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WHITE PAPER

Transitioning to the Modern World of Data Monitoring and Analysis

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Transitioning to the Modern World of Data Monitoring and Analysis

In the world of pharmaceutical supply chains, where cost reduction is king and a growing number of products are temperature controlled – collecting, communicating and analyzing temperature and logistics data is critical to success. If data is the foundation of business intelligence, why are Pharma companies still using old practices for data analysis – reviewing data by hand, doing manual entries and archaic reporting methods? All of these outdated practices and long processes create human error and surging hidden costs. Today, all of the important temperature data and automation tools are at the industry's fingertips, so why not use them?

At some multi-national pharmaceutical companies with tens or hundreds of receiving sites it's difficult to know what happens with temperature controlled products at destination. Lack of visibility of shipment performance and how products were being handled can create many challenges, often involving lengthy and tiring processes to get data back from receiving sites to have a complete picture of product temperature condition.

Often companies are at the mercy of their global supply chain having numerous receiving sites; CMOs using different temperature monitors; and different reports created in different systems – nothing cohesive. A shipment is sent with a data logger to record temperature and ensure product quality. But what if the product owner doesn't receive feedback or data back from the receiving site? If there was a temperature excursion, how quickly is it communicated and how manual of a process is it to connect the corresponding transport and product information with the particular shipment?

GDP Requirements

There are some 40 GDP regulatory documents around the world. They underline certain requirements for pharmaceutical manufacturers to provide evidence to customers and regulators that temperatures were within specification during transport and storage.

For example, China's 2013 revised «Good Supply Practice of Pharmaceutical Products» guidelines require pharmaceutical wholesalers and retailers to adopt an automatic temperature and humidity monitoring system for drug warehousing, and where a third party has been entrusted with drug transportation, the entrusting party shall examine the transportation capabilities and relevant quality assurance ability of the third party.

Specifically EU GDP Chapter 9.2 describes transportation mapping and qualification; «Risk assessment of delivery routes should be used to determine where temperature controls are required. Equipment used for temperature monitoring during transport within vehicles and/or containers, should be maintained and calibrated at regular intervals at least once a year». Also most relevant is Chapter 1.4 outlining what components of a Quality Management System companies need to have in place, including conducting CAPAs on systemic deviations to prevent future occurrences. Therefore static temperature monitoring is no longer a viable solution. Just throwing a data logger in a box will not create an audit trail and level of control regulators are looking for to meet cGDP. In pursuit of more robust processes for continuous temperature monitoring of medicinal products, pharmaceutical manufacturers are implementing new temperature monitoring devices and an aligned database for archiving and analyzing data.

Marilda Bezerra, a GDP industry professional, using ELPRO's liberoMANAGER database explains, «We wanted a system where the alarm limits and configuration profiles would be centrally managed by quality. Then the warehouses all over the world would configure the data loggers, based on the transport condition of the products they are shipping, using programs, which do not allow them to change the configuration profiles and alarm limits. We also wanted data log-

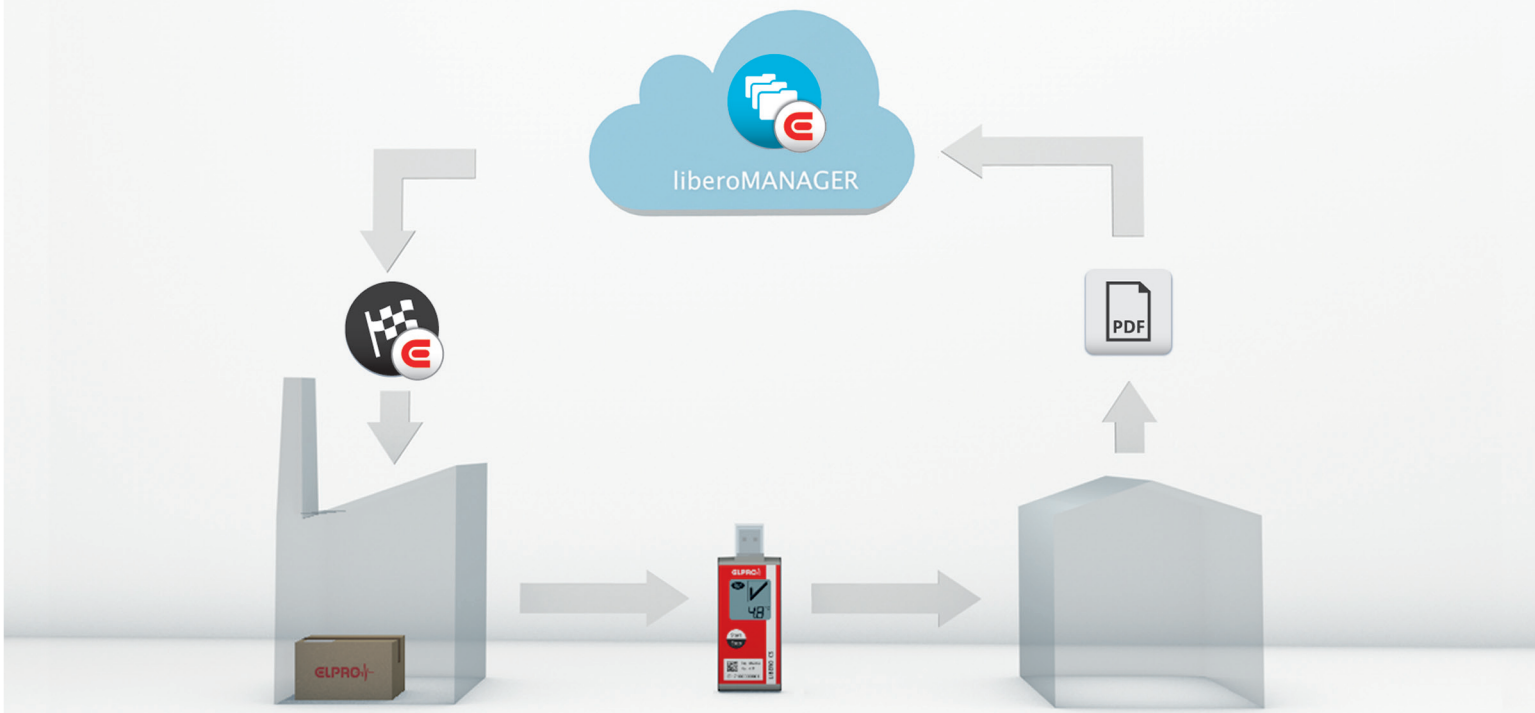
gers, which enable the recipients of the goods to identify quickly whether there was a temperature excursion during the shipment or not, in order to place only the pallets with alarm under quarantine. In addition to that we wanted a system that would support us not only with the temperature monitoring, but also with the review of our transportation routes, temperature control measures, and freight forwarder performance versus SOP.»

Simplifying end-to-end Temperature Monitoring

The aforementioned new regulatory requirements coupled with businesses driving out costs and inefficiencies, result in most companies transitioning to this modern world of data monitoring. Sophisticated temperature monitoring devices have longer memory; higher temperature accuracies; and can be programmed with up to 18 indices of product or shipment specific data. This is useful if you have extensive stability data that you can use to program devices and set multi-level alarms. There are easy-to-use PDF Loggers that allow for a ‹one-step› download of information at the destination, without software, that generates a PDF report including temperature graphs with embedded data, all in one file. This PDF can simply be emailed to any desktop worldwide, the users just need to establish strong SOPs.

One step further after using new temperature devices to simplify end-to-end data handling processes is to collect and use the data. Software as a Service (SaaS) platforms are allowing users to log in and access data from anywhere in the world. QA managers control access to their data in a secure cloud environment and are able to run customized searches on their temperature control products. These database platforms lend to creating more agile, visible cold chains, all in an easy to use virtual environment.

Cold Chain Monitoring Solution



The value of a modern data monitoring system today is not just collecting temperature data but how it's used with other logistics, transport and quality information. Bezerra says «by putting together the shipment tracking information from the freight forwarders with the temperature records, the graphic starts to have a meaning and tell the story of the transportation route, enabling us to identify the root cause for the excursions, and to determine the corrective and preventive actions, e.g.: changing transport mode, packaging solution, warehouse, freight forwarding agent or service».

In clinical studies, a quality issue could cost valuable time and knock on consequences. If a shipment came in with a temperature excursion or alarm on the data logger, the trial could be delayed. However using data loggers that generate a PDF report with embedded data automates the process by allowing the recipient to easily email the report to the QA or study manager for quick decision-making. If no alarm is displayed, a report is archived and there is no need to review, significantly cutting down the time for the clinical project leader.

Lisbeth Nielsen, Senior Clinical Supply Technician, Lundbeck uses ELPRO's LIBERO PDF Loggers. «My team defines the temperature profiles using available stability data, then site personnel download the profile at point of receipt from depots. What's nice about the LIBEROs is that we can control what information is seen by whom. The clinical sites only see if there's an excursion, or not. This cuts down a number of unnecessary steps in confirming product quality and administering the trial patient.»

Fear of Change

If the benefits of implementing a new data monitoring system are clear, why aren't more organizations making the shift? Such a massive undertaking can leave some organizations spinning their wheels. Is there a fear of change… or is it the cost of change deterring companies?

Psychologically people don't want to change. The old adage ‹fear of the unknown› holds some truth. The work, the hassle, the time needed to make such a big transition can create mental barriers to embarking on something new, even if the benefits can be clearly seen.

The cost of change can also create major stumbling blocks, including 1) physical cost – new equipment and purchases required for initial set-up and 2) organizational cost – man hours, new SOPs, training supply chain partners. In large multi-national corporations there are many different stakeholders and senior management to convince, at times in different cities or countries.

But what about the cost of not changing? How long can clinical sites continue to discard products that are subjected to inadequate monitoring and storage? Companies not only have to consider business implications such as loss of product, reproducing and reshipping medicines; but also ecological aspects of unnecessary waste of resources, additional transport pollution and extra pharmaceutical waste.

Can you put a price tag on errors? Some say yes, definitely. By taking the time to quantify how many products are wasted or unnecessarily discarded because the right data isn't collected or used, you will have a strong business case. Is there a magic number for cost savings to either switch or implement a new data system? Often, companies only look at the tangible numbers – device, service, software, and database costs. Instead, companies should calculate the costs not to change. Too often data disappears due to the data loggers not being read, lost or disconnected. Without data, action is delayed, incurring significant hidden costs.

Selling Change internally

To some people within an organization the benefits are clear. Transitioning to a streamlined global data monitoring system for temperature data is a logical, imperative next step. The cost and time investment is necessary to bring the organization's supply chain in compliance, capable of making quick product release decisions and able to implement cost-containment improvements.

However, such major projects require buy-in, support and budget from other organizational stakeholders. To create change, you have to get people to see, feel and believe why the change is necessary.

First – The project needs a champion, someone to hold the vision of the project and keep everyone focused on it. Business unit owners drive these projects while IT supports.

Second – understand the audience. The project owner needs to identify the organization's stakeholders and what will drive their decisions.

Third – build your business case around the audience. By knowing what's important to each stakeholder, you can build a business case that will address each group's concerns and goals.

Project Success Factors

Beyond convincing the powers that be internally, there are fundamental lessons companies have employed to get a new data monitoring project off the ground. Just like any major project consideration and roll-out need to be carefully planned, including:

1. **Have a first draft of the requirements ready before start**
   User Requirement Specifications (URS) should be your first step. Document exactly what you want from the devices and database, breaking down processes and roles step by step. Ideally do this first before your business plan to uncover any areas you need more information or evidence. See Figure 1.1

2. **Define roles and responsibilities**
   Beyond the project leader, who will manage the new system on-going, long term? Who will be the future system owner?

3. **Involve Logistics, QA and IT early in the process**
   «Looking back, I would have set up the Steering Group earlier: Managers from Sourcing, IT, Quality, Logistics and Depot Management. Their input is critical to ensure a cross-functional approach is taken. Although they rely on us as project managers to narrow down vendors and criteria, their agreement to secure resources and prioritizing the project early on is critical», says Lisbeth Nielsen from Lundbeck.

(Figure 1.1)

Ask yourself, and the data monitoring vendor, some tough questions for your «URS»:

- What information do I want to collect, and how do I want to use it?
- Can I use the same provider for all shipment temperature ranges?
- Can all of the information from all temperature ranges be housed in a database?
- What is the overall process from start to finish
  - Ordering devices, how inventory is affected
  - Programming / packaging devices
  - Receiving devices, generating reports, and uploading information
  - Searching information in the database
  - Generating reports and releasing products
- How can I reduce data handling errors or overcome them?
- What is the cost?
- What do I need to validate?
- How easy it is to train users and rollout the solution globally?
- Do I need a solution that integrates with my company's ERP system?

What if I currently have a database solution, is there a reason to change? Ask:

- What is the total cost of ownership including all fees?
- Can you improve the overall process (error reduction, time, inventory requirements)?
- How easy it is to use the data logger and the database?
- Is the end to end data handling process simple enough for everyone involved to ensure you, as the product owner, get the information you need?

4. **Having the long-term scope in mind, define realistic short-term goals**
   Don't sell an unattainable goal. Sell the ability to sustain long-term bottom line impact with the new solution, while scheduling short term achievable goals.

5. **Choose a design which is modular, implement step-by-step**
   Implementing enterprise solutions is easier in phases. Roll-out plans for modular applications can have clear milestone markers with clearly defined goals for training and implementation.

6. **Run an effective pilot**
   - Set goal for beginning / ending dates for the study
   - Choose a data logger model for the pilot
   - Choose only sites that are regularly used and available to fully participate in pilot; schedule training for key users; and send detailed protocol including data logger and database instructions to appropriate users.
   - Define overall data collection goals and work with the data monitoring vendor to set up programming profiles and pilot database configuration
   - Identify key users for the pilot:
     - Shipping and receiving sites
     - Who will program data loggers for the study (data vendor or your sending site)
     - What personnel will use the database and analyze data
   - Schedule training for key users
   - Send protocol including data logger and database instructions to the appropriate users
   - Inform sites of go-live date

Advancing Data Management Practices

Although there are challenges rolling out a new global data monitoring system, pharmaceutical companies are quickly realizing greater data access, transparency and simplified processesare enabling their cold chains like never before. Being able to access all shipment's temperature data centrally opens up opportunities for companies to gain tighter control of their temperature control supply chain.

For example, being able to compare total deviation time with product specific requirements can help avoid costly product loss. Some companies call this managing a stability budget, calculating total time out of refrigeration across multiple legs in a supply chain, or adding deviation time across shipping, handling and storage. Technical Report 53 of the Parenteral Drug Association (PDA) recommends this approach as best practice, «use scientific data and rationale necessary to determine an appropriate stability budget for a drug product over the entire lifecycle of a product». This becomes very important when a product is questionable to be released at destination. «Right now we manually calculate total time out of refrigeration against allowable excursion time. The challenge is adding up all deviations across the different supply chain ‹levels›», explains Takanori Aasberg Miyashita, System Manager Temperature Control, at Novo Nordisk.

Beat Rudolf, CEO, ELPRO describes the recent advances in liberoMANAGER, a cloud SaaS platform, and elproVIEWER, data analysis software; «Customers want to easily manage product stability across the supply chain, without the manual work. Today it is now possible for QA to check the availability of remaining stability budget of former transport ‹legs› and assign unspent stability budget to remaining transport ‹legs› using elproVIEWER. From a QA perspective, avoiding using spreadsheets eliminates the possibility of data manipulation because the data is embedded in the PDF and cannot be changed.»

Other advances in data management tools include some companies working toward an integrated platform of logistics data. Being able to integrate a cold chain database with ERP reduces duplication of information such as origin, destination, air bill number etc. that is already in the ERP system. Although such an integration would drastically streamline processes, there are some challenges to manually integrating the two systems.

Bezerra described their dream data monitoring system as «a system integrated with ERP, which through bar code reading, reduces the number of manual entries, by the warehouse, when configuring the data loggers. This system would also be integrated to the freight forwarder shipment

tracking system, and would automatically add the product location information to the temperature records report. This system would also automatically notify the customers about the delivery status, and follow up on open shipments, in order to ensure they send all temperature records to the data base, which proves not only that the shipment included a data logger, but that the records were reviewed. Finally, the system would automatically notify the customer with regards to the product usage decision, if applicable, e.g.: in case of alarm».

For Novo Nordisk, advanced data management would be integrating clinical study data with shipping and temperature data. «We have discussed the possibility to integrate communication between IVRS and data loggers with the suppliers, because this is an interesting perspective. However no concrete projects are planned at the moment», says Miyashita.

As companies' approaches and goals for temperature data management may vary, one thing is for certain across the industry – modern data monitoring technology today can help reduce significant hidden costs, simplify end-to-end data handling and bring your cold chain into compliance. What's stopping you?

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About the author

Courtney Becker-James is Strategic Marketing Manager at ELPRO. Courtney has been working in the temperature control pharmaceutical industry for ten years creating industry leading events and working with advisory boards that have helped shape the cold chain industry. ELPRO will be teaching a workshop at the IQPC Boston GDP event on using and trending data.