SENSITECH
COLD CHAIN VISIBILITY

WHITEPAPER

A Cold Chain Process Improvement Methodology

An Integral Component of Your Business Strategy

Organizations dealing with perishable products are beginning to find ways to improve cold chain processes that will result in maximum improvement to their bottom lines. And they're looking for big improvements, not modest ones. The good news is—this is attainable.

By continuously monitoring organizations' cold chain distribution and storage segments, companies can gain new visibility into their process dynamics. There is always something to learn about how to improve a cold chain process. And then there is the ever important end result: improved product quality and efficiency, as well as reducing the number of potential risks and wrong conclusions.

At the core of process monitoring is data collection. Within and beyond the United States, there is a surge of compliance regulations and guidelines surrounding the data harvesting of temperature-sensitive perishables, including food items, pharmacopeial articles and industrial chemicals. This new interest stems from safely securing and protecting the cold chain, as being mandated by the U.S. Food and Drug Administration (FDA). The FDA further identifies various technologies, such as radio frequency identification (RFID) monitors, to efficiently streamline the data collection process.

The cold chain is inherently complex. Regardless of what point a perishable product is in transit, it is always susceptible to temperature abuse, including goods being poorly pre-cooled or excessively cooled. The numerous interruptions in the food supply chain, for instance, often result in having the perishables remaining too long in an open-air loading dock at a distribution center or retail store, above an acceptable control-temperature setting at customs, or in the wrong sections of a multi-zone trailer.

In the pharmaceutical cold chain, complexities are numerous due to the many supply chain partners: manufacturers, distributors, third-party packagers, primary and secondary wholesalers, retail and online pharmacies, hospitals and clinics. Because of the various exchange and drop-off points, distribution environments often involve several modes of transportation, climate zones and seasonal changes.

As a result of these intricacies and nuances, U.S. and foreign regulators insist on evidence or information indicating that temperature-sensitive products have been maintained at the defined controlled requirements.

Regulations & Guidelines Requiring Cold Chain Data

The Pathogen Reduction and Hazard Analysis and Critical Control Point Rule of 1998 (PR/HAACP) is quickly becoming a standard in U.S. food service and food processing industries; it is already a requirement in meat, poultry and seafood processing. PR/HAACP is a seven-step program based on identifying critical control points in which temperature management is prioritized as a universal critical control for the elimination of microbial pathogens.

The Canadian Food Inspection Agency's "Code of Practice for Minimally Processed Ready-to-Eat Vegetables" document states that "the high moisture content of fresh vegetables, the lack of lethal process to eliminate microbial pathogens, and the potential for temperature abuse during preparation, distribution and handling

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further intensify the risk of food-borne illness." As such, the CFIA requires "finished products should be maintained at 4°C during transportation and storage." This is executed, according to the document, with "temperature measuring/recording devices," "distribution records" and "corrective action records."

In the perishable supply chain, the distribution segment is often where most temperature excursions occur, resulting in loss of quality, product degradation and inefficacy.

The United States Pharmacopeia (USP) is the official public standards-setting authority for all prescription and over-the-counter medicines, dietary supplements and other healthcare products manufactured and sold in the United States. According to the USP General Chapter <1079> guidance document, it specifically identifies four temperature storage categories, including "Controlled Room Temperature," which is between 20 and 25 degrees Celsius. The USP encourages "… those who supply articles (e.g., wholesalers and manufacturers) and delivery contractors should provide documented evidence to show that the required temperature range has been maintained during transportation."

The USP also emphasizes Good Cold Chain Management Practices (GCCMP) by stating that "manufacturers may attach temperature-monitoring devices and/or ship under specified controlled conditions to ensure that the desired temperature is maintained during distribution" as well as "validated temperature- and/or humidity-monitoring technologies" can be used to monitor the environment during shipment and distribution.

In the industrial chemicals market, monitoring the temperatures of time and temperature-sensitive (TATS) products as they move through the complex distribution chain bolsters quality control and quality assurance processes as well as complies with current and pending standards and accreditation programs.

This push toward a regulatory compliance requirement to collect cold chain distribution and storage data is a prime opportunity for organizations to take this same information and investigate their distribution and storage practices for process improvement, regardless of industry. This data can be turned into business intelligence, making process improvement an integral part of a business strategy.

A key consideration about cold chain process data is that it must be easily interpreted—to executive management as well as to regulators. There is no point in showing statistical data that cannot be quickly absorbed by important stakeholders who are not statisticians.

Process Improvement Methodologies and the Beginnings of 'SPC'

There are many forms of process improvement methodologies that rely on statistics: Six Sigma, Lean Six Sigma, Business Process Re-engineering (BPR), Total Quality Control (TQC) and Total Quality Management (TQM) are just a few.

The basis of a good process improvement methodology starts with Statistical Process Control (SPC)—a well-proven methodology dating back to the 1920s and 1930s. Walter Shewhart, a statistician, published two books, "Economic Control of Quality of Manufactured Product" (1931) and "Statistical Method from the Viewpoint of Quality Control" (1939). These books are the foundations for SPC, quality and continuous process improvement. SPC is the application of statistical methods to determine and manage the causes of variation in a process. The concept of process variation is central to SPC. Inferior quality and excess costs are the end result of process variation.

Also during the 1920-'30s, Joseph M. Juran and W. Edwards Deming were considered to be "quality" gurus in the United States. Shewhart and Juran worked together at Bell Telephone Laboratories and emphasized quality as a basis for manufacturing uniformity. During this time period, Shewhart created the first control charts,

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marking the first statistical application to manage process variation. The approach was applied very successfully in key industries such as shipbuilding during Word War II, but was not widely adapted after the war. Interestingly, it was the Japanese industry that first embraced the approach.

In the 1950s, Juran and Deming lectured in Japan about managing quality. "From them, the Japanese learned two key things: the application of statistical method to measure and control process variability and the responsibility of management for quality. Japanese leadership emphasized continuous process improvement within project structures involving all process participants. They enforced a rigorous customer focus and essentially broke away from the notion of a separate 'quality function.' For them, quality not only supported strategy, it was strategy."[1]

The Japanese developed and refined the process improvement methodology and have applied it perhaps most notably in the automobile manufacturing industry. Today, both GM and Ford are closing down operation centers around the world due to weak revenues and profits stemming from subpar vehicles, while Japanese automobile manufacturers continue to adhere to the basic principles of SPC and remain as a top-quality automobile provider.

The Mechanics of SPC: Controls Charts and Forms of Variations

How do organizations know if their processes are stable and optimized or if they are inhibiting them from delivering the best quality product? Companies need to apply some method of analysis to evaluate process. This method is a control chart, which is a time series of data. A control chart has three horizontal lines: a central line for visual reference to detect limits and trends, and two control limit designations — the UCL (upper control limit) and LCL (lower control limit). The limits are automatically computed from the data and placed symmetrically on each side of the central line. The control chart calculates what's "routine" and what's "exceptional," depending on the variation of the data. The key is that all of the data that falls between the limits is considered to be routine or predictable. Given an organization's current processes, it's predictable that incremental data will fall within those limits. The broader the limits, the more variation exists within a process. And if quality is compromised, it is likely that high variation exists.

The bottom line: Variation costs an organization, whether it's time, resources or hard dollars. Reducing variation and reaching process stability offers consistently higher quality. It also demonstrates that companies are in control of their cold chain processes—specifically that they are attaining meaningful and measurable improvements in their distribution and storage processes.

A main objective of control charting is to distinguish routine and exceptional forms of variation in order to prevent overreaction and underreaction to a process. Additionally, there is a wide range of possible variation contributors that must be considered along with the process that is being measured, including human variation (i.e., operator to operator), time variation (i.e., shift to shift, day to day, week to week, month to month, season to season), and location variation (i.e., building to building, site to site, state to state, country to country). If high variation exists, it is likely that quality will be compromised.

With control charts, the focus is on the aggregate of data, rather than trying to explain the individual events. This means that they concentrate on the underlying process that resulted in that data. Through careful analysis, companies can reduce routine and eliminate exceptional variations in unstable processes. This is accomplished by evaluating and understanding the process, taking the appropriate action necessary and re-evaluating the results—which can all be accomplished in three steps. For instance, Step 1 is to evaluate and understand the process. Step 2 is to make small but significant changes and start reducing the process variation. After re-evaluation, Step 3 is to take additional steps to maximize control and quality (see chart).

[1] "The Perfect Storm: Building of the Six Sigma Phenomenon," James Torok, http://www.isixsigma.com

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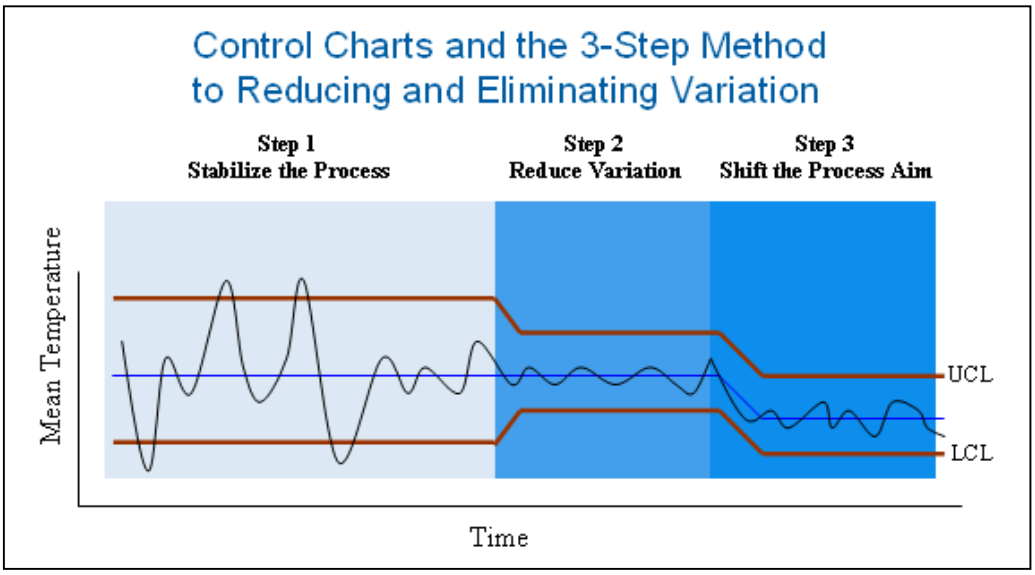

SPC Can Help Answer Big-Picture Process Questions

By applying an SPC-based methodology to the cold chain, it can help form the foundation to answer the important process questions:

- How should we measure cold chain process performance?
- How can we learn more about this process dynamics, so we can significantly improve product and process outcomes immediately?
- How are we measuring variation?
- How can a specific process influence final product quality?
- Are we certain we really know how to measure a specific process?
- Have we identified everything that was important when measuring a process?
- Are we aware if something changed in the process?
- What is deemed a significant or meaningful accomplishment?
- Would slightly higher or lower temperatures beyond specification be better, and by how much?

Sensitech's Cold Chain Expertise

Sensitech's Cold Chain Visibility Services utilize an integrated six-step methodology called the ColdStream™ Process Framework, which is based on SPC and continuous improvement—often called SPC-CI or SPI (statistical process improvement). The framework is a disciplined approach used to monitor processes driving cold chain operations for the purpose of improving quality.

1. **Define**: identify the problem and articulate a clear operational definition to outline what will be observed and measured
2. **Plan**: develop a detailed, data collection plan that is reliable and statistically valid
3. **Measure**: use Sensitech's patented data collection instruments
4. **Analyze**: evaluate data to identify weaknesses in the cold chain
5. **Recommend**: deliver easy-to-interpret reports and recommendations to prioritize changes for make measurable process improvements and results
6. **Verify**: ensure recommendations have had the desired outcome by continuing to measure for the purpose of verifying process improvements

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Our Difference: Analyze, Recommend and Verify

Sensitech's Cold Chain Visibility Advisory Team uses trademarked software to make the right assessments and conclusions. The sophisticated software system creates temperature and shipment data over specific time periods, producing an array of easily absorbed graphs for business executives who do not have a statistical analysis background.

The Advisors make solid recommendations based on 15 years of experience. It is unlikely that there is a cold chain problem that Sensitech hasn't seen. And Sensitech understands what works and what doesn't when it comes to problem-solving. For instance, if a process has ten areas of weaknesses, Sensitech can help an organization prioritize how to overcome those weaknesses, offering solutions that have an immediate and substantial impact. Additionally, Sensitech delivers the information in a format that makes sense to all stakeholders.

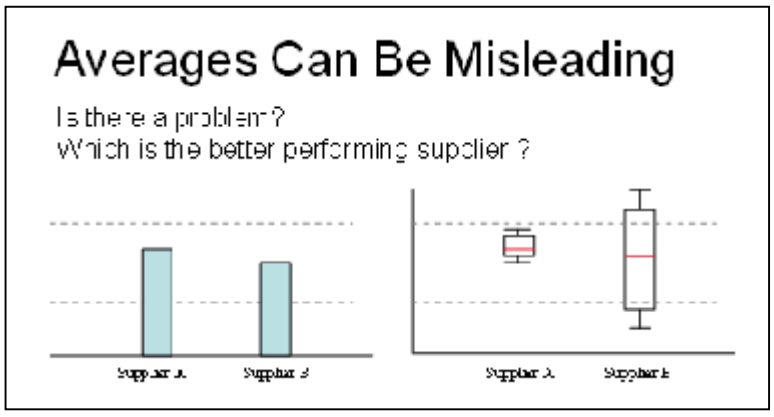
Because every process has variation, there needs to be a verification phase—creating a continuous loop of confirming the recommendations and their impact. Thus, verification must be ongoing for true process improvement.

Examples of Applying SPC to the Cold Chain

Many current information gathering and reporting tools don't tell the whole story, and they often lead to the wrong conclusions. There are many common mistakes—from the overuse of averaging for assessing cold chain performance, to the misuse of exception reporting when determining supplier performance, to the misuse of specifications when setting up acceptable unit cost targets.

For instance, average temperature is a common measurement method to determine supplier reliability and performance. But averages often lie. Case in point: Supplier A and Supplier B are undergoing an evaluation according to shipment reports based on average temperature. While both maintain temperatures well within the acceptable range, the average temperature of supplier A's shipment is a little higher than those of Supplier B's.

However, viewing the data in Sensitech's software offers a "box and whiskers" format; comparing that format with the standard bar chart tells a dramatically different story. Supplier A has low variation around acceptable standards. On the other hand, Supplier B has wide temperature variation that will compromise product integrity. Simply looking at averages hides the variation, making Supplier B look like the better performer (see below). Standard deviation is sometimes used to address this problem, but the concept of standard deviation is often not well understood and ends up being ignored by users of the information.



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Cold Chain Visibility Advisory Team

Companies often lack trained and qualified technical personnel to conduct properly designed cold chain monitoring programs. There are few experts in the cold chain industry who can both understand the physical and practical aspects of the cold chain as well as harness the power of SPC to efficiently and effectively improve the cold chain. Sensitech has that expertise on staff.

Improved cold chain management results in reduced product loss, improved product quality, enhanced food and drug safety as well as increased revenues. Taking cold chain monitoring to the next level, Sensitech's Cold Chain Visibility Advisory Team applies sophisticated statistical analysis techniques to the data collected to identify trends and patterns in cold chain performance. Understanding variability allows customers to implement corrective action before problems escalate.

The Cold Chain Visibility Advisors are uniquely experienced in analyzing cold chains in the food, life science and industrial chemicals markets. Advisors are strategically positioned around the world for direct customer interaction and appreciation for geographic considerations. Common professional backgrounds include industrial engineers, logistics and packaging experts, validation specialists, postharvest horticulturalists and food scientists.

Sensitech's advisors apply their problem-solving skills to cause-and-effect analysis, helping organizations to:

- Develop a process control plan
- Determine why problems exist
- Understand trends
- Identify optimal data collection methods
- Plan a continuous improvement project
- Conduct problem and gap analyses
- Detail the root sources and causes of process variation
- Interpret control charts
- Understand statistical thinking
- Determine if a process is stable
- Understand if a process is capable of meeting required specifications
- Identify new processes and/or streamline others
- Formulate potential solutions
- Help select the best solution
- Standardize and evaluate results and findings

The Cold Chain Visibility Advisors use Sensitech's trademarked software to aggregate numerous pieces of information and then slice-and-dice it to show which shipments went beyond required time and temperature specifications, how much variation exists within the cold chain process, and which suppliers consistently maintain the integrity and quality of the goods, etc. (see below).

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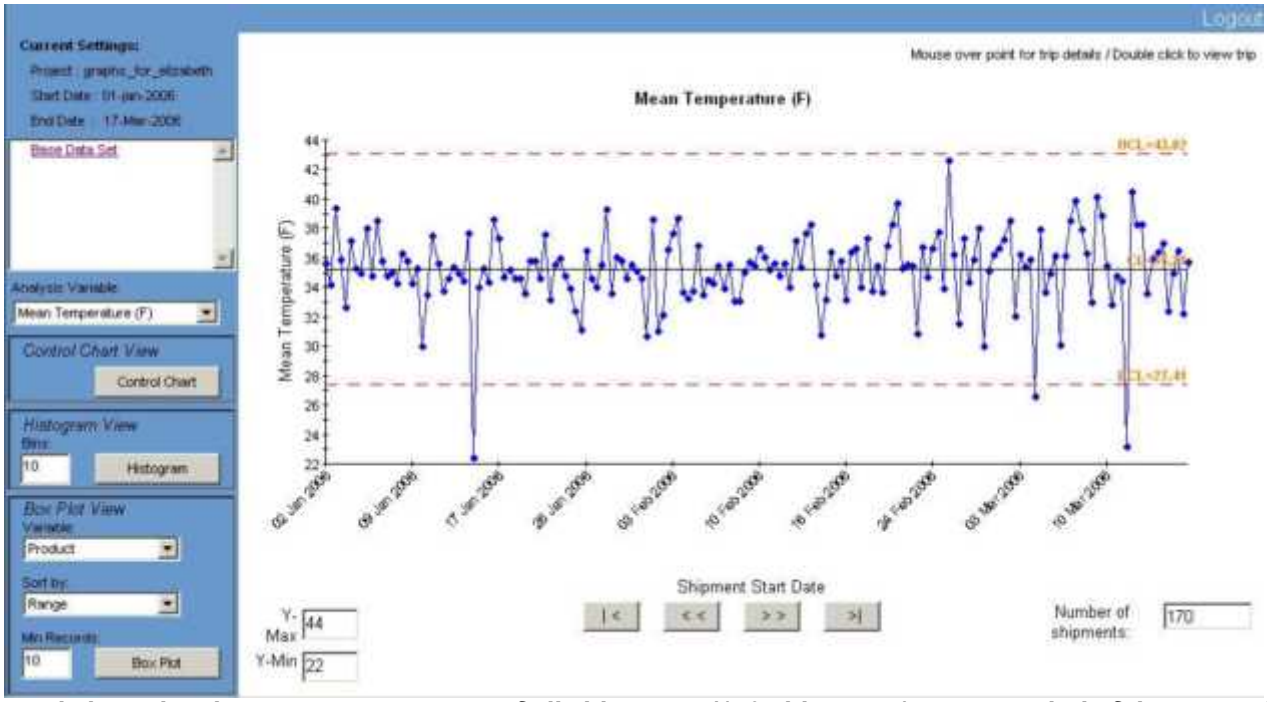
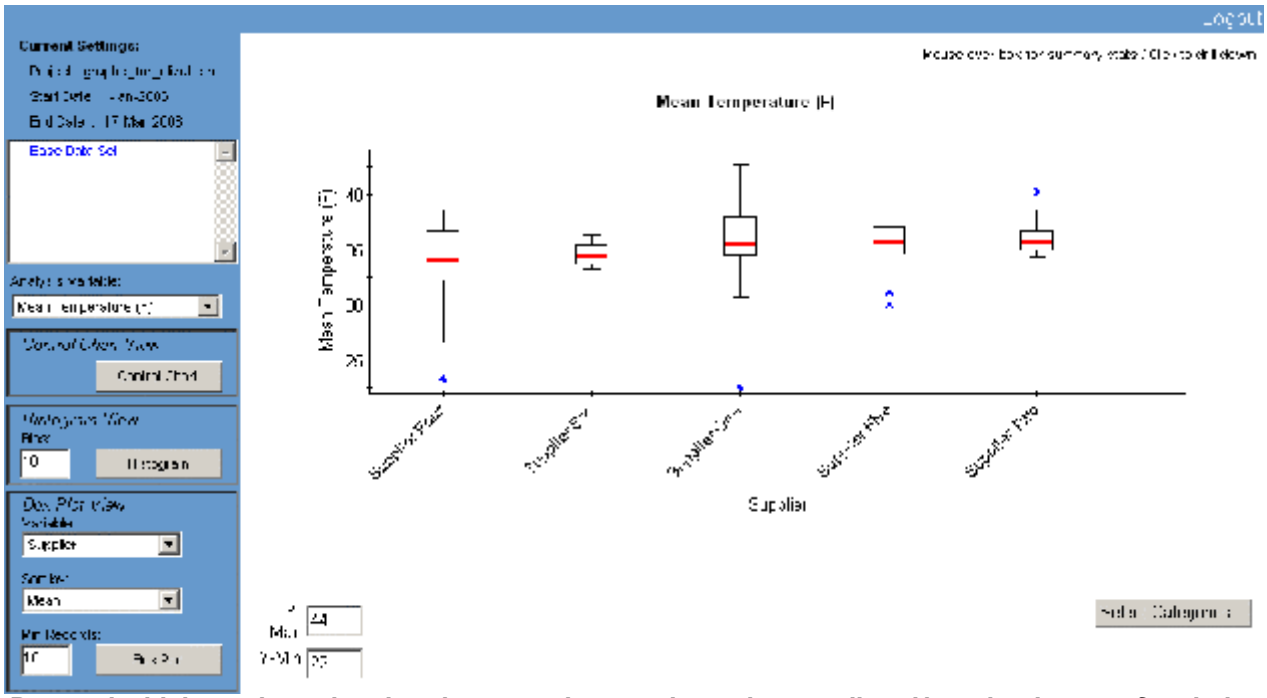


Control chart showing mean temperature of all shipments (170 shipments) over a period of three months.



Box and whiskers chart showing the same data as above, by supplier. Note the degree of variation in mean temperatures.

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Conclusions

Because product quality and process improvement are under the renewed scrutiny of regulators, organizations are in a prime position to look toward a cold chain process methodology to overcome systemic weaknesses. It also demonstrates that companies are in control of their cold chain and attaining meaningful and measurable improvements in their distribution and storage processes. And a controlled process means reduced costs.

There is no need to gamble on hoped-for process improvements—especially for pharmaceutical companies that must validate or revalidate processes. A statistical process control methodology combined with continuous improvement helps organizations with temperature-sensitive products track their quality progress.

Sensitech's ColdStream™ Process Framework methodology charts variations in processes and quickly determines what is "out of control" as well as its root cause. With trademarked tools, all the information is presented in easily absorbed graphs.

A process improvement methodology in the cold chain is not design experimentation or probability testing. It covers frequent data collection and timely feedback so that problems are detected and removed, and waste is eliminated. The end result: a higher-grade quality product.

About Sensitech Inc.

Sensitech is the world's leading provider of cold chain visibility solutions enabling global leaders in Food and Pharmaceuticals to track and monitor assets across the supply chain, protecting the integrity of their temperature-sensitive products. Sensitech is an ISO9001:2000 registered company. The company is based in Beverly, Massachusetts, and has offices in Amsterdam, Calgary, Melbourne, Redmond and Santiago with service and distribution offices around the world. For additional information about Sensitech, call 978-927-7033 or visit www.sensitech.com.

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