WHITE PAPER
The Benefits of a Cloud-Based, Real-Time, M2M-enabled Cold Chain
Abstract

Technology and globalization have improved co-operation and cohesion of the global community, making the relative distance between regions smaller while the physical distances remain a challenge. For the transportation sector, reliable worldwide distribution of goods has never been more essential. Products have grown more sophisticated and governmental regulations more complex, and at the same time, products are being shipped across greater distances than ever before.

Pharmaceutical products, food, chemical products and electronics are just a few examples of goods that can be impacted throughout the supply chain by environmental factors such as temperature, humidity and light as well as shock, vibration and pressure. To ensure that cargo does not become damaged or compromised throughout the distribution journey, businesses are increasingly relying on sophisticated cold chain monitoring technology to help manage delivery of the highest quality goods.

This white paper describes cold chain logistics and examines the challenges encountered by globalization and a highly complex regulatory environment. It surveys existing solutions in the pharmaceuticals industry as well as innovative, scalable solutions enabled by a cloud-based service enablement platform.
Cold Chain Logistics 101: a Brief Introduction

A cold chain is a temperature- and environment-controlled supply chain that helps extend and ensure the shelf life of products such as produce, seafood, frozen meats and foods, photographic film, chemicals and pharmaceutical drugs. It is often comprised of a series of containers, trucks and distribution centers that maintain consistent environmental settings and standards for specified periods of time. The cold chain starts at manufacturing and extends to the point of purchase by the end user.

In many cases, customers can only accept receipt of regulated and sensitive goods when required quality assurances are proven upon delivery. Traditionally, the only checkpoint to identify damaged products was an incoming inspection primarily accomplished by taking samples or by analyzing data loggers, sensors and other indicators that were shipped together with the goods. When quality levels of the received goods are not achieved, the recipient is most often thrust into crisis mode attempting to conduct business without the necessary products or raw materials while trying to appease customers whose orders cannot be fulfilled. Equally challenged are the manufacturers and distributors who suffer financial losses due to damaged goods while quickly increasing production to compensate for and replace damaged goods, which often requires overtime work and increased expense for expedited shipping.

Complexities and Challenges of a Globalized Supply Chain and Regulatory Environment

This situation is further complicated by the need to balance complex and multifaceted quality requirements across country and regional borders where differing regulatory standards apply. Future Pharmaceutical magazine illustrated this challenge well in a recent story highlighting LifeConEx, LLC. The company’s CEO, David Bang, explained that a typical international delivery of cold chain pharmaceuticals can involve “three airports, three ground handlers, two different airlines, two truckers, one freight forwarder, and one customs broker. The different regulations in two countries and three different climate zones compound the complexity.”
A Closer Look at the Pharmaceutical Industry

Leading the charge toward a more closely monitored cold chain is the behemoth global pharmaceutical industry where world sales of temperature-sensitive drugs and biologics products is expected to near $250 billion by 2015.² Twenty five percent of all pharma products are temperature sensitive, requiring refrigerated storage and transportation. That number is expected to climb as more and more bioengineered products are introduced with larger molecules that make them more susceptible to temperature and humidity changes. High-risk products, such as vaccines, insulin, blood products and injectables normally require storage between 2ºC and 8ºC while other products become unstable under 0ºC. All these products must be tightly controlled, monitored and stored according to the manufacturer’s guidelines in order to maintain their quality. The World Health Organization has recommended special storage conditions and continuous temperature monitoring to ensure integrity of products. Due to strong growth and the need for precise monitoring, the cold chain logistic services market is projected to grow from $6.7 billion USD today to $10.7 billion by 2017, according to the Global Healthcare Cold Chain Logistics Market Report & Forecast².

Guidelines, Standards, Logistics, Regulations and More Guidelines

A dizzying array of governmental and industry regulatory body guidelines govern the distribution of goods - the US Federal Drug Administration’s current Good Manufacturing Practices (GMPs), the World Health Organization QAS/04.068 standards, the International Air Transport Association (IATA) perishable cargo regulations, just to name a few. Product guidelines specify allowance temperature excursions that can vary significantly. Add to that, the EU’s recently published and long awaited Good Distribution Practice (GDP) guidelines and you have an extremely complex regulatory environment!

The new EU GDP guidelines are the benchmark for the world, but many stakeholders see major challenges in implementing the changes due to differing interpretations and laws in each EU member state. For instance, one of the new guidelines requires that storage conditions for medicinal products must be maintained throughout the supply chain “within the limits described on packaging information.” It is a highly complex proposition to uphold and document especially before packaging information is standardized. In addition, logistics providers across Europe offer significantly different quality standards and technology systems making consistency a challenge. Emerging countries like China and India are opening new markets and further stretching global supply chains, while increased security at border crossings and logistics hubs prolong transit times.

All these regulations put increased pressure on manufacturers to monitor the distribution process more closely than they have in the past. As a result, a trend is emerging to consolidate distribution to qualified 3rd party logistic service providers (3PLs) who can quickly implement the key provisions of new and emerging guidelines and regulations.
Several existing solutions each solve a portion of the puzzle of cold chain monitoring, but they fall short of fulfilling all the needs of tightly controlled goods. For instance, data loggers are low cost, small electronic devices that are installed in shipping containers to record data over time. Although these products are cost competitive, mature and certified, they do not provide real time monitoring and the chance to intervene when temperature excursions occur. They also do not offer GPS tracking to help quickly locate cargo and intervene when necessary.

RFID technology uses radio-frequency electromagnetic fields to identify and track tags attached to products and goods throughout distribution. The low power tags are capable of recording multiple data points including GPS location, and they are easily read by sensors passed by the tag at a short range of up to several meters. However, in order to send real time data remotely over long distances to supervisors or dispatchers, the tags need to integrate with a wireless antenna on the vehicle. This technology is limited for use by logistics partners that supply accompanying RFID hotspots with GSM connectivity.

Existing Solutions Fall Short

Machine-to-Machine (M2M) communications technology and state-of-the-art application enablement platforms provide a complete solution to solve the puzzle of monitoring and managing a globalized cold chain in real time for any vertical industry - from pharmaceuticals to food producers. Mature M2M has been around for more than a decade and is currently used successfully in a wide range of vertical markets to improve productivity, cut costs and optimize industrial operations.

Today’s leading-edge logistics companies are turning to M2M for a secure, centralized remote cold chain monitoring and control system. Gemalto, the world leader in data security, offers a complete end-to-end Cinterion® M2M Services offering hardware, security and services to quickly mobilize logistics management. The full spectrum solution is comprised of a range of advanced Cinterion M2M modules enabling reliable cellular communications, ruggedized Machine Identification Modules (MIMs)™ for secure connectivity to mobile networks, flexible subscription management services, and the cloud-based SensorLogic® Platform (SLP) to transform data points into business intelligence that is easily integrated with the customers’ backend systems. Cinterion solution components can be used independently or as an integrated solution and they are ruggedized for M2M conditions offering reliability in extreme environments of temperature, humidity and vibration.

End-to-End M2M Mobilizes Cold Chain Monitoring
Ideally suited to the challenges of the cold chain, Cinterion M2M modules are already integrated in truck trailers, cargo containers and fleets around the world. The cost effective technology establishes a reliable, scalable and long-lasting foundation to mobilize cold chain monitoring. Offering advanced GPS capabilities and precise location data, Cinterion M2M modules easily integrate with any commercially available sensor or monitoring device as well as customized monitoring solutions for exotic cargo and provide high-speed data and voice capabilities. Data from sensors are encrypted, secured by a MIM, a ruggedized, M2M-optimized SIM card, and then sent via the M2M module over cellular networks to the cloud. Encrypted data are received and securely integrated by the cloud-based SensorLogic Platform (SLP), which further analyzes and processes the data.

From Module to MIM to SLP: A Step-By-Step Description
The SensorLogic Platform Transforms Data Into Intelligence

The SensorLogic Platform works seamlessly with all M2M modules and sensors and serves as the hub connecting data, backend systems and logistics managers. The SLP’s powerful Java™ virtual engine transforms data from devices and sensors into standardized, actionable intelligence that can be accessed by logistics managers in real time via laptop, computer or smart phone. The SLP utilizes a complex event processing engine to evaluate the data and can send real time alerts via email or text message when critical thresholds for heat, humidity, shock, vibration or tilt are reached. This action allows supervisors and dispatchers to respond in real time to make adjustments to save cargo – and profits. Since M2M modules enable two-way communications, the SLP can automatically send commands back to the container’s temperature system where adjustments can be made remotely to ensure product integrity. In other cases, real time monitoring and alerts allow supervisors to proactively reroute cargo to the nearest icing station to save goods before spoilage occurs or to fulfill emergency customer requests immediately. The system also can order new shipments to replace damaged goods, which reduce distribution delays, and communicate with customers to let them know when delays are expected.

The SensorLogic Platform’s Administrative Portal, an intuitive user interface, can quickly and easily tailor the monitoring parameters to support a customer’s specific cold chain monitoring needs. Leveraging the ubiquity and flexibility of Java, Gemalto’s SLP solution can also seamlessly integrate with the logistics company’s backend CRM and ERP systems allowing automatic and immediate response if measurements exceed critical parameters.

The Benefits of an M2M-Enabled Cold Chain

When the cold chain is continuously monitored and every shipment analyzed, manufacturers and producers reduce spoilage and damage and increase revenue due to less waste. In addition, distribution routes are optimized with improved dispatching capabilities. Products can be traced to the minute and mile, which reduces surprises and provides peace of mind for customers. In addition, fleet companies and their customers have complete control of designing analytics and reporting capabilities to help meet the myriad requirements necessary for compliance with emerging regulations and divergent requests from governing organizations. Precise analytics are enabled, which help assess the success of distribution processes and equipment so that prudent adjustments can be made to continually improve outcomes. All these data can be used as an important part of internal risk management and quality assurance processes.

Reliable cold chain solutions are becoming an essential component of today’s globalized and increasingly regulated marketplace. The cold chain logistic services market is expected to grow from $6.7 billion today to $10.7 billion by 20172. To remain competitive, manufacturers, logistics providers and producers of goods need to improve their business models by adding cost effective wireless modules, MIMS and cloud-based platforms like the SLP to optimize the cold chain.

To learn more, contact Gemalto M2M: Jack Rubarth, jack.rubarth@gemalto.com

1 – Cold Chain Biopharma Logistics Sourcebook 2011
2 – Global Healthcare Cold Chain Logistics Market Report & Forecast
About Gemalto

Gemalto (Euronext NL0000400653 GTO) is the world leader in digital security with 2011 annual revenues of €2 billion and more than 10,000 employees operating out of 74 offices and 14 Research & Development centers, located in 43 countries.

We are at the heart of the rapidly evolving digital society. Billions of people worldwide increasingly want the freedom to communicate, travel, shop, bank, entertain and work – anytime, everywhere – in ways that are enjoyable and safe. Gemalto delivers on their expanding needs for personal mobile services, payment security, authenticated cloud access, identity and privacy protection, eHealthcare and eGovernment efficiency, convenient ticketing and dependable machine-to-machine (M2M) applications.

Gemalto develops secure embedded software and secure products which we design and personalize. Our platforms and services manage these secure products, the confidential data they contain and the trusted end-user services they enable. Our innovations enable our clients to offer trusted and convenient digital services to billions of individuals.

Gemalto thrives with the growing number of people using its solutions to interact with the digital and wireless world.

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