippers. LifeConEx it & Live your Life.*

*LifeConEx is supply chain party neutral (airlines, forwarders, truckers, packaging, and technology).*

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