YOUR COLD CHAIN HAS BEEN BROKEN.
NOW WHAT?

CHOOSING THE RIGHT TEMPERATURE MONITORING SOLUTION

5/23/2012

Kevin Kohleriter

Vice President of Product Management and Marketing

ShockWatch, Inc.

www.shockwatch.com

SHOCKWATCH®
SMART SOLUTIONS FOR SAFE TRANSIT

Introduction

Globally, pharmaceutical regulators are becoming attuned to cold chain issues as biologics, vaccines, and other temperature-sensitive products are commercialized. Many recommend including temperature monitoring technology in every cold chain shipment.

Documenting chain of custody for temperature-sensitive products enhances regulatory assurance and alerts shippers to conditions affecting products shelf life and efficacy. Knowing whether, when and where temperature excursions occurred helps shippers ensure safe products, protecting their patients and their own reputations. It also assigns accountability when excursions occur.

Solutions range from inexpensive indicators that alert shippers to mishandling to sophisticated monitors and data recorders that pinpoint when, where, and for how long an excursion occurred. Companies, therefore, can match the technology to their needs.

Data Loggers

Electronic recorders, sometimes called data loggers, collect information continuously. They measure and record such parameters as temperature, humidity, and atmospheric pressure. The devices can be programmed to trigger alarms at specific damage boundaries for single or multiple events. Typically, data can be downloaded directly or wirelessly, enabling analysis and documentation of when damage may have occurred. The latest technologies can be as small as a matchbook, yet read data wirelessly without anyone ever opening the packaging. This is a huge advantage for quality control and customs inspections, allowing shipments to remain in validated shippers. In contrast, opening the shipper breaks the package validation, introducing unknown conditions into the cold chain.

Data recorders are best for high-value shipments and challenging shipping lanes. They are particularly important for large crates or reefers using active cooling systems that are subject to mechanical failure and

human error. Their use is limited by memory capacity and battery life, particularly during multi-month transits. Therefore, data recorders should have the ability to conserve batteries to enable at least 30 percent longer life than the expected shipping and storage duration to minimize the risk of data loss towards the end of the journey. Because battery life is diminished by constant use, it is more efficient to record data periodically. Their cost ranges from less than $50 to several thousands of dollars, based on technology requirements.

Data Monitors

Like data recorders, data monitors can track temperature, humidity, and impact but, in contrast, only report excursions from predefined thresholds. This extends battery life by up to 12 months and allows shippers to make quick decisions based upon instantly identifiable incidents. Their small size makes them easy to insert into shipments without adjusting the packaging.

Temperature data monitors are best used to ensure that product stability data after shipping matches the data before shipping. They also can be correlated with transit records to determine when and where single or multiple excursions occurred, and to indicate time and temperature for mixed-product loads. Because data monitors are less expensive than data recorders they are good solutions for last-mile transport.

Chemical and Mechanical Indicators

Indicators identify excursions visually, changing color when single or multiple thresholds are passed. For example, an indicator may be activated if the product temperatures are outside predefined parameters.

Indicators work in a wide range of conditions, including frozen and deep frozen (-75°C and below) shipping. They are moisture- and tamper-resistant, irreversible, and are highly accurate. They can be activated at any point during the packaging and shipping process, sometimes without any preconditioning required.

Due to their lower cost indicators make good candidates for smaller packages that often are non-returnable and non-recyclable. Chemical indicators don't use batteries and have a shelf-life of one to three years, so can be purchased in bulk and stored. They may be mounted on the product, inside the packaging, or on the packaging. While internal mounting shows environmental conditions inside the packaging, external mounting provides a visible deterrent to mishandling. Both provide a permanent exposure record.

Combinations

Indicators often are combined with data monitors or recorders, providing a double layer of protection. Temperature indicators also can be combined with impact indicators. Many protein-based products cannot be dropped without affecting their efficacy, and glass vials are susceptible to cracking if mishandled, contaminating the product.

Not every product requires a high-tech solution. Choosing technology based upon the product and its risks can contain costs while still providing needed assurance.

About ShockWatch

ShockWatch is the global leader in the innovation and optimization of logistics and cold chain risk management systems. With over 200 worldwide partners in 62 countries, ShockWatch solutions currently enable the Fortune 500 to mitigate risk, reduce costs, and optimize their supply chain. For more information on the company's robust solution set, visit us at www.shockwatch.com.

The ShockWatch portfolio of temperature products

ShockWatch has a vast portfolio of monitoring devices, including the TrekView wireless temperature recorder. These products include the ColdMark and WarmMark temperature threshold indicator line. The indicators are designed to ride along with temperature recorders to assure integrity of those individual shipments that may be split at a distribution points, such as for retail, pharmacy, supermarket or blood bags.