

ColdStream.CCM

Cold Chain Manager

Increase Control and Manage Risk

Regulatory-Compliant Central Repository for Temperature Data

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. A comprehensive monitoring system is a critical tool for increasing visibility into the cold chain and enabling a risk-based approach to cold chain management. A system should include secure data collection, management, and presentation options. By combining logistics and temperature data, a more comprehensive view is available. With increased visibility, companies can confirm that their temperature-sensitive pharmaceuticals and biologics are maintained throughout the entire cold chain, helping to ensure product quality, patient safety, and compliance with global regulatory expectations.

ColdStream® Cold Chain Manager (CCM) is Sensitech's Internet-enabled software application designed and built to comply with 21 CFR Part 11 guidance and to meet current Good Manufacturing Practices (cGMP) guidelines for electronic recording keeping. With Sensitech's secure and comprehensive data management system, you can view, store, retrieve and analyze detailed shipment (logistic) information and critical time-and-temperature data. ColdStream CCM provides users with remote access to such key information as temperature history, trend analysis reporting, and audit trails, all readily available for internal and external audit inspections.

Features and Benefits

- Supports Sensitech's full range of TempTale4 products for comprehensive data collection
 - Meets FDA data storage requirements for temperature shipment information through a secure, hosted database
 - Accelerates the product release process by making time and temperature data readily available for disposition decision making
 - Fully documented to support customer validation for record-keeping requirements
 - Automatic, date-stamped event audit trail for complete record management
 - Electronic signatures and permission-based user profiles for enhanced security
 - Runs on a wide range of non-US English MS operating systems for global flexibility
 - Automated alerts and notifications for the most up-to-date transactional details
 - Selective access controls data access for different user groups
- Multi-lingual support, including online Help, for global ease of use
 - Capable of interfacing shipment information with ERP, logistics and other third-party software applications for enhanced shipment records
 - Offline operation mode when Internet connectivity is unavailable for uninterrupted workflow
 - Facilitates sharing of transactional and event-based data for increased efficiency
 - Increases visibility of supply chain partners' performance for better control



Information Views from ColdStream

ColdStream CCM can improve visibility across temperature-sensitive distribution environments by enabling more efficient management of time and temperature data. ColdStream CCM provides secure, timely, and convenient access to critical information where, when, and how you need it.



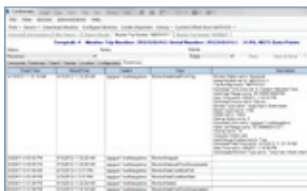
Single Trip Graph
Several views available for individual shipment information—graph only, shipment and temperature summary, or composite.



Multi-Alarm Trip Graph
One shipment monitored by our TempTale4 Multi-Alarm Monitor—view all six (6) alarms on one graph for a complete view.



Summary Statistics
All the facts about a shipment in one place: time periods, temperature statistics, and alarms for any TempTale monitor.



Event Log
Automatic date-stamped event trail for audit backup of who-did-what-when.

Information Available in Real Time



Site-configurable notifications can be routed to defined recipients - temperature graph along with statistical data associated with monitor where and when a recipient needs it.

Leverage ColdStream Reporting

ColdStream Reporting is a business tool portal available to assist customers in demonstrating a higher level of control by aggregating cold chain shipment information over time for the purpose of continuous process improvement.

Summary Statistics
Shipment Start from 11/20/10 to 10/20/10 (GMT)

Origin	Product	Monitor Count	Min. Temp. Range	Max. Temp. Range	Min. Duration Range	Max. Duration Range	Time Above Threshold	Time Below Threshold	Temp. Length
Origin A	DPF 12345 (PTC)	20	47.7472	1.74e4	28.111.1	1.71e3	16.4482	8.2418	0.741.1
DPF 12345 (PTC)	20	8.2418	1.74e3	16.4482	1.71e3	1.71e3	1.71e3	1.71e3	1.71e3
Temp Period	1	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4
Origin B	DPF 12345 (PTC)	20	18.4418	8.44e3	28.111.1	1.71e3	16.4482	8.2418	0.741.1
DPF 12345 (PTC)	20	18.4418	8.44e3	28.111.1	1.71e3	1.71e3	1.71e3	1.71e3	1.71e3
Temp Period	1	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4
Origin C	DPF 12345 (PTC)	20	28.111.1	16.4482	8.2418	1.71e3	1.71e3	1.71e3	1.71e3
DPF 12345 (PTC)	20	28.111.1	16.4482	8.2418	1.71e3	1.71e3	1.71e3	1.71e3	1.71e3
Temp Period	1	16.4	16.4	16.4	16.4	16.4	16.4	16.4	16.4

Summary Statistics by Shipment Origin

Monitor Shipment List
Shipment Start from 11/20/10 to 10/20/10 11:30 PM GMT

Temp. Number	Start Date	Origin	Product	Distribution	Monitor Location	Min. Temp. °C	Max. Temp. °C	Min. Duration Range	Max. Duration Range	Temp. Length	Graph
12345	11/20/10	Origin A	DPF 12345 (PTC)	Distribution 1	Monitor 1	28.1	16.4	1.7	1.7	1.7	
12345	11/20/10	Origin B	DPF 12345 (PTC)	Distribution 1	Monitor 1	28.1	16.4	1.7	1.7	1.7	
12345	11/20/10	Origin C	DPF 12345 (PTC)	Distribution 1	Monitor 1	28.1	16.4	1.7	1.7	1.7	

Summary Statistics of Monitors Shipped per Date Segment

As the world's leading provider of cold chain visibility solutions, Sensitech Inc. enables global leaders in the life sciences, food, and industrial markets to track and monitor assets across the supply chain in order to protect the integrity of temperature-sensitive products. Sensitech is an ISO 9001:2008 company based in Beverly, Mass., with more than 30 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. © 2012. Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc.