CASE STUDY

Software-Based Alarming: Assessment Results in Minutes Instead of Days

we prove it.

SWISS QUALITY

Acino and ELPRO collaborate to develop software-based alarming as a standard configuration in liberoMANAGER for even more successful temperature-controlled supply chain projects in the future.

In this case study, you will learn how:

- Acino implements a uniform GDP-compliant temperature monitoring system with a central, cloud database for analysis and trending;
- Acino reduces processing times for temperature deviations from an average of three days to under 15 minutes, streamline global collaborations irrespective of time zones, and freed up resources for critical tasks through efficient digitalization and automation;
- This pilot project ensures that software-based alarming will become a validated, standardized software configuration within liberoMANAGER in the future.

"Our goal was to catapult ourselves into the 21st century, into the age of digitalization."

VINCENT MARTY, HEAD OF LOGISTICS & OPERATION, ACINO

Project Partner

- Pharmaceutical company, headquartered in Zurich, Switzerland, that develops, manufactures and internationally markets proven and innovative pharmaceuticals in novel drug delivery forms
- Founded in 1836 near Basel, since 2022 part of ADQ, an Abu Dhabi based investment and holding company
- Over 3,000 employees
- Group sales in 2023: > 653 million euros
- Focus on high-growth markets across the Middle East, Africa, Latin America, Ukraine and the CIS region
- More information at https://acino.swiss

acino

General Conditions

Acino strictly complies with GMP and GDP regulations, essential requirements for all companies operating in the highly regulated pharmaceutical and life science environments. In the past, demonstrating compliance with temperature limits and the tracking of corresponding deviations involved labor-intensive paper-based methods, which were inefficient and time-consuming. Acino is fully capable of addressing any questions during customer or government audits. However, to enhance efficiency and streamline the process, the company set out to adapt a more modern, digital approach that is more suited for today's fast-paced environment.

Challenges

For decades, Acino has been using ELPRO data loggers to monitor temperature on shipment level, adhering to the temperature profile of the most sensitive product in each shipment. However, the application of the strictest product-specific monitoring profile to multiple product shipments (mixed loads) placed a considerable burden on quality assurance (QA).

Labor-intensive, time-consuming manual reassessment of deviations

Less sensitive products, whose stability data clearly covered the deviations, were also placed in quarantine unnecessarily. This caused a significant workload, as the responsible departments needed to answer inquiries to the stability behavior and verify the completeness of data loggers included in the shipment. The reliance on paper-based processes was time-consuming and labor-intensive, largely due to different time zones, the varying availability of contact persons, especially on weekends, and a lot of manual tasks. As a result, even minor deviations could delay the release of genuinely compliant products from quarantine by several days.

Lack of global data overview

Managing the data associated with their operations became a significant bottleneck to Acino. They consolidated all necessary data in Excel sheets, a massive undertaking for those responsible. It took an extreme amount of effort to keep track of their operations. There was no global data overview and trend analysis, and the introduction of key performance indicators (KPIs) to effectively measure the progress was not feasible.

> "ELPRO's approach to project communication stands out as one of the best I've come across in my professional career."
>
> CHRISTIAN RIEGER, SENIOR MANAGER QA, ACINO

Objectives

Managing deviations resulted in a substantial manual workload that required close collaboration between QA and distributors. With numerous internal and external stakeholders involved, Acino sought a solution focused on one key objective: digitizing data for seamless accessibility and full visibility. Acino Head of Logistics & Operation Vincent Marty, the driving force behind the pilot project in Switzerland to convince management of regional as well as global success and feasibility, outlined the following objectives:

- Ensure full GDP compliance
- Establish a centralized database to enhance transparency and improve data availability
- Implement streamlined and automated temperature deviation processes to save time and reduce manpower (FTE)
- Enable immediate notifications for quicker, proactive responses and action initiation
- Enhance supply chain visibility and route mapping to gain real-time insights into shipments, facilitating informed discussions and improvement processes during supplier qualification

At the sending site, a LIBERO PDF data logger is started and enclosed with the shipment.

Requirements

Vincent Marty and his project team, comprised of individuals with extensive process knowledge and practical experience, established the following requirements for a new system:

- Intuitive and dependable technical solution with minimal training and manual tasks required
- Solution for multiple product shipments (mixed loads) utilizing product-specific temperature monitoring profiles
- Capturing of shipment and product data in the system to enable automated assessment and software-based alarming
- Streamlined report gathering for a comprehensive archive, reducing manual effort
- Database for data analysis through dashboards and trending
- Data integrity in accordance with ALCOA+ principles

"With the ELPRO solution, we confidently showcase our adherence to ALCOA+ standards and our complete data control."»

CHRISTIAN RIEGER, SENIOR MANAGER QA, ACINO

Fit

Acino and ELPRO have nurtured a longstanding, successful business partnership. For many years, Acino has relied on the dependable LIBERO data loggers for monitoring goods in transit. In ELPRO, Acino found a trusted partner with a proven track record in similar projects.

ELPRO, in turn, sought a pilot customer to collaborate on refining their software-based alarming within liberoMANAGER. The goal was to establish a validated standardized software configuration for customers with temperature controlled supply chain projects that is easy to implement and, if necessary, adaptable with manageable effort. Acino's organizational structures, processes and product requirements provided an ideal blueprint for this project.

"We placed our trust in ELPRO for this project due to the convincing expertise and professionalism of our project partners. Their guidance and commitment ensured the success of the entire process."

VINCENT MARTY, HEAD OF LOGISTICS & OPERATION, ACINO

Success Factors

Both partners agree on two of the most important success factors: the careful selection of those involved in the project and open communication.

Strategic team selection and involvement from the outset
Vincent Marty and his team gathered individuals who possessed a profound understanding and practical experience of daily operations, not just theoretical processes. These individuals will actively utilize the new system and perform the work in the future.

For ELPRO, the deep understanding and firsthand experience of the project team were essential for accurately analyzing real processes and routines. Their expertise was crucial for mapping all cases effectively within the standard software configuration.

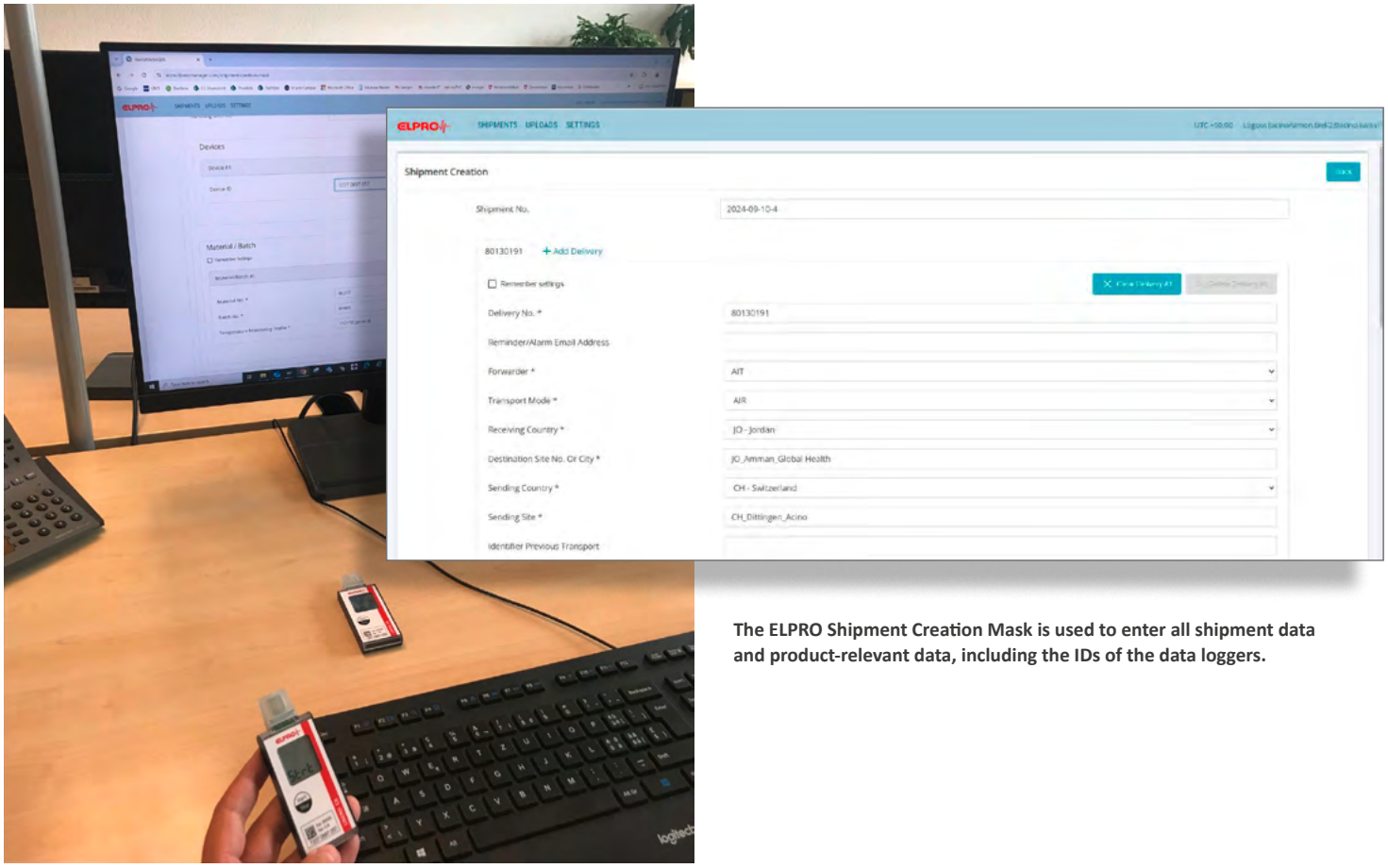
Continuous and open communication
Due to open communication among all project participants and the exchange of knowledge in both directions, ELPRO successfully developed a validated software module for software-based alarming within liberoMANAGER, ready for immediate use by future users.

"Involving these experts ensured acceptance of new work routines and fostered project-wide motivation and enthusiasm. Their commitment was key to going the extra mile."

OLAF BECKER, GLOBAL TRANSPORT MANAGER, ACINO

"Acino combined three essential success factors for projects of this nature: visionary leadership, committed project management and a solution that motivates those involved to make the necessary effort."

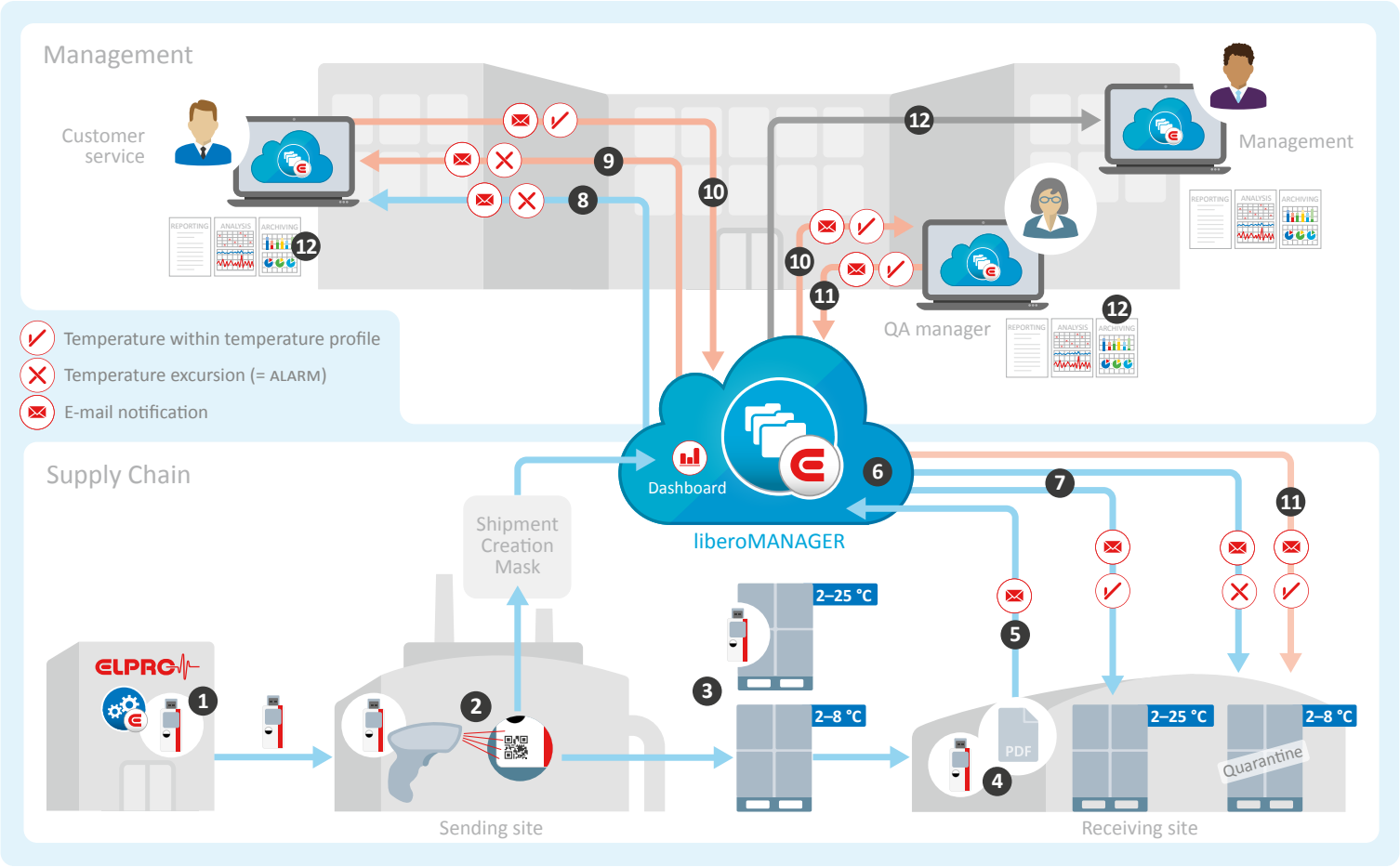
DANIEL REICHEN, GLOBAL KEY ACCOUNT MANAGER, ELPRO



The ELPRO Shipment Creation Mask is used to enter all shipment data and product-relevant data, including the IDs of the data loggers.

Solution

Acino continues to rely on LIBERO data loggers. In their updated process, Acino employs the cloud-based database liberoMANAGER to conduct auto assessments by comparing recorded temperature data with product-specific temperature profiles. Subsequently, the software triggers appropriate actions – either release or alarm (software-based alarming).



1. ELPRO provides pre-configured LIBERO PDF data loggers.
2. At sending site, shipment data and product-relevant data (i.e. stability budgets) are exchanged with liberoMANAGER via the ELPRO Shipment Creation Mask. Data is entered by scanning barcodes, using drop-down menus and filling in free text fields. The IDs of the data loggers that will be enclosed with the shipment are also scanned. (Shipment data and product-specific data can also be exchanged fully automated between ERP systems and liberoMANAGER.)
3. The data logger is started and enclosed with the shipment.
4. Upon arrival, the LIBERO PDF data logger is stopped. Once connected to any USB port, it automatically generates a PDF report with the transport logging results.
5. The receiving site sends the original LIBERO PDF report to liberoMANAGER via email, where it undergoes a data integrity check and is then archived. liberoMANAGER verifies that all necessary LIBERO PDF reports for assessing the shipment's products have been uploaded and then alerts the sending site about any missing report.
6. liberoMANAGER performs an auto assessment by comparing monitoring data and specific temperature profiles of each temperature-sensitive product of the shipment (software-based alarming).
7. liberoMANAGER sends an assessment notification with the assessment result on product level to the destination.
8. If a PDF report is not uploaded in time, the system sends a missing logger notification to the customer service to follow up with the destination.
9. In case of an alarm, the destination must set the product into quarantine, and an alarm notification is sent to the Customer Service.
10. Customer Service has the option to perform a reassessment directly in liberoMANAGER, which automatically sends an 'Assessment Saved' notification to the QA manager for approval.
11. After approval, the reassessment notification will be triggered to share the final result with the receiving site.
12. For continuous improvement, analysis and the evaluation of KPIs, all stakeholders such as Customer Service, QA manager and management can analyze data at any time via the dashboard.

Outcome

The system has significantly reduced the effort to assess a sending, to release products and to manage minor deviations.

Notifications in under 15 minutes

Previously, it took in average three working days to process a temperature deviation due to numerous administrative steps and guidelines, including the 4-eyes principle. Nowadays, customers receive the results within a maximum of 15 minutes after notification.

Unrestricted by time zones or working hours

Acino's collaboration with partners in the Middle East and Latin America is now streamlined without the constraints of time zones or differing work schedules. Through the digitalized, automated process, Acino and their stakeholders can access quality-relevant data anytime and anywhere, facilitating seamless communication and operations across regions while sustaining uninterrupted workflow and productivity.

More time for critical tasks

Setting up the profiles initially required effort, but the system now operates smoothly, reliably, and swiftly. Auto assessment and software-based alarming free up time for crucial tasks like addressing actual deviations and conducting assessments, research, or investigations. With a single comprehensive database, Acino can effortlessly access and present all essential information at the click of a button during customer or regulatory audits, for KPI evaluations, or for continuous improvement initiatives.

> "Comparing our old process to the new one is like comparing a bike to a car. Both can cover a certain distance, but in terms of speed and comfort, they are incomparable. The new solution stands for long-term modernization, digitalization and entry into the modern world."
>
> VINCENT MARTY, HEAD OF LOGISTICS & OPERATION, ACINO

At the sending site, the goods are ready to be shipped to Latin America, South Africa and the Middle East.

Outlook

The new solution was enthusiastically received locally. The management of Acino recognized the success of the pilot project in Switzerland and even honored the project participants with an award. Build on this experience, Acino will further improve the solution and plan a global rollout. In doing so, those responsible are focusing on thorough preparation and planning sufficient time for implementation and training in order to ensure comprehensive stakeholder involvement and minimize stress. Vincent Marty is convinced that this approach will support the successful rollout in further regions beside Latin America and the Middle East.

”We can now dedicate our attention to critical tasks that require human expertise, beyond the reach of digitalized automated solutions.”

CHRISTIAN RIEGER, SENIOR MANAGER QA, ACINO

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

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