Cold Chains Are Hot!

EXECUTIVE SUMMARY

Mastering The Challenges Of
Temperature-Sensitive Distribution
In Supply Chains

RFID in Life Science Series: Part 1

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About ChainLink Research

ChainLink Research, Inc. is a Supply Chain research organization dedicated to helping executives improve business performance and competitiveness through an understanding of real-world implications, obstacles and results for supply-chain practices, processes, and technologies. The ChainLink Inter-Enterprise Model is the basis for our research; a unique, real-world framework that describes the multi-dimensional aspect of links between supply chain partners.

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Executive Summary

Cold Chains Take Center Stage

Tsunami, hurricane, landslides – in responding to the needs of the victims of these natural disasters, the effective delivery of food, pharmaceuticals and life saving products are now in the spotlight. Supply challenges related to transportation, infrastructure and other issues require careful planning and coordination. And then there is another element – the need to ensure that these products are carefully handled and maintained at the correct temperature. Variations are not an option – product purity is at stake. These are the challenges of the Cold Chain – a critical subset of supply chain management.

When Customers Lose, Companies Lose

And even in normal circumstances this “extreme” supply chain needs careful attention. Variations in temperature, humidity, altitude – all factors that can transform modern medical miracles into useless materials! Billions of dollars spent in research; manufacturing and FDA approval are at risk as these products move through the global chain of custody from supply to demand. The stakes are high – brand integrity, customer confidence and market share are all at risk in the fragile Cold Chain.

Emerging Technologies Create New Opportunities

Securing the Cold Chain requires innovation, collaboration and communication, ensuring that each of the critical links in the chain understands product storage and handling requirements. Advanced technologies, to include sensors, RFID, wireless and wired networks are all potential components of a Future Forward model that will ensure an ongoing ‘portable record’ of each product throughout its lifecycle. Information related to the ‘state’ of the product is critical – remedy and control are required to ensure that product is not compromised or contaminated.

Using '3Pe' To Guide Your Path Ahead

The combination of enhanced Policy, Process, Performance and Enablers provides the key to success for Cold Chain management. Leveraging technologies that have been pioneered in the Food industry, it is possible to create a Cold Chain infrastructure that understands and prepares for the constraints of Cold Chain distribution.

The case for action is compelling – lives are at stake! The ROI proposition is straightforward.

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(Photo element of cover graphic—courtesy of MedPro RX)

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Understanding the Cold Chain

WHAT IS A COLD CHAIN?

Cold Chain refers to a subset of the total supply chain involving the production, storage and distribution of products that require some level of temperature control in order to retain their key characteristics and associated value.

The term Cold Chain originates from the terminology for the 'chain of custody' in the production, packaging, distribution and control of temperature sensitive product. This includes the traditional areas of supply chain, to include raw material acquisition, transformation and manufacturing process, packaging and product protection, storage and distribution.

COOL VS. COLD: WHAT'S THE DIFFERENCE?

The Cold Chain comprises the storage and distribution of products that are chemically and physically stable based on the following parameters (which should be indicated on all product packaging and documentation).

Category	International Storage and shipping requirements (stated in Celsius and Fahrenheit)
Frozen	- 25° and -10° C (-13 and 14° F)
Cold	Any temperature not exceeding 8° C (46°F)
Cool	Between 8° and 15° C (46° and 59° F)
Temperature controlled	Thermostatically controlled temperature of 20° to 25° C (68° to 77° F)
Room temperature	Temperature prevailing in a working area; not thermostatically controlled
Warm	Between 30° and 40° C (86° and 104° F)
Excessive heat	Above 40° C (104° F)

Table 1: Variables to Consider in Cold Chain Compliance

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Life Sciences & Pharmaceuticals: Cold Chain's New Frontier

HIGHER PRODUCT VALUE; HIGHER STAKES

Cold Chain is increasing in importance for those enterprises engaged in the discovery, manufacture and distribution of pharmaceuticals and other health care products that are impacted by variations in temperature. These include products used in treating human diseases as well as in animal health. In fact, health care for animals is a critical area. The concern is equal, whether the animals are destined for consumption or are part of a home or homestead.

Many of these products are relatively unstable, comprising biological and other components that become inactive or contaminated if handled incorrectly. Vaccines in particular need to be maintained at the correct temperature – not always an easy task when transporting or administering these to humans and animals in remote locations. The careful handling of these products is critical, especially as there is a global shortage of some vaccines – as evidenced recently in the United States, with the resultant rationing of Flu vaccines to 'at risk' elements within the community.

COLD CHAIN'S WEAKEST LINK: OVERLOOKING THE 'LAST MILE'

These Cold Chain products, literally the lifeblood of the healthcare industry, in many cases have a long manufacturing cycle time. Years can pass from the initial discovery process, to extended and controlled clinical trials, to the final FDA approval. It is estimated that each new drug that passes approval incurs costs of literally billions of dollars.

In addition, especially with respect to some active ingredients that are undergoing clinical trials, there are only a couple of batches manufactured each year, with long and complex processes involved. Added to which certain of these products have a single source and limited supply, as in the case of some oncology and Aids drugs. The proposition is compelling – if it takes years to make a product, the yield is low and the costs are high, why take a risk in the 'last mile' of the supply chain, ruining product through careless handling?

The 'last mile', in the case of these products, is the point of consumption such as a hospital, doctor's office, or home. There are many horror stories of products that have been carefully stored and transported, only to find their way into home environments that are

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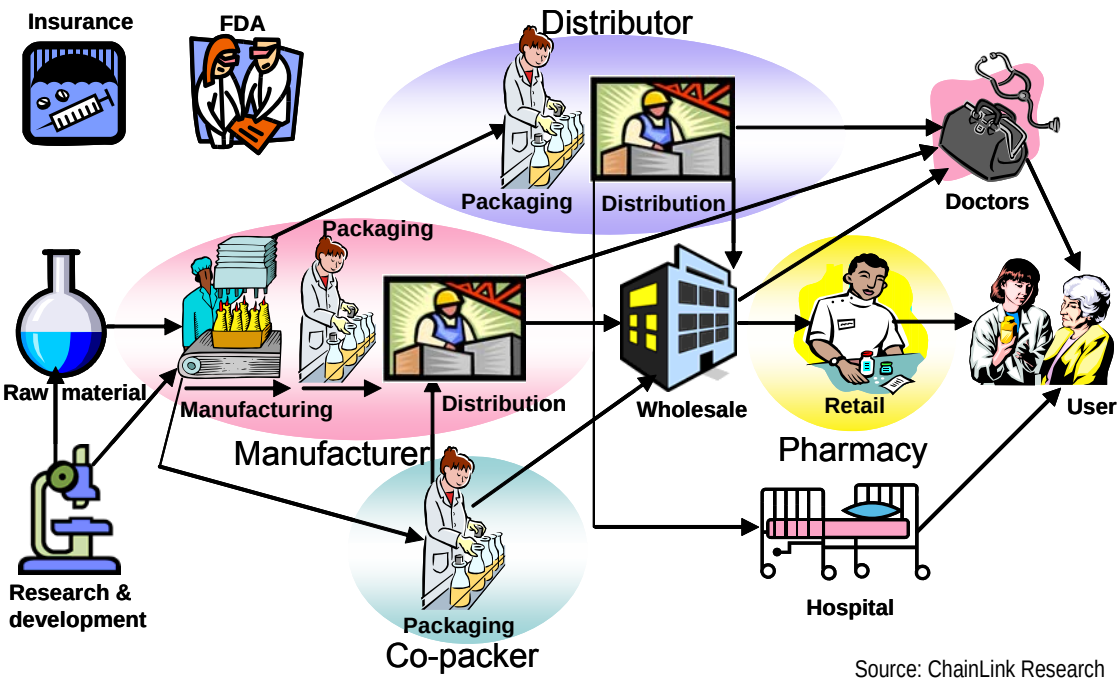
Connecting the Dots: Who Does What?

THE PLAYERS IN THE SUPPLY CHAIN

The global manufacturing, storage and distribution of Cold Chain products are a sub-set of the pharmaceutical supply chain. As such, the same processes, players and performance criteria apply – the primary difference is that the Cold Chain products have minimal tolerance for variation when it comes to the correct packaging, storage and transportation.



Source: ChainLink Research

Figure A: Holistic View of Pharmaceutical and Life Sciences Cold Chain

The Pharmaceutical and Life Sciences Cold Chain includes many different potential configurations, with certain functions – for example, packaging and distribution being performed by outsource partners. In addition, product distribution has many variables, some product shipped from manufacturers to large Pharmacy Retailers, and other items distributed through a global network of wholesalers and distributors. As identified earlier, the 'state' of the product is critical – temperature variations resulting in loss of product, revenue, and potentially even penalties.

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Key Players in the Global Cold Chain (continued)		
Partner Profile	Responsibilities	Performance Measurement Criteria
3rd Party Logistics Providers	• Outsourced Distribution Process • Storage • Pick, pack and ship • Transportation • Product quality • FDA compliance	• Product Delivered on time and in good order • Damage and returns identified and communicated throughout the Chain • Monitor product throughout process to ensure that there are no deviations from temperature control
Regulatory and Control Agencies	• Provide guidelines for the packaging, storage and handling • Monitor and Control	• Product Quality • Batch and lot control • Product recalls and destruction
Insurance Providers	• Compensation for loss or damage • Monitor to ensure responsible product handling environment	• Claims handling • Monitor and control • Loss avoidance

Cont. Table 5: Roles, Responsibilities and Performance Measurement

WHERE DO YOU NEED TO GO?

Once you have assessed the current situation in terms of your performance relative to your position in the Cold Chain, the next question is where do you need to be? Based on industry research, ChainLink develops a vision document which we call the 'Future Forward' model. And in keeping with the **3Pe** framework, the Future Forward model articulates an end-state in terms of target performance metrics and the underlying recommendations for Policy, Process, and technology Enabler changes to achieve this goal.

Adopting the Cold Chain Future Forward Model

As companies become aware of the need to think and plan for Cold Chain products independently from mainstream items, it is possible to move from 'state of the industry' as reflected in current good practices to best practices as illustrated in the following Figure C.

(Detailed briefings on the Cold Chain Future Forward model are available for ChainLink clients. Please contact ChainLink to arrange a discussion.

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