A validated, decision-support and documentation system designed for the life sciences industry that includes the business tools needed to help increase control and manage risk throughout the temperature-sensitive supply chain.

Data Collection • Data Management • Reporting Portal • Dashboard Views

Throughout the supply chain, there are many unforeseen and uncontrollable factors that can cause products to be exposed to temperatures outside of their acceptable ranges. A comprehensive monitoring system is a critical tool for increasing visibility into the cold chain and enabling a risk-based approach to supply chain management. Such a system must include validated data collection and data management; the inclusion of data analysis and presentation options provides the business tools needed for continuous improvement. By adding logistics data into the system, an even more comprehensive view can be realized. With increased visibility, companies can confirm that their temperature-sensitive pharmaceuticals and biologics are maintained throughout the entire supply chain, helping to ensure product quality, patient safety, and compliance with global regulatory expectations.

Validated Data Management

ColdStream® Cold Chain Manager (CCM) is Sensitech’s Internet-enabled software platform designed and built to comply with 21 CFR Part 11 guidance and to meet current Good Manufacturing Practices (cGMP) guidelines for electronic record keeping. With Sensitech’s secure and comprehensive data management system, users 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.

How ColdStream CCM Data Management Works

- 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-English Microsoft operating systems for global flexibility
- Automated alerts and notifications to support decision making
- Multi-lingual support, including online Help, for global ease-of-use
- Capable of interfacing shipment information with Enterprise Resource Planning (ERP), logistics and other third-party software applications for efficient data entry
- Increases visibility of supply chain partners’ performance for better control

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Improving 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 users need it.

### Informational Views from ColdStream CCM Data Management

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

#### Multi Trip Graph
View multiple independent trip graphs in one window for easy evaluation.

#### 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.

### Real Time Information Access

#### 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.

### Reporting Portal

Uniquely configured for each customer, the Reporting Portal is a business tool that provides a central point of access for aggregated Key Performance Indicator (KPI) reporting. The Reporting Portal is secure and divided into three key areas:

#### Report Manager
On-demand dynamic program administration and cold chain performance reports – including dashboards.

#### Document Libraries
Upload and share work instructions, reports, and industry requirements with your internal team.

#### Lists and Discussions
Collaborate and access frequently used information.

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Dashboard Reports

Dashboards are an efficient way to access reports reflecting results against Key Performance Indicators (KPIs). Reports based on aggregated data collected across many shipments, lanes, seasons, modes and pack-outs allows for a risk-based approach to improvement initiatives and resource allocation. Choosing the right KPIs are the key to success for dashboard reporting. KPIs can be created around supply chain factors, job functions or levels of accountability.

Sample Dashboard Views

**Administrative Dashboards** focus on the performance of the program itself: shipments made by origin, shipments received with or without monitors attached, downloads by location, etc. KPIs being measured appear at the top with trending indicators to compare against a previous time period.

**Temperature Dashboards** focus on data collected by TempTale® monitors while in the field. Exterior Temperatures are ambient temperatures outside of a given package or container. Interior Temperatures are payload temperatures where the product is being stored. Exploring “Exterior Temperatures by Lane” can identify the most extreme transportation legs to be further explored, while “Average Temperature by Package” can quickly indicate which packaging is averaging temperatures within desired range.

**Alarm Dashboards** focus on global alarms and causation: alarms by package and by origin help to improve supply chain performance by pinpointing trouble spots; alarm cause/resolution/product disposition can be part of a quality program and measure costs associated with out-of-spec temperature. KPIs being measured appear at the top with trending indicators to compare against a previous time period.

**Trip Length Dashboards** tell a story based on trip length hours beyond the expected trip lengths. Users can quickly identify which transportation measure requires the most attention; i.e. sea container trips may have a maximum trip length of 14 days, while overnight trips take no longer than 30 hours. The approach of time above expected or maximum trip length normalizes each and shows where potential problems may lie.
Program Administration Reports

Verify that every element of a cold chain monitoring program is in compliance through Program Administration Reports.

<table>
<thead>
<tr>
<th>Summary Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Origin</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Origin A</td>
</tr>
<tr>
<td>Origin B</td>
</tr>
</tbody>
</table>

Assure the following:

- Proper use of TempTale® monitors by suppliers
- Proper recovery and download of TempTale monitors by receivers
- Complete records incorporating shipment information and logistical details
- Automated data entry error detection, along with unusual activity warnings
- Complete summaries of user activity (i.e. data entry, downloads, etc.)

Cold Chain Performance Reports

Quantify and analyze the performance of critical supply chain elements (by product, supplier, and carrier) through Cold Chain Performance Reports.

<table>
<thead>
<tr>
<th>Monitor Shipment List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor ID</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Digi9</td>
</tr>
<tr>
<td>Digi10</td>
</tr>
</tbody>
</table>

Graphically view the following:

- Key statistics including mean temperature, average minimum/maximum temperature, time above/below specification and trip length
- Grouped statistics by shipment attributes; e.g. product, carrier, supplier, receiver, shipment date
- Opportunities for improvement through control charts, box plots and histograms which provide context and help to identify trends

Why Sensitech

ColdStream CCM is backed by Sensitech’s world-class support infrastructure:

- Utilizes Sensitech’s ISO-certified, NIST® traceable dataloggers and ColdStream®, the validated, data management software platform built to comply with 21 CFR Part 11 guidance
- Benefits from Sensitech’s 20+ years of experience placing monitors and implementing protocols; our field support has successfully passed regulatory scrutiny from FDA, Health Products Regulatory Authority (HPRA), Health Canada, and Medicines and Healthcare Products Regulatory Agency (MHRA)
- Relies on Sensitech’s Professional Services team for expert data analysis and expertise in cold chain, packaging, industrial engineering, data visualization and much more
- Sustained by Sensitech’s Technical Support team strategically positioned around the world for optimal coverage should customers have any questions at any time

Sensitech Inc. is a leading provider of supply and cold chain visibility solutions that enable our customers – global leaders in the food, life sciences, and industrial markets – to track, monitor and protect the quality and integrity of their temperature-sensitive products across complex supply chains. Through its logistics security division, FreightWatch International, Sensitech also offers origin-to-destination services that provide customers with real-time cargo transparency, helping them to mitigate such risks as theft, diversion, counterfeiting, and chain of custody. Sensitech Inc. is an ISO 9001:2008 company based in Beverly, Mass., with more than 36 sales, service and distribution locations around the world. Sensitech is a part of UTC Building & Industrial Systems, a unit of United Technologies Corp., a leading provider to the aerospace and building systems industries worldwide. Visit www.sensitech.com for additional information. © 2016. Sensitech Inc. All Rights Reserved. Unless otherwise indicated, all trademarks and service marks are the property of Sensitech Inc.