Digital Automation: A “Game Changer” for Pharma Cold Chain Temperature Monitoring

A scarcity of skilled labor, escalating expenses, and a burgeoning emphasis on sustainability in product and service manufacturing and distribution are driving up the demand for automation across various sectors to attain essential efficiency improvements. Alongside the primary objective of delivering life-saving medications and therapies to patients worldwide, pharmaceutical and life science industries are confronting these same challenges. The cold chain stands as a linchpin in guaranteeing the effectiveness and safety of temperature-sensitive medicines. The complex demands of ensuring regulatory compliance regarding temperature-controlled storage and transportation present hurdles in streamlining operations, enhancing process efficiency, and mitigating risks. Digital automation has emerged as a potent agent of transformation.

This article on the subject of automation in pharmaceutical cold chain monitoring, published as part of the *elproINSIGHTS* series, was written with significant contributions from the following industry experts:
Daniel Reichen **Global Key Account Manager at ELPRO, and**
Emanuel Schäpper **Head of Global Business Management at ELPRO**

Temperature Monitoring – Critical but Often Cumbersome

Digital automation within the pharmaceutical cold chain involves implementing technology-driven solutions to optimize processes related to the storage, transportation, and monitoring of medications and therapies. The utilization of sensors, data loggers, and monitoring systems that seamlessly record and document the environmental conditions of the products, ensure compliance with GxP standards throughout their entire lifecycle, from production to patient delivery. The quality-relevant monitoring data can be dy-

"We must guarantee that procedures and tasks related to environmental monitoring prioritize simplicity, user-friendliness, and extensive automation."

EMANUEL SCHÄPPER

namically assessed in real-time or after arrival at the destination for purposes such as automated alerts and shipment assessments.

Emanuel Schäpper, an expert in temperature-controlled logistics at ELPRO, emphasizes, "For many stakeholders in the cold chain, monitoring solutions are critical and often complex. Hence, it's imperative to prioritize simplicity, user-friendliness, and extensive automation in the associated processes and actions."

Human Error: The Greatest Threat to Quality and Process Efficiency

Monitoring environmental conditions and product status during transportation frequently demands manual intervention. This introduces a potential for human error, leading to inspections that cause delays in shipping, slower product release times, additional CAPAs, and ultimately higher cost. Tasks such as preparing, configuring, initiating data loggers with a button press, packing them into boxes, unpacking at receiving sites, and, in some cases, USB port data retrieval are essential. Subsequently, reports generated must be submitted to authorized personnel for shipment evaluation and product release. Each of these steps is time-consuming and prone to errors but remains critical for producing quality data.

"The most significant manual workload arises when dealing with deviations," acknowledges Schäpper. "This entails labor-intensive tasks such as locating stability relevant data for products, recalculating and reevaluating measurements, and engaging multiple stakeholders, which consumes considerable time and adds significant cost. This can quickly add up to several thousand euros per deviation."

Automating these procedures ensures data integrity and delivers insights that are more reliable. It also enables a faster, focused, proactive response, especially when using real-time data loggers, and allows for a fast evaluation of each shipment upon arrival. Consequently, it protects product quality and patient safety while reducing waste and enhancing overall operational efficiency.

The device ID is read into the customer's ERP or WMS system, which then automatically shares the shipment information with the monitoring software via an API.

Opportunities for Enhancement: Particularly in Transportation of Products

The level of automation in stationary monitoring, such as warehouses, freezers, or cryogenic containers, is already quite advanced. Real-time data loggers continuously provide measurements, while remote monitoring automatically sends alerts about deviations to designated recipients. Additionally, reports are generated automatically and on a regular basis.

Nevertheless, according to Schäpper, there is still room for improvement in the transportation of sensitive products. Companies can implement automation options in these processes as well. Utilizing product stability data within cloud-based software solutions like ELPRO’s liberoMANAGER, complex workflows and notifications can be automated through software-based alerts, leading to significant efficiency gains.

Daniel Reichen, Global Key Account Manager at ELPRO, unveils remarkable outcomes. “A customer employing our solutions for both commercial shipments and clinical trials has made astounding strides in deviation management,” Reichen reports. “Through proactive utilization of stability data rather than rigid temperature profiles (e.g., 2 °C to 8 °C), our customer slashed manual reassessments on shipments by over 90 percent. These remarkable achievements are common with the adoption of ELPRO’s automation solutions.”

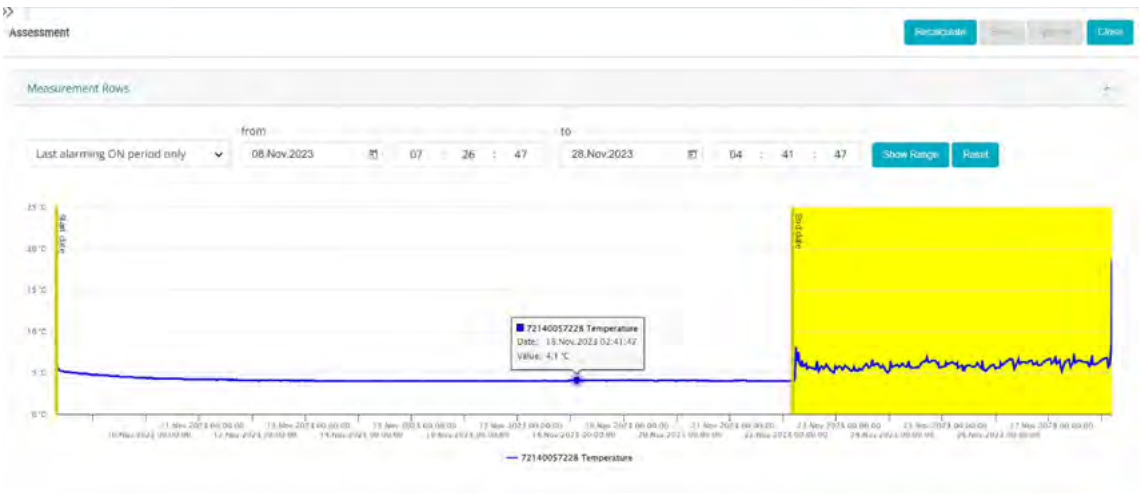
“Through utilization of stability data our customer slashed manual reassessments by over 90 percent.”

DANIEL REICHEN

Possibilities and Actualities

Monitoring solutions operate with a singular objective: to effectively demonstrate and document the efficacy of measures taken to safeguard products on the way to the patient. “Hence, our customers rightfully anticipate the progressive automation of all repetitive manual tasks necessitated by our solutions,” clarifies Reichen.

Schäpper highlights that significant potential lies in the automation of tasks such as data logger handling, data exchange between applications, deviation management, notifications, and reporting. Many of those tasks can already be automated through the clever integration of ELPRO’s hardware and software solutions.



By adjusting the start and/or end time of the measurement or by adjusting the temperature profile, quality personnel can adjust the reassessment of a product in accordance with the underlying SOP and in a traceable manner in the audit trail.

Digital automation solutions, such as ELPRO’s hands-free Bluetooth® data logger detection application, recognize incoming data loggers and initiate predefined processes such as stopping the data logger, reading out the PDF reports and sending the PDFs for product assessment and release.

- **Shipment data handling:** Software interfaces enable the automated exchange of shipment information between the customer’s ERP or WMS system and the liberoMANAGER monitoring software.
- **Data logger configuration:** The applicable temperature and/or stability profile of a shipment is managed directly in liberoMANAGER.
- **Start of recording:** Data loggers are started automatically as soon as a predefined target temperature is reached.
- **“Hands-free” data logger handling at receiving sites:** The LIBERO Cx BLE automation solution recognizes incoming data loggers even in large shipments and sets predefined processes in motion. This includes stopping the data logger, reading out the PDF reports and sending the PDFs to liberoMANAGER for evaluation and approval of the consignments.
- **Reassessments:** When faced with temperature deviations, authorized personnel can promptly conduct a reassessment within liberoMANAGER. Subsequently, recipient sites are automatically notified of the outcome.
- **Email notifications:** Appropriate parties receive pertinent information based on diverse criteria.

Leveraging modern real-time data loggers facilitates transmission of data empowering supply chain stakeholders to take proactive measures upon detecting deviations, eliminating the need for labor-intensive manual data collection and enabling faster product release. Furthermore, centralizing data storage in the cloud provides reliable data integrity and facilitates 24/7 access for faster decision-making and continuous enhancements by visualization of fundamental process performance indicators.

Automation: A Gradual Process with Contingency Measures

Merely automating an existing process doesn’t ensure success. To find the optimal solution, it’s crucial to conduct a comprehensive analysis of current processes, requirements, and objectives. Risk assessments or lane mappings can pinpoint vulnerable elements or segments in the systems. This often prompts a reevaluation and revision of existing processes before automation is implemented. Reichen attests to this through numerous customer projects. “As trusted providers of industry-leading monitoring solutions, our first priority is collaborate with our customers to ensure that their investment in automation aligns proportionately with the efficiency gained,” he says.

The intricacies of the cold supply chain present a distinct challenge for automation initiatives. Integrating numerous locations and external partners such as contract manufacturers or logistics service providers necessitates access to various software applications, networks, and applications. Therefore, adopting a gradual approach to automate a new system is prudent. Schäpper views his role as partner in this endeavor. “Together with the customer, we outline the progression towards an automated system and then deploy our modular, scalable solutions,” he explains, stressing the importance of maintaining a manual or semi-automatic fallback process in case integration challenges arise with a partner, specific geographical area, or transport route.

Conclusion

Automation in pharmaceutical and life science cold chain monitoring addresses challenges such as labor shortages, escalating costs, and the imperative of sustainability. It holds considerable promise in eliminating manual tasks, preserving quality, reducing human error, saving labor hours and cost. While manual procedures remain prevalent, incremental solutions provide a means to navigate the intricacies of supply chains. The future entails the gradual, strategic integration of hardware and software solutions, guided by comprehensive analyses and compliance.

About ELPRO-BUCHS AG

Founded in 1986, ELPRO is a globally acting Swiss provider of innovative monitoring solutions specifically designed for the highly regulated pharmaceutical, life science, and healthcare industries. As a leader in these fields, ELPRO is a “full service” organization offering state-of-the-art data loggers, cloud SaaS software platforms, including data analytics and a team of validation engineers to support the system integration into their customers’ business processes. ELPRO is part of the Bosch Group.
More information at www.elpro.com

Leading Minds Network™
Powered by ELPRO

For more industry best practices and industry benchmarking opportunities, visit our Leading Minds Network online platform at leading-minds-network.com

Mehr ELPRO-Artikel, Case Studies, White Papers und Checklisten finden Sie online unter: www.elpro.com/de/resources