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Boehringer Ingelheim and ELPRO make complex harmonization project for uniform in-transit temperature monitoring a success.

In this case study, you will learn how Boehringer Ingelheim:

- > implemented a uniform GDP-compliant temperature monitoring system with a central, cloud database for analysis and trending;
- > manages tens of thousands of complex mixed loads shipments and countless product assessments in a highly efficient way:
- > harmonized and automated their processes across all four business areas; and
- > successfully rolled out their "MOVE IT" project in 2020.

Project Partner

- > Independent, family-owned company, founded in 1885
- > Around 52,000 employees
- > Net sales in 2020: 19.6 billion euros
- > Business areas: Human Pharma, Animal Health, Biopharmaceuticals, Innovation Unit (Clinical Trial Supplies)
- > 30 production facilities in 18 countries, external manufacturers all over the world
- > Global research network of 26 locations in 13 countries
- > More information at www.boehringer-ingelheim.com

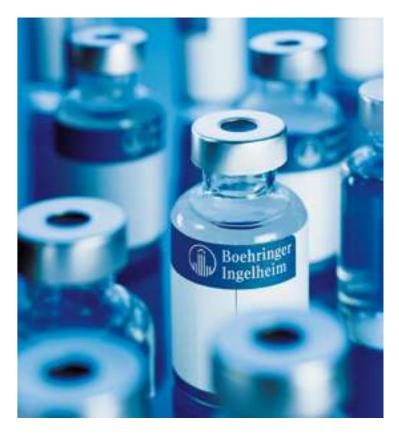






To ensure GDP compliance within their global supply chain, Boehringer Ingelheim, like all companies operating in the highly regulated pharmaceutical industry, must be able to guarantee continuous temperature monitoring of products requiring a controlled environment during transport.

Time-consuming, labor-intensive GDP compliance due to non-harmonized system and process landscape
Until 2018, Boehringer Ingelheim faced the challenges of a non-harmonized system and process landscape for in-transit temperature monitoring across the business areas. The upload rate for PDF reports with embedded monitoring data was not satisfactory and resulted in a considerable amount of manual work. Always applying the strictest product-specific monitoring profile to multiple product shipments (mixed loads) created an undesirable workload for quality assurance (QA). On a corporate QA level, it was difficult to ensure a global overview for data analysis and trending.



Target

As part of a top-level global logistics and distribution strategy, Boehringer Ingelheim set up the "MOVE IT – Monitoring Oversight in Transportation" project in February 2018 to implement a uniform in-transit temperature monitoring system based on harmonized, automated processes. Robert Müller, Senior Manager Global Logistics & Distribution – GDP Governance, and his cross-functional team defined the following project goals to be achieved within the complex project:

- > Ensure full GDP compliance
- > Harmonize processes across all business areas
- > Implement a uniform in-transit temperature monitoring system
- > Find an easy and reliable technical solution requiring a low level of training and manual tasks
- > Identify a multiple product shipment solution (mixed loads) using product-specific temperature monitoring profiles to increase efficiency and safety, significantly reduce manual effort, and cut costs by means of automation
- > Set up a centralized database to increase transparency and data availability for continuous improvement
- Reduce manual effort to gather reports for a comprehensive archive and data base for data analysis (dashboard) and trending

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Fit

Boehringer Ingelheim and ELPRO have enjoyed a close, successful business relationship even before "MOVE IT". For more than 10 years, some business areas have been using the reliable LIBERO data loggers to monitor goods in transit, and they have successfully been using the LIBERO Cloud solution as an archive since 2012. The established and qualified supplier also achieved a high degree of fulfillment of the user requirements of all business areas involved. Within many projects, ELPRO had made a name for itself as an experienced provider of reliable, GxP-compliant hardware and software assuring data integrity and IT security. ELPRO's strong international focus ensured worldwide availability of data loggers for all Boehringer Ingelheim sites and partners.



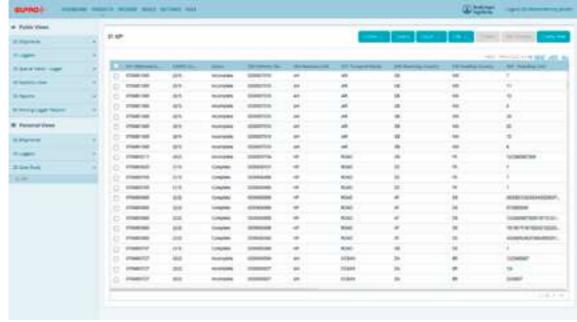
Approach

At the end of 2018, ELPRO was appointed as the supplier for the "MOVE IT" project. Daniel Reichen, key account manager and contact person for Boehringer Ingelheim for five years, was the project manager at ELPRO and reflects on the project's success factors: close involvement of all stakeholders from the beginning, agreement on a common goal, and the team's willingness to make changes and adjustments as needed.

ELPRO, in turn, contributed to the project's success with a validated, out-of-the-box software solution, flexible enough to be adapted to customer-specific requirements while guaranteeing continuous improvement. The experienced supplier has been supporting Boehringer Ingelheim during the project phase and beyond with process validation and hardware qualification. With box level indicators or IoT devices, amongst others, ELPRO offers sustainable fit-forfuture solutions.

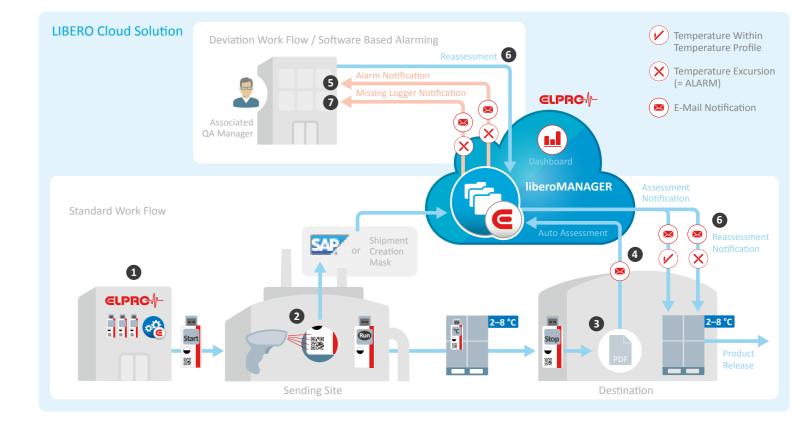
It's the people behind the project that make it a success. According to Robert Müller, the cooperation with ELPRO was characterized by a high degree of initiative, agility, and round-the-clock availability of ELPRO's Daniel Reichen.

Shipment overview on product level in liberoMANAGER



Solution

ELPRO's LIBERO Cloud perfectly harmonized software and hardware solutions to form a comprehensive value-added combination.



- ELPRO provides LIBERO data loggers containing a specific Boehringer Ingelheim technical configuration.
- At sending site, the logger ID is scanned and automatically uploaded to the cloud software liberoMANAGER together with shipment data and product-specific data (i.e., stability budgets) from SAP or alternative ERP systems. (For involved third parties like CMOs or CROs, the liberoMANAGER can also assign customized shipping information to configured data loggers with the Shipment Creation Mask.)
- 3 At destination, the receiving site generates the LIBERO PDF report and sends an e-mail with the PDF report to liberoMANAGER where all reports are stored fully GDP compliant in the archive and can be analyzed via the ELPRO dashboard.
- 4 liberoMANAGER compares monitoring data and specified temperature profiles of each stock-keeping unit (SKU) and sends an assessment notification (OK or ALARM) to the destination.

- In case of an alarm, the destination must set the SKU into quarantine, and an alarm notification is sent to the respective QA manager (software-based alarming).
- 6 If the destination forgets to stop the logger upon receiving the shipment, QA has the option to perform a reassessment and adjust the data in the LIBERO Cloud accordingly, which automatically sends a reassessment notification to the destination.
- If a PDF report is not uploaded in time, the system sends a missing logger notification to the respective QA to follow up with the destination.



"Robert Müller closely involved all parties right from the start and agreed upon a common goal. The highly resilient project team was willing to make changes and adaptions where necessary, but perseveringly kept the initial goal in mind. They went through the process step by step. At the end, they reached the top of the mountain, a real accomplishment."

DANIEL REICHEN, GLOBAL KEY ACCOUNT MANAGER, ELPRO-BUCHS

Outcome

Despite pandemic challenges, Boehringer Ingelheim has successfully automated and digitized their processes and implemented a harmonized temperature monitoring system for its global supply chain in 2020. A key user concept has been established, a well-run organization is in place, and the central database ensures global oversight. Today, a substantial amount of product deliveries rely on ELPRO's hardware and software solutions thathave earned a high level of acceptance among all business areas.

Robert Müller is proud of what Boehringer Ingelheim has achieved within its organization and together with ELPRO. An essential aspect will now be to look ahead. The company will exploit additional advantages of the new solution, especially the wide range of evaluation possibilities.

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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