RISK MITIGATION

The Invisible Component of Cold Chain Management

Overview

The practice of cold chain management continues to evolve rapidly. New developments in hardware, software and global connectivity provide an unprecedented window into cold chain performance. This has led to dramatic improvements in handling, storage and distribution, and the promise of greater cooperation among supply chain partners.

This has also convinced cold chain managers that their monitoring program must be greater than the sum of its parts. Robust, responsive and accurate dataloggers are essential, as is powerful software and reliable, secure web hosting. However, smart cold chain management looks beyond the visible components of monitoring programs to address their underlying structure and stability. One of these critical but less visible components is risk mitigation.

Defining Risk Mitigation

Risk mitigation of cold chain management is defined by three key, auditable elements:

- IT security and redundancy
- Supply chain risk management
- Disaster recovery planning

If these three components are properly structured, the long-term viability and efficacy of a cold chain program is substantially strengthened, as is the confidence of the cold chain management team.

In addition, knowledgeable managers also look to the stability, industry knowledge and thought leadership of their solution provider as another way to assess the strength and competitiveness of their program.

SENSITECH
COLD CHAIN VISIBILITY

A Company Commitment
Quality Management System (QMS)

Sensitech's QMS represents a companywide commitment to Quality that enhances every activity the company undertakes. As a supplier of "critical components," the company tests its hardware and software products against rigorous standards, including the National Institute of Standards and Technology (NIST), ISO 9001:2008, and applicable elements of common Good Manufacturing Practices (cGMP). Sensitech adheres to validation protocols and enforces quality control at every level. The underlying QMS is grounded in a well-documented and audited program of continuous process improvement and incorporates standards in Relentless Root Cause Analysis (RRCA) and Corrective Action / Preventative Action (CAPA). Finally, Sensitech's manufacturing principals are grounded in six sigma and lean manufacturing programs.

Element 1
IT Security and Redundancy

Sensitech is a subsidiary of Carrier Corporation, which is part of UTC Climate, Controls and Security, a $19 billion unit of United Technologies Corporation. The internal IT resources available to Sensitech, and the standards for redundancy and security it must meet under UTC quality guidelines, embody world-class practices.

Designed with redundant architecture, Sensitech's ColdStream® solution is used by customers to collect data, monitor shipments and provide notification and alarms. The ColdStream smart client installed on customers' desktops works in online or offline modes, reducing impact on the real-time acceptance of product and ensuring data integrity in the event of intermittent internet connectivity at a remote receiving site. Network infrastructure and servers are fully redundant to insure minimal impact to customers in the event of a server or network issue.

Customer-specific ColdStream databases are hosted in a hardened data center, located in an offsite, independent facility that provides power sources, redundant points of connectivity to the Internet, and security mechanisms against fire, physical threats and natural disasters. All ColdStream databases are monitored and supported 24x7 with a fully replicated mirrored site in a separate geographic region of the United States. Data is synchronized between the two sites, regularly audited and compliant with Statement on Standards for Attestation Engagements (SSAE) 16.

The ColdStream application and data hosting components are built to satisfy the requirements of FDA 21 CFR Part 11, including audit trail and traceability for all electronic records, multi-layered permissioning, and backward compatibility for previously acquired data files.

Customer data is backed-up according to information technology best practices. Before the data is stored in an offsite data vault, the back-up process includes encryption and compression; these formats remain throughout the length of storage. Backed-up data is tested and verified to be recoverable annually.

Sensitech's ColdStream environment and Quality Management System (QMS) have successfully passed all customer audits, now numbering more than 100 over the past decade, to the satisfaction of our cGMP customer base. Sensitech securely hosts cold chain and logistics data for over 200 companies around the globe.

KEY QUESTIONS
1 Is data integrity ensured?
2 Is data warehousing adequate, and compliant with 21 CFR Part 11?
3 Can these cold chain protocols be audited?

Element 2
Supply Chain Risk Management

Many of Sensitech's customers consider temperature dataloggers and their related systems to be "critical components" of a Quality Management System. Therefore a disruption in the supply of monitors can lead directly to disruption of the shipment of a customer's product.

Sensitech has three primary means of mitigating this risk:
- Adequate safety stock
- Dual-sourcing strategy for critical components
- Multiple manufacturing sites

Sensitech employs best-in-class standards to meet its goal of adequate safety stock, factoring in the variability of demand at the component, work-in-process, and finished goods levels. The use of a pull-based replenishment system supports global flexibility and drives a high-velocity supply chain. Sensitech maintains at least three month's finished goods inventory in various global locations, at manufacturing sites and in-transit. Safety stocks are verified through scheduled reporting and site visits.

The company's dual-sourcing strategy incorporates alternate component qualifications, as well as testing and validation of goods produced with these alternate components. Sensitech's quality procedures insure continuous testing from the component specification to the finished goods level with quarterly reported statistics. Additionally, unit-level calibration is linked to the unique serial number at the device-level and documented in certificates of validation provided with each order.

Finally, Sensitech's product can be manufactured in Asia, Eastern Europe and the United States. Each manufacturing facility has the assets and infrastructure to meet all Sensitech volume requirements. Sensitech's primary manufacturers also have remotely-located sister companies that support the manufacturer's disaster recovery program and provide added assurance to Sensitech.

QUESTIONS TO ASK
1 Does my cold chain provider keep adequate safety stock?
2 Does my provider have a credible plan for the dual-sourcing of critical components?
3 Does my provider have the reach and supply chain muscle to carry out its plans?
4 Do I feel comfortable that the risk of product disruption is minimized?

Element 3
Disaster Recovery Planning

Under UTC's guidance, Sensitech adheres to a Business Continuity and Disaster Recovery protocol designed to either maintain or resume mission-critical functions in the event of a disaster. The Sensitech plan specifies annual readiness evaluations, and the ability to deploy multiple monitor programming sites and fulfillment operations around the globe. Sensitech's practices mandate the monitoring of adequate safety stock, coverage by appropriate levels of general liability insurance to protect Sensitech assets and infrastructure, and immediate notification to customers in the event disaster recovery is invoked.

At all times Sensitech has access to the corporate resources of Carrier, UTC Climate, Controls and Security and UTC.

QUESTIONS TO ASK
1 Does my cold chain provider have a Business Continuity / Disaster Recovery Plan?
2 Is it adequate to meet the needs of my cold chain in the event of a disaster?
3 Are notification practices adequate?
4 Are my cold chain provider's insurance levels adequate to protect its assets and infrastructure?

Stability and Thought-Leadership

Founded in 1990, Sensitech is a global leader in cold chain monitoring. First certified under ISO in 1999, Sensitech has an unbroken history of recertification in its primary facilities, and currently is certified to ISO 9001:2008 standards. All of Sensitech's outsourced manufacturing sites are certified to ISO 9001:2008 and ISO 13485 standards for medical device manufacturing.

The first company to offer a global, single-use, electronic monitoring programs, Sensitech has provided almost a quarter century of innovation and thought-leadership in driving Good Cold Chain Management Practices (GCCMP) for the Pharmaceutical, Food, and Industrial Chemical industries.

This includes active membership in the Parenteral Drug Association (PDA), participation in a number of subgroups, and contributions to Technical Reports. Sensitech has also participated as a member of the technical steering committee of the PDA's Pharmaceutical Cold Chain Interest Group (PCCIG), the International Safe Transit Association (ISTA) Thermal Council, the Association Francaise du Froid (AFF) French Cold Chain Council, and is on the International Air Transport Association's (IATA) Time and Temperature Task Force (TTTF) a subgroup of its Live Animal and Perishable Board (LAPB). Additionally, Sensitech has contributed documentation of best practices to U.S. Pharmacopeia's (USP) Packaging and Storage Expert Committee for the re-write of USP General Chapter <1079> Good Storage and Distribution Practices for Drug Products.

Sensitech efforts over the past decade have helped to clarify standards for lithium battery compliance, and for electromagnetic interference (EMI) compliance and documentation. In support of this effort, Sensitech was awarded the Cool Chain Europe 2010 Best Quality, Qualification or Risk Management Project by Pharma IQ.

Beyond regulations, Sensitech continues to provide the cold chain industry with best-in-class electronic dataloggers, software, and global cold chain programs that presently serve 3,000 customers around the world.

Sensitech
Putting it All Together

Sensitech is proud of its commitment to a disciplined Quality Management System, rigorous Security and Redundancy practices, comprehensive Supply Chain Risk Management, powerful Disaster Recovery Planning and thought-leadership throughout the global cold chain monitoring industry. Taken together, these practices provide customers with a level of Risk Mitigation that is unique in the industry, and an essential component of every Sensitech customer offering.