

Cal/Amp®

Cold Chain Integrity:

Visibility for Safety
and Compliance



Transport and storage of temperature and condition-sensitive products such as pharmaceuticals and food is complex, demanding, and expensive. The risk of loss or damage to the cargo has the potential to grow as global shipping drives least cost transport and complicates the cold storage chain. Regulations are tightening, while at the same time both quality standards and shipping volume make logistics ever more sensitive. A growing middle class in developing nations will continue to push for higher-quality food products at greater distances, with very stringent quality requirements. More and more specialization in the pharmaceutical industry is resulting in an increase in shipments of drugs and vaccines that are extremely sensitive to temperature, shock, light and other environmental factors.

The Cold Chain

“Recent regulations in the United States and the European Union have set specific temperature requirements for transportation of both food and pharmaceuticals.

In the past, supply chain requirements were less stringent. Cargo temperatures were recorded but not reported in real time, and in most countries there were no standards for temperature control during shipments of medicines or vaccines. Recent regulations in the

United States and the European Union have set specific temperature requirements for transportation of both food and pharmaceuticals. The U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA), passed by Congress in 2010 and signed into law in 2011, focuses on solutions that prevent spoilage and food-borne illnesses. The European Union Guidelines on Good Distribution Practice, which went into effect in 2013, provide temperature regulations for pharmaceutical transportation. The price and challenge of compliance continues to escalate.

Manufacturers and logistics companies are stepping up investment in solutions that document and monitor procedures, processes, and environmental factors at every step of the supply chain, not only to comply with regulations but to reduce cost and improve responsiveness when a problem occurs.

Pharmaceuticals in the Cold Chain

Pharmaceuticals have special requirements with regard to temperature, making it critical that the cold chain is never broken. An increasing array of pharmaceutical products require cold chain transport, including all vaccines, many drugs, and a significant proportion of biological samples and diagnostic tools. Most vaccines require storage temperatures of 35°F–46°F

(2°C–8°C) and are even damaged by excess heat or cold. Over the last 20 years or so, new vaccines have emerged with different temperature requirements that make vaccine storage more complex. According to the Centers for Disease Control and Prevention (CDC), 7% - 37% of providers expose vaccines to improper storage temperatures.

The potency of most vaccines can be affected by heat during transport or storage. In many cases, vaccines that are shipped to third-world countries are rendered useless due to heat exposure. Patients who have been injected with the damaged vaccines are actually put at greater risk, thinking that they have been immunized when they have not. Some vaccines are more sensitive to heat than others.

A number of vaccines must never reach freezing temperatures, especially ones that use adjuvants such as aluminum. The World Health Organization notes that a majority of vaccine shipments are exposed to freezing temperatures. When a vaccine is damaged by freezing, its loss of potency is permanent and cannot be restored.

Although it is often health workers who are responsible for maintaining the cold chain during drug transport and storage, the logistics staff is becoming more involved. Training, processes, equipment and logistics mechanisms are required to ensure not just the temperature during shipment but the fuel, spare parts and supplies that keep the cold chain equipment itself running properly. According to the 2017 edition of Pharmaceutical Commerce’s Annual Biopharma Cold Chain Sourcebook, managing cold chain transport will total \$13.4 billion this year, and the value of temperature-controlled pharmaceuticals themselves will grow 10.7%.

Food Products in the Cold Chain

Expanding global markets have resulted in wider distribution and tighter requirements for quality, safety and shipment

integrity in the food industry. At the same time that shipments are traveling longer distances, the market is demanding premium products with short shelf lives and sensitivity to temperature fluctuations. Most cold food warehouses must maintain multiple separate temperature zones to maintain product quality, from deep freeze to about 14°C or 57°F.

With complex requirements for food safety during transport and storage, and with a limited time before inevitable spoilage, it's no surprise that even the most well-regarded and established brands can be tarnished by illnesses resulting from breaks in the cold chain. According to the Centers for Disease Control and Prevention (CDC), 1 in 6 Americans contract a food-borne illness every year. Of those, 128,000 are hospitalized and 3,000 die. Proper cold chain food handling processes are the first line of defense against this preventable tragedy.

The U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) specifies procedures for cold storage, pre-cooling and cleanliness of shipping containers and trucks before loading, and temperature monitoring during transit. To prove compliance, shippers must maintain temperature logs that prove there have been no temperature spikes during the entire shipping and storage process. The aim of the FSMA is to shift food safety tactics from response to prevention. As the market demands a larger number and higher quality of fresh food products, the cold chain market will only continue to grow. According to Markets and Markets' "Cold Chain Report," the cold chain market will exceed \$271 billion by 2022. The ability for companies to address this market while lowering their own costs will require continual improvement of cold chain processes to move products more quickly with less waste and loss.

Fresh Produce

Fresh produce has a very short product life-cycle even under the best cold chain processes, and often must be managed separately from other food products. Damage to produce is immediately apparent to the consumer, who will not buy any products that look even slightly less than fresh.

Maintaining quality of produce during shipment and storage is uniquely complex even among food cold chain logistics. The time between harvest and cooling is as important as an unbroken cold chain in ensuring freshness. Keeping the temperature of the fruits and vegetables at the proper temperature is critical in retarding spoilage. Real time monitoring should be an integral element of protecting fresh produce throughout the supply chain.

Auditing and Compliance

Monitoring and logging temperature and other environmental factors are important steps in complying with storage and transport regulations for perishable products. When something goes wrong, logs and audit trails can help determine what caused the problem and when it happened. This data helps improve processes, training or equipment to ensure the same failure does not occur in the future.

Maintaining equipment regularly can help prevent failures that can cause spoilage of sensitive goods. Logging and auditing can provide valuable hindsight when failures occur. But it is also important to consider technology solutions that provide real-time data to enable a pivot to solve or avoid a problem before damage occurs.

The Game-Changer: Real-Time Visibility

Real-time monitoring of goods is now possible during storage, multi-modal shipping, drayage and at every waypoint in supply chain movements. The best solutions use intelligent sensors that provide constant data about the shipment's location, temperature and other environmental factors such as G-force, shock, humidity and light exposure. These sensors can be assigned to individual pallets or cartons to provide discrete

“ Real-time visibility changes the game by making it possible to avoid problems on the fly.

information for less-than-truckload (LTL) and smaller shipments. The sensor tags communicate with a master unit, which captures data in a log that can be used for auditing later.

This approach not only provides real-time information that cargo has maintained environmental requirements, but also enables data-driven decisions to continually optimize operations, lowering cost and waste. Real-time visibility changes the game by making it possible to avoid problems on the fly. If a food shipment exceeds its temperature threshold, for example, it can be delivered to a closer market for faster sale to account for the shortened product life.

The master unit tells personnel when the truck is cool enough to load, ensuring that the cargo starts its journey at the correct temperature. As goods are readied for loading, each bill of lading is matched to a tag so that the solution is aware when the entire load is successfully on board. In this way, every part of the shipment is individually tracked so that all interested parties can be notified of the progress of the shipment right up to delivery.

Problems that might not become known in time using traditional tracking methods are immediately apparent with real-time location monitoring. From the moment a shipment is prepared for departure, personnel can verify that all cargo has been loaded properly in the correct trailer or container. While a load is in transit, location monitoring provides immediate notification if the cargo deviates from its prescribed route or stops at any unauthorized location.

What to Look For in a Solution

As shipments become smaller, everyone involved in the cold chain must become more and more nimble. When choosing a cold chain visibility solution, look for the following:

- **Real-time sensing**—look for a solution with sensor tags that can be attached to individual pallets or cartons and can communicate with a master unit installed on the vehicle to provide real-time data about temperature, shock, light exposure, air quality and other factors.
 - **Real-time location tracking**—choose a solution that uses GPS for real-time tracking of a shipment to provide up-to-date delivery estimates, current location and progress reports even when the cargo is in the hands of a third-party logistics provider.
 - **Geofencing and route fencing**—the solution should be able to send an alert in real time if the cargo deviates from its planned route or strays from authorized waypoints, to prevent diversion and theft.
 - **Stationary and movement detection**—look for a solution that can detect whether the shipment is moving or stalled, especially en route between waypoints.
 - **Critical alerts and notifications**—at the heart of visibility is immediate access to data when a load goes over temperature or out of its authorized route. Choose a solution that provides instant alerts and notifications so that problems can be solved in time.
 - **Reporting and data analytics**—make sure the solution provides complete logging of data for later auditing. The logs can prove that the cold chain was not broken, or if it was, help diagnose what went wrong. The best solutions log at both the sensor tag and the master unit, to provide auditing data for both the entire load and individual independent LTL shipments.
- **All modes of global transportation**—look for a solution that works with all modes, on land, sea and air, without relying on carriers or third parties to provide infrastructure.
 - **Clear chain of custody and control**—use a solution that provides guaranteed evidence of shipment custody and control throughout the supply chain.
 - **Ability to integrate with EDI**—make sure the solution can integrate via EDI with your existing systems to facilitate information sharing, collaboration and transparency along the entire supply chain.
 - **Visualization portal**—look for a solution with a web-based and mobile-enabled portal that lets you access data in real-time and gives you control over order and shipment tracking.
 - **24/7 call center**—find a solution provider that goes beyond a pure technology solution and provides a fully-staffed command center to assist in alerting, escalation and remediation as necessary, including contacting law enforcement.

Conclusion

As today's global marketplace demands higher and higher quality and an ever-increasing variety of products, the demand on logistics and shipping companies will only increase. Smaller, faster shipments and a growing body of regulations are putting pressure on companies to manage deeper and deeper real-time data to improve processes, reduce waste and spoilage, and save money. Technological solutions are now available to track pallets and cartons rather than entire loads, and to provide a continuous stream of temperature, location and other information.

This data-driven approach can enable shippers of sensitive goods such as food and pharmaceuticals to maintain cold chain integrity. As a result, in many cases, issues can be avoided entirely or resolved quickly when they occur.

About CalAmp

CalAmp (NASDAQ: CAMP) is a telematics pioneer leading transformation in a global connected economy. We help reinvent businesses and improve lives around the globe with technology solutions that streamline complex IoT deployments and bring intelligence to the edge. Our software applications, scalable cloud services, and intelligent devices collect and assess business-critical data from mobile assets, cargo, companies, cities and people. We call this The New How, powering autonomous IoT interaction, facilitating efficient decision making, optimizing resource utilization, and improving road safety. CalAmp is headquartered in Irvine, California and has been publicly traded since 1983. Lojack is a wholly owned subsidiary of CalAmp. For more information, visit calamp.com, or LinkedIn, Twitter, YouTube or CalAmp Blog.

© 2017 CalAmp. All specifications are typical and subject to change without notice.



CalAmp
15635 Alton Parkway, Suite 250
Irvine, CA 92618
Tel: 949.600.5600
calamp.com