

ColdStream™ CCM

Cold Chain Manager

Increase Control. Demonstrate Compliance. Manage Risks.

ColdStream Cold Chain Manager (CCM) is an Internet-enabled, validated, 21 CFR Part 11 compliant software application designed to meet FDA regulations and cGMP guidelines for electronic record keeping. CCM implements a secure and comprehensive data management system for viewing, storing, retrieving and analyzing detailed shipment (logistic) information and critical time-and-temperature data of temperature sensitive shipments. The CCM application also provides users with secure remote access to detailed shipment information, temperature history, trend analysis reporting, and audit trails that are readily available for internal and external audit inspections.



Features

- Fully validated system
- Usability on a wide range of non-US English operating systems
- Compliance with 21 CFR Part 11
- Permission-based user profiles
- Automatic alerts and notifications
- Customizable views of data for different user groups
- Intuitive user interface
- Automatic date-stamped audit trail
- Electronic signatures and security access controls
- Offline operation mode when Internet connectivity is unavailable
- Powerful data export capabilities
- Online Help File

Benefits

- Improves quality control by demonstrating that Standard Operating Procedures (SOPs) are delivering acceptable results
- Increases visibility into cold chain processes and the performance of supply chain partners
- Provides instant access to transactional event-based data which expedites shipment disposition process
- Enables implementation of a risk-based approach for cold chain management
- Demonstrates compliance with Good Cold Chain Management Practices (GCCMP) and FDA 21 CFR Part 11 requirements
- Allows timely decision making earlier in the distribution process when automatically notified of a questionable shipment
- Reduces operating costs

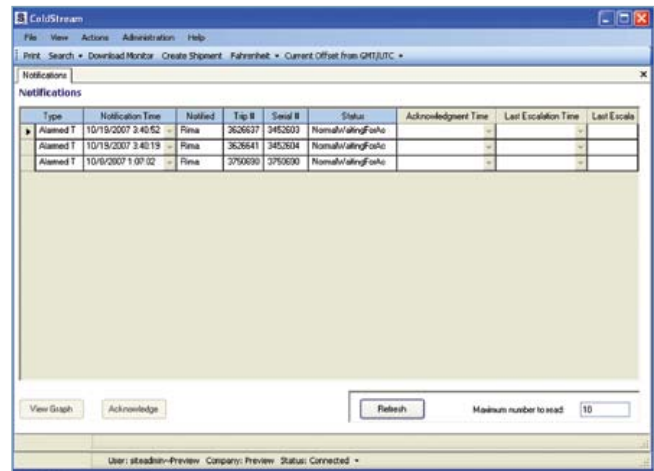
Benefits Realized When Implementing the ColdStream CCM Application

Throughout the cold chain, there are many unforeseen and uncontrollable factors that can cause products to be exposed to temperatures outside of their acceptable range for storage and distribution. This may result in a loss of product quality. Implementing the ColdStream CCM application provides a

comprehensive monitoring tool for your cold chain. This increased visibility assures that your temperature sensitive pharmaceuticals and biologics are maintained throughout the entire cold chain—therefore ensuring product quality and patient safety.

Real-Time Quality Control Benefits

- Delivers real-time alarm notifications to your PC and/or mobile messaging device
- Allows fast and effective preventative maintenance measures to be taken to maximize the quality and safety of valuable shipments
- Provides immediate access to critical trip data in order and to make efficient, qualified shipment disposition decisions
- Allows 24/7 monitoring and management of mission-critical alerts to ensure safe and quality-controlled transport of your valuable temperature sensitive shipments
- Empowers users with increased visibility into their cold chain



Transactional Benefits

- Demonstrate a higher quality of control over your cold chain by aggregating cold chain shipment data in meaningful formats
- Continuous process improvements: Evaluate performance, new package designs, pack-outs and supply chain partners
- Improve your decision making process by identifying patterns of thermal variability



As the world's leading provider of cold chain visibility solutions, Sensitech enables global leaders in Food and Pharmaceuticals to track and monitor assets across the supply chain to protect the integrity of temperature sensitive products. Sensitech is an ISO 9001:2000 company and is based in Beverly, Massachusetts, with offices in Amsterdam, Calgary, Melbourne, Mumbai, Redmond, Santiago and Shanghai as well as service and distribution offices around the world. Sensitech is a unit of Farmington, Conn.-based Carrier Corp., the world's largest provider of heating, air conditioning and refrigeration solutions with operations in 172 countries. Carrier Corp. is part of United Technologies Corp., a Hartford, Conn.-based provider of a broad range of high technology products and support services to the aerospace and building systems industries worldwide. For additional information, please call +1-978-927-7033 or visit www.sensitech.com. © 2008. Sensitech Inc. All Rights Reserved. All trademarks and service marks are the property of Sensitech Inc.