Transforming Temperature Data Management Practices to Reduce Labor Costs and Improve Visibility and Control

Abstract There are a number of temperature monitoring database options available to the biopharma supply chain professional and choosing the right one can significantly improve workflow which will reduce administrative time. This article will provide insight into practices for improving common processes through enhanced database functionality in the areas of managing data loggers by expiry date, storing and retrieving calibration certificates and acknowledging/documenting common temperature excursion events. Additionally, it describes the unique features and benefits of the Berlinger Smartview® data management system. Smartview® is a "Software as a Service" (SaaS) platform designed to efficiently and accurately manage both workflow and data in a regulatory compliant manner (21 CRF Part 11 & Annex 11). This comprehensive temperature data management system ensures reliability, accuracy, security, accessibility, and visibility to supply chain professionals, enhancing Good Distribution Practices (GDP) of temperature sensitive shipments.

Background

Central to the Good Distribution Practices of a biopharma company is the reliability and traceability of temperature data associated with temperature sensitive shipments. Compliance requires data loggers to have unique serial numbers, calibration certificates and expiry dates. Current and historic temperature information can be questioned for its legitimacy if it is not clear that the data logger was used before it's expiry date or during its certified temperature accuracy period as stated on the calibration report. Every organization has it's own methodology for handling these requirements. Often they are decentralized, off-line procedures that expose the company to lost certificates, lack of inventory rotation control and countless man-hours to store and retrieve calibration certificates even years after a device has been used.

Additionally, some data logger excursions can be classified as routine occurrences. In a survey administered by IQPC's Cold Chain IQ group, the respondents who acknowledge temperature excursions with products in transit, indicated excursions occurring in more than 15% of their shipments (Cold Chain IQ 2012). One common occurrence can be observed when temperature sensitive materials are received in good order, moved to a secure/temperature-controlled environment, and the data logger is turned off hours later. Biopharma firms have established procedures for documenting these occurrences without launching a full quality investigation. Yet even these simple procedural steps incur significant labor costs. The initiator must alert responsible people to the issue, get them to take action and develop the right technical information to approve the use of the materials while documenting the decision for regulatory compliance files. Delays occur when people do not respond to emails or while files are searched looking for all the necessary information (e.g. a calibration certificate).

Current Methodology

Of paramount importance for a compliant temperature monitoring program is the ability to effectively manage data logger inventories on a "First Expiry, First Out" (FEFO) methodology. Most companies are managing this process manually, through spreadsheets and/or a "kanban" system (employing the use of product identification cards for demand driven inventory management) that require significant front-end organization and data entry. Seldom is the data logger supplier leveraged for management of data logger expiry and certificates of calibration. When they are, it is typically done on a case-by-case basis through email. Hours can be spent tracking down these certificates (see Fig. 1).

Additional time is spent manually inspecting and inventorying devices to create a FEFO inventory management process. Standard ERP systems (SAP, Oracle) are helpful; but are not robust enough to support the cGDP practices of the biopharma industry.

Unwanted temperature events that occur during manufacturing, storage, transportation, and distribution are commonly referred to as "excursions." Within an organization, excursions outside acceptable temperature ranges captured with data loggers can be dealt with in a manual, extremely labor-intensive manner by a dedicated supply chain quality management group or department. Emails are generated passing data logger temperature information to be compared with the timing of logistics services of a shipment. In many instances, data loggers without a USB interface are transported back to someone with the necessary hardware and software to read the data. An additional labor intensive process then begins to insure all the required data is collected, that the responsible parties formally address the data and the decision to move materials to the appropriate next step is documented properly. These documents typically require signature approval and must be filed in a retrievable manner. It can take anywhere from 1 to 30+ days depending upon circumstances associated with the specific materials involved to complete these steps. Indications are that the costs for administering an excursion event are between $10,000 - $100,000 per occurrence (Goff, 2008).

The frequency and severity at which these excursions occur varies from company to company depending on the complexity and structure of their logistics practices and the robustness of their quality management systems. The documentation and sign-off process is rarely streamlined, and can often be disjointed with fragmented roles and responsibilities. If 5% – 10% of shipments experience "common excursions", as is often reported, it is easy to see how these labor costs can quickly add up to hundreds of thousands or even millions of dollars every year.

Proposed Solution

The Smartview® system enables work flow steps like excursion alerts and missing data loggers to be automatically generated and sent to the responsible person(s). Additionally, workflow steps for acknowledging the review of temperature data, especially data with a recorded excursion, can take place within the Smarview® system. Notes about the root cause and other information can be appended to the shipment data. Non-relevant temperature data (e.g. warm temperatures recorded after delivery from an active data logger on someone's desk) can be easily adjusted out of the relevant data set to close out excursions. All of these workflow steps create an auditable trail based on the unique user ID and password and meet 21 CFR, Part 11 & Annex 11 requirements.

When a completely cloud based system that incorporates both data storage and software service is introduced to the biopharma supply chain, many costly administrative steps and processes can move towards automation. When data is generated and

collected for the purpose of facilitating decision making and trending over time, then the opportunity for automated additional workflow steps can be realized.

An employee with the appropriate user rights should be able to access one portal, from any computer, anywhere in the world, to review the inventory of devices by expiry, and download the calibration certificates for individual data loggers (see Fig. 1). This database should remain accessible for a time period that is relevant to the customer's requirements instead of off-line in a data archive. The Smartview® system enables a firm to do this with ease, at their discretion.

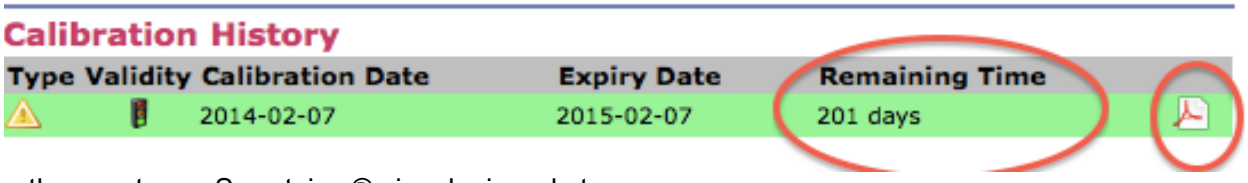
Once Smartview® is integrated into a firm's daily routine, the use of the system to acknowledge temperature shipment data or to document excursion issues will reduce the administrative-hours needed for these activities. It also enhances accountability by automatically sending alerts to responsible individuals and escalating the alert if action steps, like acknowledging the event, exceed pre-determined time limits.

With Smartview® operating in the cloud. Email communication of excursion events are sent automatically to the responsible party immediately after a data logger is uploaded. That person can sign into Smartview® via his/her smart phone or other enabled wireless device to document the receipt of an alert notification, journalize steps taken, and close out an excursion with an assigned root cause. By providing an audit trail for everyone who interacts with the system, Smartview® is designed to ensure regulatory compliance for document control (21 CFR, Part 11 & Annex 11 compliant).

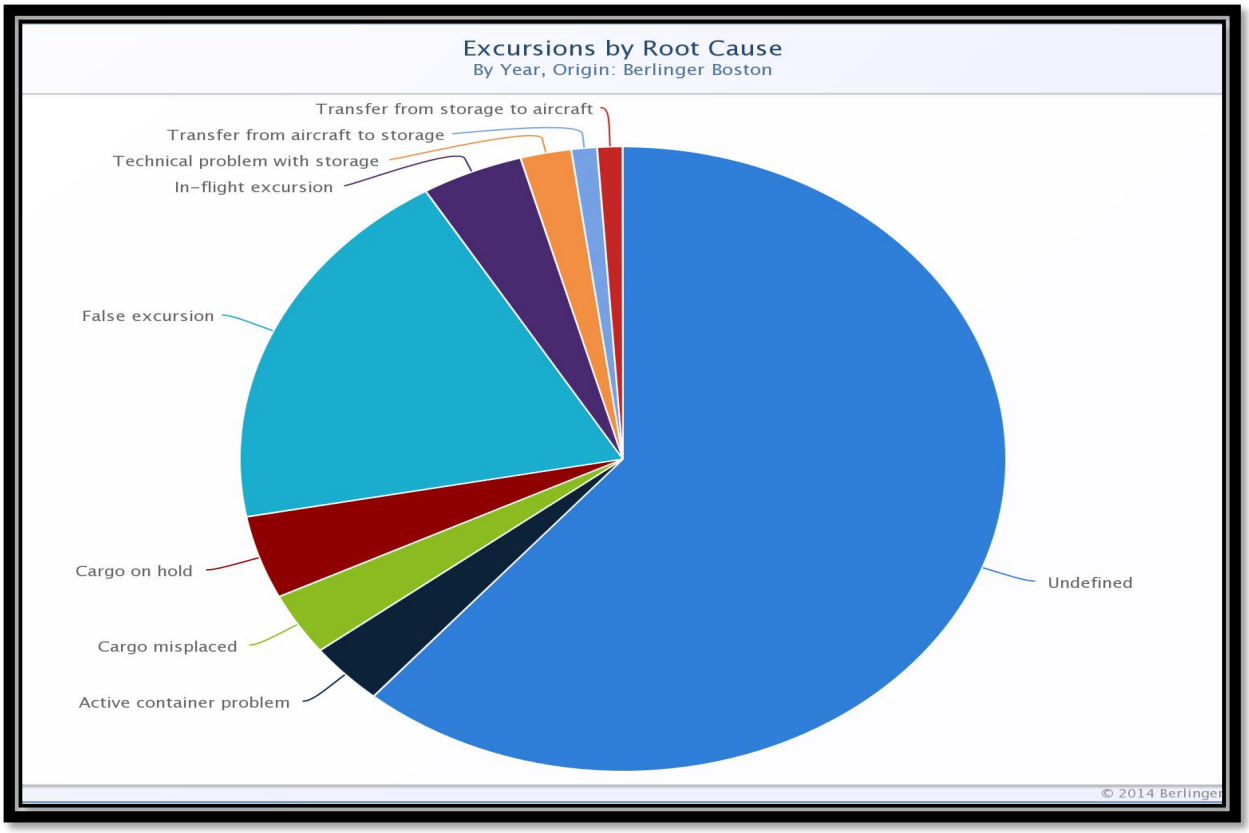
Supply Chain Directors are often more interested in aggregate information for trending analysis and process improvement. By storing all temperature data files in one, globally secure system, it is possible to manage the data in unique ways (see Fig. 2). It is impractical and grossly inefficient to rely on email, manual filing systems or a vendor as the means to sift through historic temperature data. It is also costly and time consuming to rely on outside vendors to compile the data into trending reports and key performance indicators (KPI).

Personnel with the appropriate user rights can access the aggregate data through a Reports Module contained in Smartview®. In this module, it is possible to trend data using data base filters to reveal shifts in trends over time, between shipping lanes, by product, customer, 3rd party service supplier, or other metric.

Easy to comprehend info-graphics allow the user to visually determine where improvements are occurring and where more effort may be beneficial. An organization can gain full, documented and regulatory compliant control over temperature excursion investigations and remediation steps while substantially reducing their time and administrative costs through implementation of the Berlinger Smartview® system



(Fig. 2)



Conclusions

- Current methodology for identifying, investigating and documenting temperature excursions within the pharmaceutical supply chain are inadequate, time-consuming, inefficient and costly to an organization.
- It is unjustifiable to rely on communicating via email, phone and manual filing systems to manage and document temperature excursions.
- Smartview® is a comprehensive temperature monitoring software system that ensures reliability, accuracy, compliance, secure data visibility, accessibility, and efficiency of critical time and temperature-sensitive shipments.
- Its imbedded web-based data analytic tools allow for a significant reduction in time and labor cost of temperature deviation investigations in the framework of a completely validated and regulatory compliant environment.

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