# An Approach to Cold Chain Management In the Manufacturing Facility

*An Industry White Paper*

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11-1040-1211

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# The Special Case of Cold Chain Products

The value chain for temperature sensitive products has lengthened significantly over the last decade. Consumers have become increasingly accustomed to going to the supermarket in the dead of winter and purchasing fresh fruits and vegetables from around the world. Major restaurant chains are able to offer unlimited quantities of seafood on a nationwide basis with the majority of the supply coming from the other side of the world. Life-saving medicines are routinely and widely available, regardless of their sensitivity to temperature changes.

This new level of availability has been driven by advances in logistics, information technology and temperature management in both packaging and transit. Refrigerated transportation is now common, and the sophistication of the supply chain has made it more cost-effective to use it. At the core of these improvements has been a very significant focus by the members of the supply chain as they view this type of product movement—the cold chain—as a process , in the same way that manufacturing a product is viewed as a process, with system inputs, outputs and performance measurements.

The greatest attention to cold chain process management has been given to the warehousing and logistics portions of the value chain. This is understandable as there is a large number and wide variety of assets employed, along with an inherent variability that comes from using an asset pool belonging to third-parties, with each specific asset having its own performance profile. Great time and investment has gone into specialized packaging and standard operating procedures (SOPs) to control for this variability. Consequently, well-controlled cold chain distribution processes have been critical to the growth of several industries. However, there is a portion of the overall value chain has not had the same level of interest but is completely in the manufacturer's control: temperature control during manufacturing.

The gap in control is certainly not within unit operations. Temperature control is one of the critical criteria in production of perishable goods. During continuous processes, temperature management can be built-in. It is during product transfer between unit operations and in holding/wait times that are often part of batch processes that temperature information may be missing, and therefore, creating an opportunity for product quality to diminish. The margin for error can be relatively small, as finished fresh food products begin to degrade at temperatures over 5˚C (41˚F) and finished biologic products are at risk outside 5˚C to 8˚C (41˚F to 46˚F). However, Process Development and Quality Control groups will have set acceptable temperature ranges for process environments and in-process and holding product temperatures, along with limits for out-of-range time and temperature.

The remainder of this paper explores one approach to managing cold chain information within the facility, prior to outside distribution, taking into account data acquisition and management, along with exception, KPI and other reporting.

## The Approach

As in many process improvement activities, data acquisition is the first step. Facilities temperatures can be sourced from sensors within environmental systems—either hard-wired or stand-alone, which would require manual reading and data entry. Care should be taken when using such data; room temperatures can vary greatly as seasonality, air flow, insulation, proximity to lighting/doors and other factors influence the consistency of temperature within a space. It may be prudent to conduct a temperature survey of any temperature controlled space to determine the level of variability.

Product temperatures can be taken manually or pulled from sensors within the production process. Temperature in transit and/or holding is more problematic. While direct product temperature measurement produces the best data, facilities data can be used as a proxy, particularly if the hold/wait time is significant. The same comments above regarding facilities data apply here as well.

It is necessary to consider the "location" of the product within the manufacturing environment. Location information can be derived from an automated identification and data capture (AIDC) such as a bar code matched to a location, from a radio frequency identification system, or it may be entered manually. Location information provides the basis for matching temperature data that comes from a static sensor. In addition, having the data on specific materials' entry and exit to a given area provides a proxy for the location of the materials while in process.

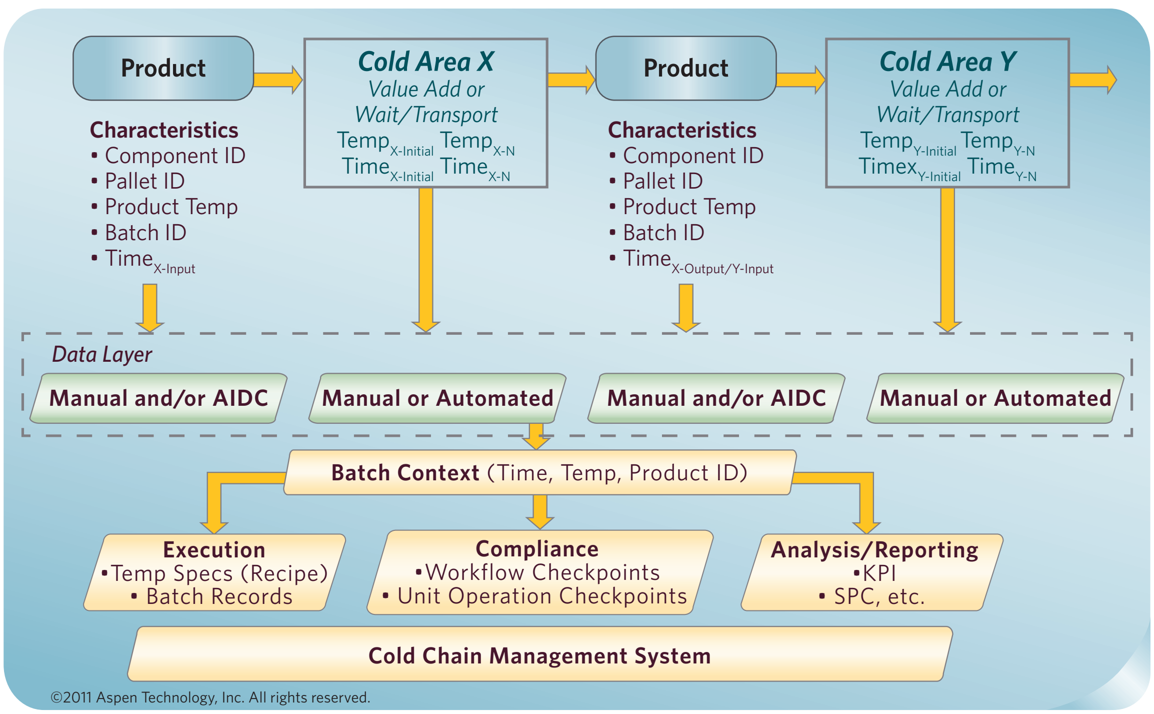


*Figure 1: Example of an in-facility Cold Chain Management System.*

Acquired data also need the batch "context". Context provides the ability to group data into meaningful sets that allow comparison and analysis. Batch context for cold chain data must mirror that of the production process so that raw materials, designation of intermediate products, batch numbers, work orders, etc. are meaningful. A method must also be derived to add this contextual information during product movement, whether by manual data input or by pulling data from other databases and/or control systems. Figure 1 portrays an example of a full cold chain data acquisition and compliance system that also provides the capabilities for process analysis and improvement.

In addition to providing the data and batch context, the system in Figure 1 provides for SOP compliance. Should the SOP call for an area in the facility to be a given temperature and that temperature is not met, a deviation can be recorded as well as the corrective action and authorization. The system can also be designed for 21CFR Part 11 compliance, with electronic signatures and appropriate data storage. Further, when the cold chain is viewed as a process, appropriate data analysis provides the foundation for process improvement. Reporting on key performance indicators (KPIs), such as the high temperature registered in a cold area or too much time in transit or storage, tells operations personnel when the process is out of control. Some organizations use a "time out of refrigeration" (TOOR) metric as a KPI and an important part of the overall quality control scheme.

TOOR can be derived from an overall cold chain management system using time-stamped data coming from a combination of sensors that travel with the product, location information (in- or out-of a refrigerated environment) and temperature information from environmental sensors.

Analysis using statistical process control (SPC) is also a useful technique for understanding the consistency of unit operations performance. Looking at a cold area as a unit operation, SPC can provide insights into the temperature consistency as well as the source of variation. Performing SPC on batch-level TOOR and wait/hold time data can also provide a risk profile for the overall process as well as targets for process improvement.

## Summary

The industries that produce and move temperature-sensitive goods have made great strides in managing the cold chain. While great attention has been paid to the in-transit portion of the cold chain, the in-process portion is equally important. In the production of temperature-sensitive goods, temperature control within the manufacturing environment is a critical part of assuring that the overall process delivers high quality product. Batch processes, in particular, benefit from this approach. Due to their discontinuous nature, hold/wait and transit times are built in, providing opportunities for the product to spend time out of refrigeration.

With this overall construct, cold chain management systems can be implemented within the facility. Appropriate data to be acquired include product identification and time-stamped product location and temperature data—both facility and product temperatures. In addition, overlaying a batch context on this data supports batch-specific quality control activities and provides the foundation for batch comparison and process improvement using such tools as statistical process control.

Taking the cold chain process into account can minimize production and final quality risks, and therefore minimize product rejection and overall costs.


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