Reducing Risk and Costs in the Global Supply Chain

Global Quality & Compliance Services for the Life Sciences Industry

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Protecting the Life Sciences Supply Chain Can Be Costly

Maintaining the efficacy and potency of temperature-sensitive products throughout the life sciences supply chain requires a significant investment for biological, pharmaceutical, chemical, and clinical manufacturers. This is also true for other life sciences' companies with temperature-sensitive goods, such as the manufacturers of medical devices, diagnostics products, reagents and animal health medicines.

Not only is product efficacy and potency critical to the health and well-being of patients, but maintaining patient safety and assuring compliance in the cold chain is also paramount to the brand reputation of a company and its profitability.

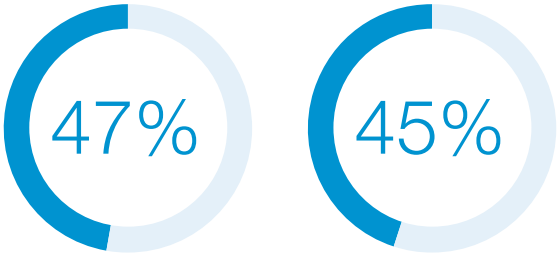
As an example of the costs associated with protecting medicinal products throughout the supply chain, here are a few insights from the pharmaceutical industry.

- According to the 2017 Biopharma Cold Chain Sourcebook, the global market for pharmaceuticals is nearly $1.2 trillion in revenue, and by 2021, it is projected to grow by 41%. Of today's market value, $283 billion is product that requires refrigerated storage and transport. This segment alone is projected to grow by 70% by 2021, a rate that is more than twice the expected growth of non-refrigerated products.[1]
- For the transportation segment of this market, the cost of protecting these temperature-controlled products (refrigerated and frozen) is estimated to be $13.4 billion in 2017—and by 2021, this will rise to $16.6 billion.[2] Add in compliant packaging and storage throughout the entire supply chain, from manufacturing to final destination, and the costs mount even higher.

Clearly, protecting products in the supply chain and reducing risk during shipment and storage is an area that helps maintain control and lessens these challenges.

Life Sciences Supply Chain Challenges

The top two issues for life science companies are:



Quality Management Issues

Supply Chain Optimization

Source: LNS Research[3]

Quality assurance and compliance amidst change

According to the Life Sciences Logistics Playbook, the transport of final drug products is one of the most difficult tasks in the pharmaceutical supply chain. This is because of the sensitive nature of the product and the complexity of a modern logistics network. For instance:

- Constantly changing variables, along with evolving regulatory requirements, present an ever-present demand for risk mitigation.
- Factors such as temperature conditions at origin and destination, seasonal variances, packaging, carriers, special handling requirements, and load configurations can disrupt optimal cold chain management. Transport routes, time in transit, stop-over points, and handling at each transition point can also introduce inconsistencies that affect product integrity.
- Any unforeseen or uncontrollable factors—such as delays in shipping, shock or vibration en route, extreme temperature or weather variations, human error, or packaging and equipment failures—could have significant ramifications.

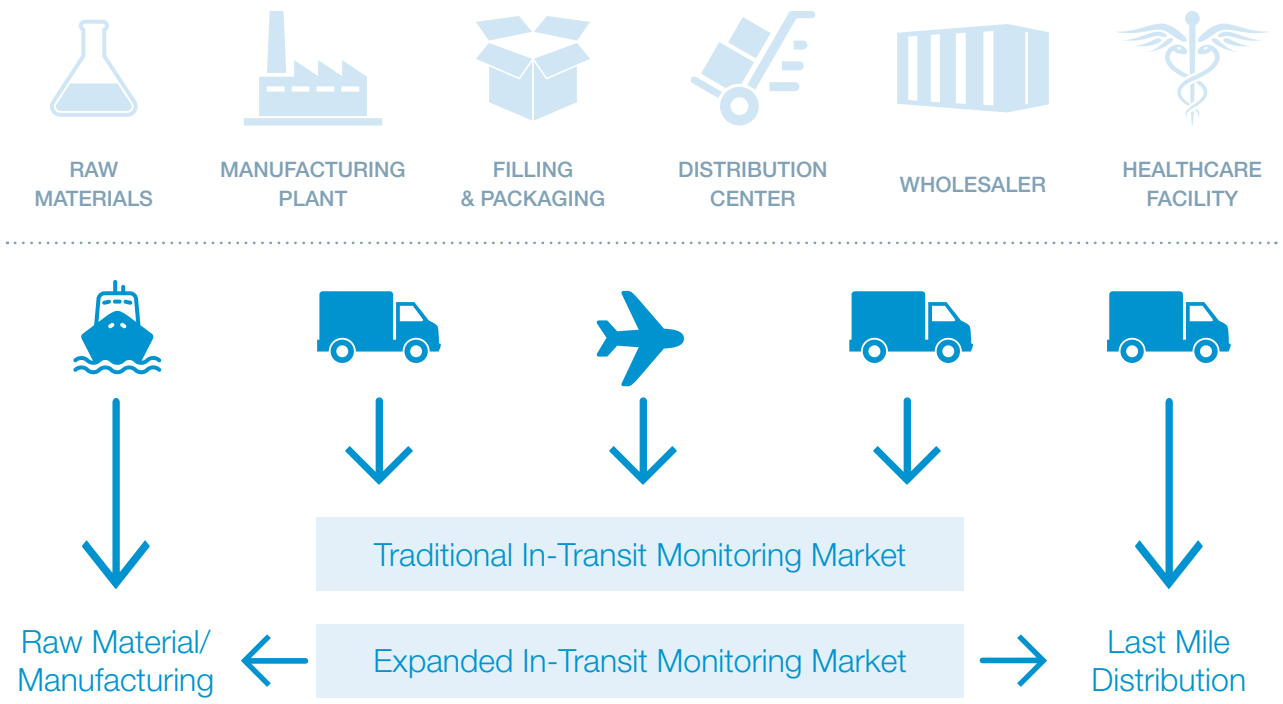
Whenever there is an excursion from an ideal temperature range, the expenses related to any subsequent required actions could range from hundreds of dollars to millions. Whether it's a QA inspection, or the rejection of product, these are costs that manufacturers want to minimize.

Consequently, it has become imperative for life sciences companies to invest in a continuous improvement program that monitors temperature compliance and corrects cold chain weaknesses before they incur major costs or increased regulatory scrutiny.

A continuous improvement program goes beyond adherences to stability budgets and takes risk mitigation to the next level by collecting data while products move through the transportation and storage segments of the supply chain. This kind of program provides a truer picture of the amount of acceptable risk in relation to product value and risk tolerance. It also helps companies identify the subsequent consequences for potential compliance failures and issues that would be questioned in audits.

It's only through this kind of visibility and transparency that product quality is ensured and patients are confidently protected.

Visibility Throughout the Life Sciences Supply Chain



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Supply Chain Visibility through Continuous Improvement

From manufacturing and packaging to facilities, storage and transportation, the optimal cold chain requires constant, in-depth visibility—along with continual oversight, maintenance and improvement. This kind of hands-on analysis can ensure that a company's standard operating procedures (SOPs) are continually safeguarding products and reducing risk.

End-to-end supply chain visibility is achievable through a continuous improvement program that uses temperature monitoring to ensure the adherence to Good Cold Chain Management Practices (GCCMP) and global regulatory compliance.

A continuous improvement program includes quality and compliance management that can proactively identify cold-chain weaknesses and non-compliance issues throughout the supply chain and offer remedial actions that drive efficiencies and cost-effectiveness.

With such a program, manufacturers gain assurance that the processes between them and their customers, suppliers and partners have the proper validation and qualification. Inherent risks that naturally arise with temperature-sensitive products are avoided as supply chain processes are continually monitored, adapted and improved.

A commitment to such a program helps companies reduce risk and achieve:

- Greater product value, quality, and efficacy
- Increased assurance of patient safety
- Comprehensive global regulatory compliance
- Enhanced shareholder value
- Improved brand equity

The Sensitech Approach to Continuous Improvement

Sensitech is a global leader in supply chain visibility solutions that track, monitor and protect products across the entire cold chain for companies in the life sciences, food, consumer goods and industrial markets.

Our unique global continuous improvement programs for life sciences companies combine technology, data analytics and multi-disciplined expertise in a unique and unrivaled manner. We work with 18 of the top 20 global pharmaceutical manufacturers, and help them identify the optimal balance between controllable costs and uncontrollable risks. Through our programs, these customers develop a culture of continuous improvement that escalates control, manages risk, increases regulatory compliance, and improves efficiencies—all while reducing costs and ensuring consistent quality throughout the supply chain.

We have extensive expertise in qualification and validation methodologies and techniques as well. We help our customers qualify their processes to assure that replicable processes meet acceptance criteria under variable ranges. And we help them validate and demonstrate that their processes produce consistent results that meet acceptance criteria under highly controlled and uncontrolled conditions.

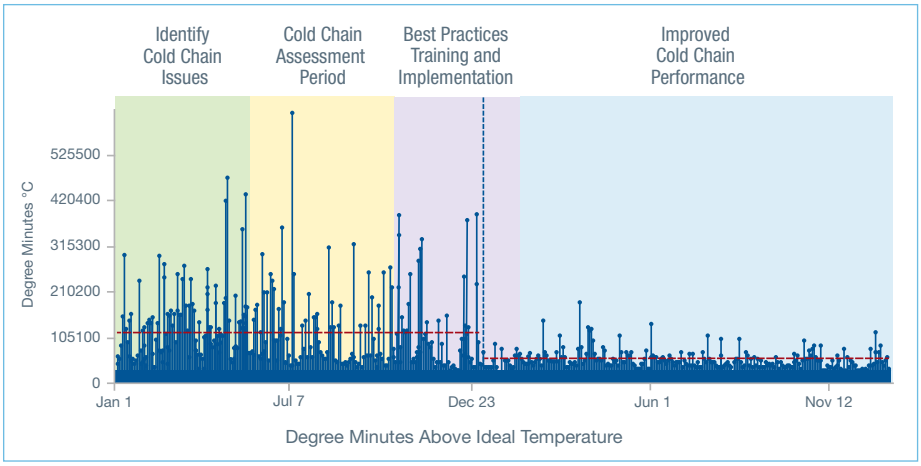
Our continuous improvement programs are specifically tailored to the unique requirements of life sciences companies. Accordingly, they include recommendations for corrective and preventative actions (CAPAs) as governed by the U.S. Food & Drug Administration (FDA), the European Union Good Manufacturing and Distribution Practice (GXP) guidelines, and other global regulatory entities.

The Sensitech Continuous Improvement Program

End-to-End Supply Chain Visibility for Life Sciences

- Go beyond shipment-level acceptance and rejection decisions.
- Track, monitor, and protect the quality and integrity of temperature-sensitive products across the global supply chain.
- Identify systematic weaknesses and variability in cold chain processes.
- Qualify and validate processes throughout the chain.

Continuous Improvement Over Time



Continuous improvement benefits: Less product loss or waste and improved operations with better work flow, more informed decisions, and performance-based accountability.

Throughout the Supply Chain

AT ORIGIN

Manufacturing, Processing, Storage, and Distribution

IN TRANSIT

Trailers and Transport Containers

AT DESTINATION

Pharmacies, Hospitals, and Clinics

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At the Heart of Our Program: Sensitech Global Professional Services Team

To achieve the rigor that is required by a continuous improvement program, we offer life sciences companies the extensive expertise and resources of our Sensitech Global Services.

This team of dedicated, world-class professionals combines their strong life sciences expertise and supply chain best practices with state-of-the-art monitoring technology and analytics to help improve quality and reduce risk.

Our experts have the industry experience and knowledge to ensure the greatest return on a continuous improvement investment, with skills that go well beyond the basic compliance, validation, and qualification requirements. And they provide the insight needed to drive process enhancements that can dramatically improve a customer's bottom line.

Collectively, our Global Services team works closely with our customers to:

- Assess and analyze existing practices to see how they align with proper cold chain management.
- Train employees and business partners in the use of temperature-sensing monitors.
- Evaluate monitoring processes and standard operating procedures' effectiveness in order to discover troublesome trends and patterns within the supply chain.
- Uncover root causes of cold chain issues and identify how to improve processes, quality and compliance.
- Identify the corrective actions that remediate issues and provide continuous improvement over time.
- Increase quality and profits while reducing costs.

Sensitech Global Professional Services for Life Sciences

Program Management

For each customer, there is a dedicated Program Management Team that oversees every facet of a Sensitech Continuous Improvement Program.

- A Program Manager leads a team of experts that have the knowledge needed to optimize every aspect of the life sciences supply chain.
- The Program Management Team has expertise in end-to-end program and project management, data collection and analysis, customer support, and technology services.
- They deliver application engineering, deployment and integration support; customized reporting and analytics; data management services; training; and technical and client support services.

Industry Expertise

To fully execute continuous improvement for customers, Sensitech provides on-staff industry experts for consultation. These professionals are life sciences experts, computer scientists, industrial engineers, and validation engineers. There are specialists in logistics and packaging, as well as statisticians. These professionals deliver insights and expertise in the following areas:

- Storage cooler and freezer management
- Freezing and cooling equipment operation
- Distribution
- Logistics and transportation management
- Marine and air transportation
- Loading and unloading practices
- Global compliance
- Standard operating procedures (SOP)
- Quality assurance

An Overview of Our Professional Services

Temperature-sensitive supply chain assessments

In these assessments, our Services Team assesses, evaluates, and documents internal and external practices as they relate to proper and compliant product storage, handling, and distribution. Each assessment is customized to meet the specific needs and objectives of each customer, with the goal of identifying thermal compliance gaps and opportunities for improvement. For instance, an assessment can include the overall evaluation of global supply chains over multiple seasons, or it could be tailored to evaluate a specific trade lane, product, or other variable.

Validation services for storage

We provide documented testing performance under highly controlled conditions to demonstrate that a company's processes, methods, and systems consistently produce results that meet pre-determined acceptance criteria for storage.

Qualification services for transportation

Our Services Team documents testing performance to demonstrate that transport processes, methods, and systems consistently produce results which meet pre-determined acceptance criteria for in-transit storage against label claims.

Lane segmentation analysis

Our Team analyzes the legs and hubs shipments take over multiple modes, providing descriptive data on where excursions occur, where corrective action should be taken, and delivers a clear understanding of who was in control of the shipment at a particular point in time. This analysis enables corrective actions, improves data quality for insurance claims, and supports continuous process and cost improvements. Continuous process improvement is important to cost-effectively plan for extreme temperature lane segments.

Thermal mapping studies

We help companies create temperature profiles and determine improper variability within any storage or transportation location, including facilities, trailers, intermodal containers, or air cargo holds.

Shipping studies

In addition to the above services, we conduct performance studies to evaluate if specific shipping systems maintain the proper temperature as per design specifications and requirements in an actual distribution environment.

Ambient temperature profiles

Sensitech has developed a proprietary methodology for measuring the variable temperatures in a shipping environment and modeling the environment's inherent thermal risk. The Risk-Controlled Ambient Thermal Profile (RCATP) helps companies define optimal supply chain requirements for packaging and the associated investments required to maintain product quality, patient safety and regulatory compliance.

Site facility monitoring

Our Services Team helps customers automate the temperature monitoring and documentation of their storage facilities and equipment to ensure compliance with current Good Manufacturing Practices (cGMP). We can put flexible, wireless temperature sensing tools with automated record-keeping and reporting capabilities into facilities, refrigerators, freezers and cold rooms.

The Continuous Improvement Framework

For each delivery in our Continuous Improvement Program, we use a multi-layered framework that includes four key steps: validated data collection, compliant data storage and management, expert analysis and reporting, and intelligent corrective action.

Each step of the framework is managed by a dedicated Program Manager that utilizes experts within the Sensitech Global Services team network as needed.

It's All About the Data

Most life sciences companies already collect supply chain temperature data to meet the basic requirements of global regulatory compliance or simple shipment-level accept or reject decisions. However, the data can become a major asset when it comes to supply chain visibility, quality and compliance management, and continuous improvement.

Here are some interesting findings in a recent survey by Pharma Logistics IQ:[5]

- One of the top data challenges for pharmaceutical companies is that their organization is not using data effectively.
- The use of stability data in temperature monitoring is one of the top trends directing supply chain strategies for these companies.
- Temperature controlled logistics professionals also shared how important data is for the future of their firm's progress in the supply chain, with 53% saying it's vital, and 43% saying it's important.

Data is at the core of meaningful and measurable related insights that can help identify systemic weaknesses and variability in cold chain processes and isolate problems before they occur.

Companies can move beyond shipment-level decisions and use actionable, relevant data to drive critical quality and safety decisions throughout the supply chain that help them more rapidly meet and exceed critical key performance indicators (KPIs). For instance, data and expert analysis can help:

- Improve processes such as temperature monitoring on individual shipments. Notifications can alert companies when products are out of ideal product ranges so corrective actions can be put in place quickly.
- Identify trends and patterns that can help longer-term process improvement, as well as better resource allocation, improved quality and cost reduction. For example, data aggregated from hundreds or thousands of shipments can be used to identify the root causes of temperature problems, ensure the continuous improvement of the cold chain, and minimize the occurrence of future problems.

Sensitech is one of the few companies that collects and aggregates cold chain data for purposes of evaluating processes such as the ones mentioned here.

1. Validated Data Collection

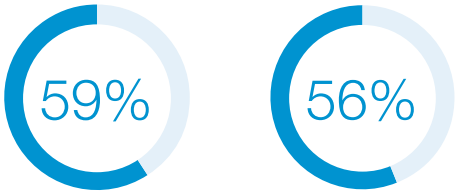
The initial step in a Sensitech Continuous Improvement Program is the use of validated data acquisition and data logging instruments for in-transit, handling, and in-storage monitoring.

Our Global Professional Services Team helps customers define appropriate data acquisition or data logging goals and objectives utilizing a proven risk-based approach. For instance, our experts can help companies create a plan for what will be observed and measured, establishing key performance indicators (KPIs) to provide a baseline measurement to define and measure progress against organizational goals.

The Team then recommends the appropriate Sensitech instruments for collecting temperature-sensitive data for the analysis of processes, packaging, carriers, special handling services, transportation modes and lanes. They can set up alarm specifications that are mapped to specific stability data or other key criteria. Next, our experts develop a detailed data collection plan that is reliable and statistically valid. For instance, they can provide standards-based guidance in determining the sampling size and monitor placement protocol for the appropriate level of granularity and accuracy of data collection.

A key component of this program is ensuring that all the stakeholders in the supply chain—from the customers to their suppliers and partners—work together cohesively. Our Team trains and works with people in each stage of the supply chain to ensure the proper use of the temperature monitors and the appropriate collection of clean and comprehensive data. We have quality controls that ensure all of these activities are done in a manner that meets global compliance requirements.

In the Eighth UPS Pain in the Chain Survey of healthcare and life sciences companies, participants shared what they used to reduce product damage and spoilage:



Source: https://www.ups.com/media/en/UPS-PITC-Executive-Summary-North-America.pdf

2. Data Storage and Management

The data, once collected, is uploaded to the Sensitech ColdStream® Cold Chain Manager (CCM) database, which is validated for the collection of a continuous chain of clean and comprehensive data.

Private cloud-based ColdStream CCM software includes a full validation package that is built to comply with EU GDP, EC Annex 11, and FDA 21 CFR Part 11 requirements.

ColdStream CCM software provides a secure and comprehensive data management system that our experts and customers can use for viewing, storing, retrieving and analyzing of critical time-and-temperature data as well as detailed shipment and logistics information.

Many customers want to use this data in combination with other metrics and information from other sources. This could include temperatures from manufacturing and packaging through to distribution and to pharmacies or other end users. Some customers include data from their financial systems, including product costs, internal tracking numbers, or data from their logistics or warehouse management systems. When available, they also add in information from third-party carriers, with data on various shipping points, international customs arrivals and other pertinent metrics. For more robust profiles, customers are also including local traffic and weather data to help them identify optimal shipping routes based on seasonality and other factors.

3. Analysis and Reporting

Throughout this process, Sensitech Global Professional Services experts leverage a wealth of industry experience to identify supply and cold chain weaknesses. They use industry-standard and proprietary data analysis tools to measure critical control points, map, and analyze the cold chain, and provide insight for process improvement.

For instance, an enormous amount of raw data is collected on shipments and temperature. To extract the full value, our experts analyze data on shipment attributes, such as suppliers, origin, destination, product, product type and transport company, which can be correlated with temperature data.

Using detailed time-stamped shipment information and temperature history, our team can examine individual shipment and aggregated data to measure critical control points to identify root causes for variation or poor performance. And through statistical process control (SPC) methodology, the Team can help customers identify variations outside of allowable tolerances and regulatory requirements.

They can provide insights on the compliance of programs and whether shippers and receivers are complying with SOPs with data on time-and-temperature monitors, shipping and receiving, unusual activities, data entry errors, and user activities. With all this knowledge and insight, our services team identifies weaknesses in the cold chain and determine root causes.

Documentation of these insights can be used to meet regulatory requirements and hold supply chain partners accountable and in compliance with established technical quality agreements.

4. Corrective Actions

Once the data has been analyzed, the Global Professional Services Team then delivers clear and concise reports with easy-to-interpret graphs and tables to customers to facilitate turning information into action plans that provide continuous improvement.

The various services we offer, such as onsite assessments, thermal mapping studies, and shipping studies, can help customers discover root causes to alarmed or rejected shipments. After the implementation of these discovery projects, we then provide recommendations for remedial measures for process improvement and corrective actions. For instance, with data visualizations, we help customers prioritize the required changes and help ensure they have a meaningful and measurable impact on the supply chain.

Our experts help customers focus resources where they will have the greatest impact, driving continuous improvement of the cold chain processes. They work closely with our customers to ensure that process changes maintain the desired outcome through KPI measurements over time. The Team also can facilitate communication to integrate the analysis and recommended changes across the supply chain between customers, suppliers and, partners.

Using the identified trends and patterns as a base line, ongoing monitoring can then show how those process changes led to measureable improvements.

The Intelligent Supply Chain in Action

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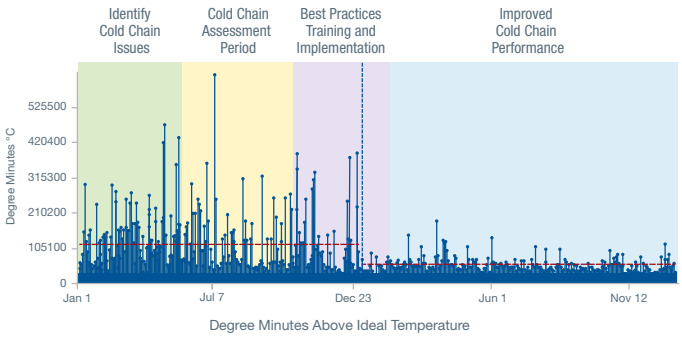
Continuous Improvement Over Time



The Impact of Continuous Improvement

When data and analysis are combined with Sensitech Global Professional Services expertise and action by our customers, the results are significant—with considerable cost savings, process efficiencies, and most importantly, reduced risk for both manufacturers and patients.

A continuous improvement program takes an ongoing and determined approach to identifying issues and then making process improvements. The examples here provide a quick overview of some of the key achievements that are possible in a continuous improvement program for significantly reducing costs in the supply chain.

CASE STUDY #1

Ensure Proper Shipping Service Level

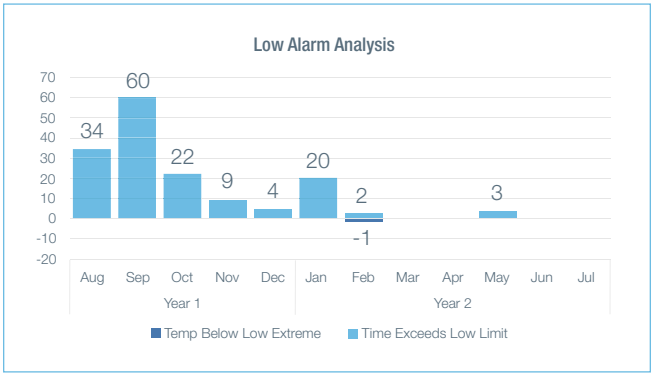


Figure 1: Reduced alarms over time

In a continuous improvement program, temperature-monitoring data can help identify issues that are contributing to excessive costs in the supply chain. For instance, a major pharmaceutical company started using monitors in its diabetes care division as a standard operating process. Within a short time period, the company discovered a significant amount of alarms on shipments of an ambient product through an outsourced supply chain provider. In fact, there were a number of time excursions occurring outside the lower limit of a broad ideal temperature range. Upon further quality assurance exploration, the company found out that its product, which did not require refrigeration during shipping, was being shipped with refrigerated products in reefer trucks. Because this type of transportation mode can be as much as three times more expensive than regular shipping, the company was able to reduce its shipping costs by hundreds of thousands of dollars annually. It also saved significantly by eliminating nearly all of the alarms and reducing the costly quality assurance checks for temperature deviations.

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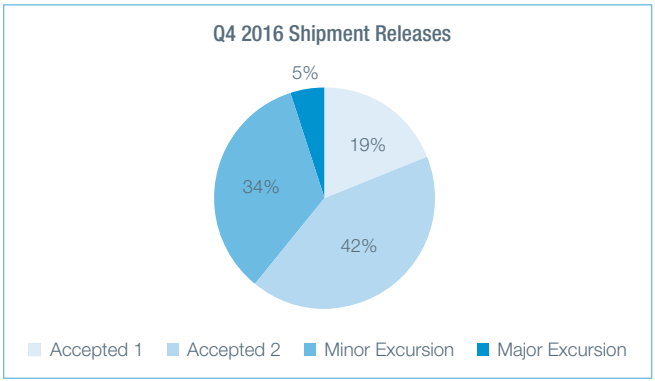
CASE STUDY #2

Reduce Quality Assurance Investigations



A large pharmaceutical manufacturer wanted to reduce the cost and time associated with QA investigations on alarmed shipments. To help this customer achieve this objective, Sensitech created an automatic shipment release for bulk shipments of its vaccines that contained up to 60 monitors per shipment.

Typically, a program with that number of monitors would require several hours to download, process and analyze the data from each monitor. To reduce that time, the company established a set of rule-based protocols and, based on those rules, Sensitech created a system that analyzed the high and low stability temperatures for each monitor. The system also analyzed the number and type of alarms, and based on those rules, allowed for the disposition of product automatically based on these calculations.

In the graph above, which is based on data from approximately 3500 monitors from a single origin, all minor (34%) and major (5%) excursions would have required investigation through a QA process. However, with the sophisticated rule-based system, now only those with major excursions (5%) go through QA while 34% of the products with minor excursions are released automatically instead of being delayed for days for investigation.

Other Continuous Improvement Successes

- A packaging analysis for a large U.S.-based pharmaceutical company that uses approximately 200,000 temperature-sensing monitors a year helped reduce shipping costs significantly. Sensitech helped the company analyze its next-day packaging and identify that it was robust enough for two- to three-day shipping without any compromise to the product. With less need for overnight shipments, the company was able to adjust its shipping processes and save an amount in the low millions annually.
- A large diagnostics company uses ColdStream CCM data and automated reports to increase efficiency, save considerably and improve patient safety. By sending advanced shipping notifications (ASN) to a select group, this company can now advise only the specific people involved with impending shipments and arrivals around the globe. Emails are sent to quality assurance and local shipping personnel to alert them of the arrival of shipments with monitors that need downloading. Upon arrival, product qualification can be implemented quickly, allowing good products through and ensuring that compromised ones are not released for sale into the mass market. This enhances the program compliance, improves communication, and reduces operational inefficiencies as rule-based reports highlight non-compliance issues and conditions.

As Sensitech continues increased collaboration with our customers, we can help them reduce supply chain costs, improve efficiencies, reduce risk and improve patient safety.

Conclusion

Protecting temperature-sensitive, life sciences product, meeting regulatory compliance, and controlling the costs of logistics services, materials, equipment, and product loss is paramount to running a risk-averse and efficient supply chain. Visibility and analytics into the performance of the supply chain provide additional operational focus and opportunity for improvement. Sensitech's Global Professional Services Team, with more than 15 years of Life Sciences' engagement experience, uniquely provides recommendations, guidance and analysis based on a history of cold chain shipments.

Before committing to a full continuous improvement program, companies can start with a smaller engagement such as a global assessment or a shipping study to evaluate the opportunities that continuous improvement brings.

End Notes

[1] http://pharmaceuticalcommerce.com/supply-chain-logistics/pharmaceutical-cold-chain-logistics-13-4-billion-global-industry/

[2] ibid

[3] http://www.qualitydigest.com/inside/quality-insider-article/top-challenges-facing-life-sciences.html

[4] https://www.logisticsforthelifesciences.com/life-sciences-logistics-playbook

[5] Digitalization and Big Data's Impact on the Pharma Supply Chain, Pharma Logistics IQ, https://www.pharmalogisticsiq.com/logistics/white-papers/digitization-and-big-datas-impact-on-the-pharma

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About Sensitech

Sensitech Inc. is focused on delivering supply chain visibility solutions that track, monitor and protect products for global leaders in the food, life sciences, consumer goods and industrial markets. Our solutions are focused in three key areas: quality and compliance, supply chain security, and logistics performance management. Quality and compliance solutions address temperature-sensitive, complex supply chains focused on delivering the highest quality possible, while our supply chain security solutions help to mitigate risks associated with theft, diversion and chain of custody.

Sensitech's logistics performance solutions deliver origin-to-destination, real-time transparency to any in-transit journey. Sensitech Inc. is an ISO 9001:2008 company, headquartered in Beverly, Mass., with more than 35 sales, service and distribution locations around the world. Sensitech is a part of UTC Climate, Controls & Security, a unit of United Technologies Corp., a leading provider to the aerospace and building systems industries worldwide. Visit www.sensitech.com for additional information.

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