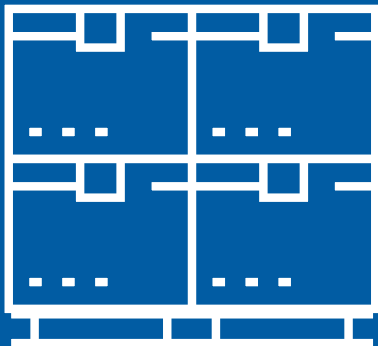
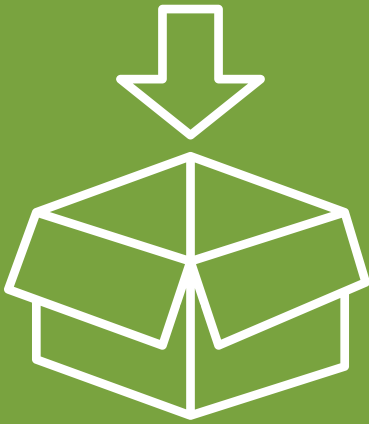


# Optimizing Temperature- Controlled Supply Chains with ColdStream<sup>®</sup> Select



A Carrier Company

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Cloud-based enterprise data management systems can significantly improve compliance, security, and transparency for life sciences companies. Globalization, tighter regulations, complexity and cost pressures have added strain to pharmaceutical supply chains. Additionally, to avoid quality issues and improve control during distribution, companies are relying more heavily on precision tracking across their entire supply chain. The change outside a temperature sensitive product's designated temperature limits can adversely impact product efficacy, your company's reputation, and bottom line.

To alleviate these challenges, Sensitech® has created ColdStream® Select. As the third generation of Sensitech's enterprise data-management system and the evolution of ColdStream CCM, this extended and modernized platform was built to provide a reliable and forward-thinking platform to speed product release and comply with regulations. ColdStream Select helps you monitor and manage your end-to-end temperature-sensitive in-transit supply chain comprehensively and precisely.

This paper outlines a detailed description of the capabilities, features, and ways in which ColdStream Select works to support your company and temperature-sensitive products in the most reliable method possible.

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*ColdStream Select is an end-to-end, risk-mitigation cloud solution that protects validated data for product release decisions critical to product integrity and patient safety.*

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# An Inside Look at ColdStream Select

ColdStream Select is an end-to-end, risk-mitigation cloud solution that protects validated data for product release decisions critical to product integrity and patient safety. This extended and modernized platform supports and grows with your organization's needs, helping you and your partners manage your temperature-sensitive supply chains from origin to destination.

## System Traceability

As a private cloud application, ColdStream Select provides centralized time-and temperature records, organized in a relational database and is the gold standard for in-transit supply chain regulated condition monitoring, electronic record keeping and system traceability. It additionally supports system-of-record, streamlining CAPA workflows and product release.

## Improved Compliance

ColdStream Select provides companies with full system traceability that supports product disposition and CAPA workflow system of record.

Designed to comply with FDA 21 CFR Part 11, EC Annex 11 and cGxP guidelines, Coldstream Select delivers a system that can be validated for intended use and supports E-signature capabilities at both the shipment and monitor level.

Enhanced excursion/exception management increases your compliance and also provides more data about more shipments. Now you can automatically upload time and temperature data from validated real-time IoT dataloggers seamlessly to ColdStream Select.

ColdStream Select's flexible and configurable security settings also match customer IT requirements and policies such as expiration frequency and log-on format.

## Supports Global Supply Chain Operations:

- Supports multiple business units and workflow configurations
- Available in multiple languages: Chinese, Dutch, English (US, UK, AU), French, Italian, German, Russian, Spanish, and Japanese
- Users can view data in their local time zone. The data is stored in GMT/UTC time zone

## Supporting Systems and Logistics

ColdStream Select balances supply chain performance optimization and protects the integrity of a validated supply chain database. This solution was designed to take care of future developmental needs by focusing on forward-thinking processes and integrations:

- Improves quality processes and aims to help companies reduce excursion rates and shorten quarantine time
- Provides a globally-accessible web-based solution from a private cloud application
- Complies with and meets auditor expectations as outlined in FDA 21 CFR Part 11 and EC Annex 11
- Offers simplified validation with its single platform that supports multiple business units and divisions
- Facilitates easy system-to-system integration with other technology vendors and supply chain partners
- Enables faster product release through increased automation
- Reduces costs by providing more automation capabilities with software business rules
- Supports an enterprise, mission-critical model (24 X 7 X 365, the goal of 99.9% uptime including maintenance)
- Compatible with a full range of TempTale® Ultra products and TempTale GEO Ultra for comprehensive data collection
- Provides end-to-end temperature monitoring to ensure patient safety
- Reduces adoption barriers with deployment and validation improvements
- Integrates with other core business systems for improved automation efficiencies and reductions in human error
- Assists companies analyze shipments over time to improve SOP compliance and find ways to reduce costs in the supply chain



# Benefits From Utilizing ColdStream Select

Relying on ColdStream Select for your product disposition and in-transit data management supports continuous improvement. Sensitech's advanced analytics and deep professional services expertise deliver valuable data insights and can help reduce supply chain costs. Here are the core benefits:

## Ease of Adoption

**The platform is designed to be easily adopted into pre-existing workflows. It accomplishes this by supporting these additions:**

- Private cloud-based software application, no software installation is required
- Improved third-party ease of use when working across multiple pharma customer databases
- Available shipment API for streamlining shipment creation

## Faster Product Release

**ColdStream Select is designed to expedite the product release process through these additions:**

- Configurable notifications inform personnel when events occur and action is required (shipment in transit, quarantine, product released, etc.)
- Ability to release mixed product shipments faster with software-based alarming
- Automate disposition of minor, routine temperature alarms with business rules to drive workflow
- Closed shipment capabilities designed to meet Annex 11 restricts all end-users from editing any part of the shipment or associated monitors
- Bulk conditioning focuses on relevant temperature data for all monitors within the shipment

## Tailored Workflow Configuration

Multiple business units such as animal health, clinical, and commercial can all have their own workflows under one validated system, saving on validation and IT effort and expense.

Product disposition workflows are specifically tailored to user roles. This reduces human error while increasing efficiency. Alongside this benefit, saved search templates can also be used to share best practices.

## Streamlined Administrative Management

The role-based system increases speed and accuracy when adding new users for administrators. ColdStream Select supports single sign-on such as OAUTH or Active Directory, which also helps streamline admin management.

# ColdStream Select Feature Enhancements

Since evolving from ColdStream CCM, this platform has undergone several feature enhancements that allow it to level up with the demands of modern life sciences companies and changing supply chain regulations and operations.

## Flexible, Configurable, Automatic



### Provides flexibility and global access

A web-based application with permissions allows for global supply chain usage

Comes in 9 different languages and provides for local timezones



### Security settings are more configurable

This enhancement aligns with your company's requirements and security policies

Provides selective access for third party partners, configured for what their view and role designates



### Integrates with a variety of systems

API integrations with ERP, TMS, WMS, clinical trial IRT/IVR, logistics service provider software, etc



### Shipment creation

Auto create shipment data by integrating with other systems or via manual creation



### Mark events automatically

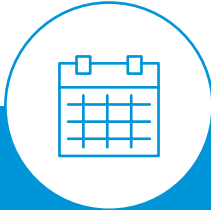
Able to integrate timestamped data directly from carriers as marked events



### Supports company workflows

Content is very configurable and tailored to each company's workflow

## Improved User Experience



### Streamlined user management

User Access administration is controlled by Selective Access, User Permissions Groups, and User Roles

The system automatically captures administrator and user audit trails through the event log



### Automatic touchless data upload

Receive automatic, touchless, real-time IoT time and temperature shipment data in validated system

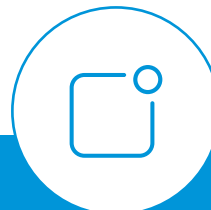


### Receiving enhancements and Quality improvements

Conditioning can now be finalized through single or multi-graphs at once

Save graph annotations for audit documentation

Provides streamlined excursion exception management



### Expanded notifications

Expanded notifications and configurable email content to notify of status change or to take action

# Software-Based Alarming

With the addition of software-based alarming, ColdStream Select provides more flexibility to apply stability alarm configurations. Software-based alarming allows for more complex mixed product shipments with faster product release capabilities. Simplify pack-outs and reduce the need to order and store different configured monitors.

## Backed by Professional Services and Support

ColdStream Select is backed by a worldwide support team dedicated to assisting clients in making critical business decisions to improve their management of the cold chain. The goal of ColdStream's program managers and data analytics is to help identify critical and actionable insights to create a continuous improvement cycle, improve compliance with SOPs and reduce costs across the temperature-controlled supply chain.

**Reach out today to learn how ColdStream Select can benefit your supply chain.**



# About Sensitech

Sensitech Inc. is a global leader in delivering supply chain visibility solutions. Our innovative monitoring products and services help to maintain the quality, integrity and security of our customers' valuable products at every step in their journey, all around the world. For 30 years, leading companies in the food, pharmaceutical, industrial, consumer goods and other industries have relied on Sensitech to help protect their products—and their bottom lines.



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