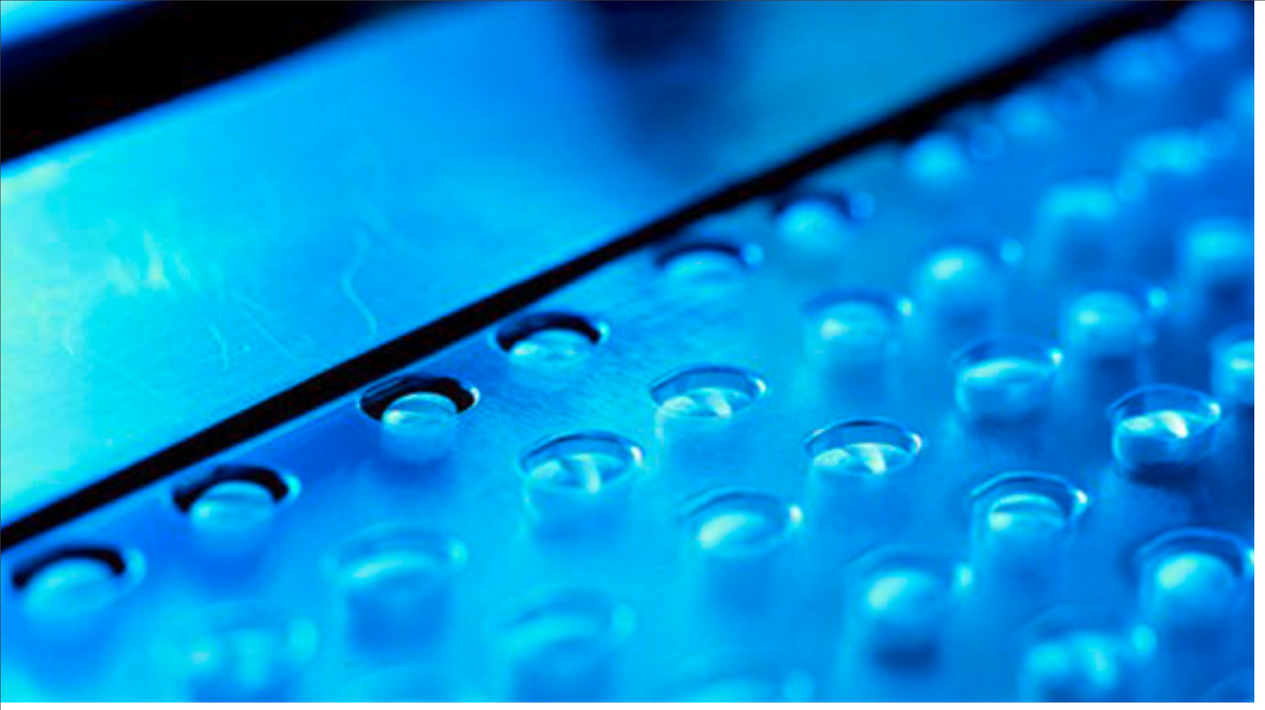
CASE STUDY

How Lundbeck is Achieving Greater Efficiency and Transparency in a Company-Wide Monitoring Approach

we prove it.

SWISS QUALITY



Project Partner

Lundbeck is a global pharmaceutical company specialized in brain diseases. For more than 50 years, they have been at the forefront of research in neuroscience. Their key areas of focus are alcohol dependence, Alzheimer's disease, bipolar disorder, depression/anxiety, epilepsy, Huntington's disease, Parkinson's disease, schizophrenia, stroke, and symptomatic neurogenic orthostatic hypotension (NOH).

Lundbeck's supply chains are extensive and global. For clinical trials, they use ten clinical depots and vast number of clinical sites across the globe, depending on the hospital's patient population and need for the therapeutic. For each study, there is a new product with new temperature requirements, new lanes and sites. Extreme flexibility and reliability in a temperature monitoring solution is a must.

Lundbeck's commercial supply chain spans all major regions worldwide, shipping high volume bulk via air, road and sea. Trucking is a mode often used in European and local distribution. They are increasing their use of sea freight to benefit from lower costs and constant temperature in reefers. Yet sea requires more careful planning due to 6+ week's transit time. Lundbeck has production sites in France and Denmark for finished products, and two chemical API plants in Denmark and Italy.

Limitations and Challenges

Lundbeck's clinical supply chain has been using ELPRO's liberoMANAGER since 2013 and have established robust processes with the system.

However, Lundbeck's commercial supply chain had been using a different monitoring solution, without any automation in place. The previous solution had various limitations:

Too slow and inflexible:
- If the temperature was exceeded, the data logger had to be sent to Lundbeck's quality assurance department by post
- All notifications for alarms and other issues were manual which created significant time delays
- With multiple consignments, the strictest temperature profile had to be applied to the entire consignment, which in the event of a temperature excursion, the entire consignment was quarantined

Lack of transparency to optimize the process and costs:
- Missing baseline data to create statistics that can be used for continuous improvements
- No collected data to evaluate services of transport partners and sites
- Not sufficient data to evaluate packaging performance and optimize packaging costs

No harmonization between departments:
- Qualification of different data loggers
- Implementation and maintenance of different SOP's
- Missing economies of scale at the supplier

Project

It became clear to Lundbeck stakeholders across the business that using the same LIBERO Cloud solution that Clinical has been using for many years, also in the Commercial department, would realize substantial harmonization benefits.

The flexibility of the LIBERO Cloud solution allows for specific workflows for each department. Within the software, the different processes work independently of one another and still achieve maximum synergy effects, including:

- Use of the already qualified data logger family LIBERO Cx
- Upgrade from the existing liberoMANAGER account to the latest software version that allows completely different processes to work independently of each other
- Automate commercial supply chain processes to reduce human error and costs
- Identify cost savings and continuous process improvements across logistics service providers, packaging and lanes

"liberoMANAGER has enabled transparency across our organization. With critical temperature data in the cloud, our supply chain teams across global sites can access the information for transport validations and make informed decisions for routes they are booking. We can foresee problems better and make informed decisions to protect our products."

MIKKEL PIND, SPECIALIST GDP, LUNDBECK

Design Workshop

In a design workshop with all key departments, the individual process steps and possible solutions were discussed with the ELPRO key account manager responsible for Lundbeck. This collaboration between Lundbeck and ELPRO allowed for a thorough definition of system set up and benefits. Having all stakeholders involved ensured an acceptable and robust long-term solution that met each department's needs, and the overall business cost-saving and operational objectives.

Clinical Supply Chain

Lundbeck Clinical Supply Chain aims to create the most simplified, error-free process for clinical partners, while at the same time keep clinical trial managers in QA control.

Study-specific stability budget
The stability budget is calculated for each clinical study after production. The LIBERO CS is a programmable data logger with up to 8 alarm areas which "allows" excursions above /below certain pre-set alarm levels for a limited time. LIBERO CS is configured in a very simple manner by the clinical depot with the "SmartStart" application to apply a predefined configuration profile and shipment specific data is added at point of packing.

Safe and easy process at sending site
With LIBERO CS, there is no software installation necessary. SmartStart is an executable (.exe) file that is easily downloaded and run from the ELPRO ClientArea, a secure hosting website. Each clinical depot has a separate ClientArea with only their study profiles and other relevant documents.
In this way, Lundbeck has full control over which temperature profiles are applied to the logger, since SmartStart does not allow access to or changes to critical settings such as temperature limits or measuring intervals.

SmartStart automatically generates a report with all details of the configured LIBERO's (e.g. LIBERO ID, selected profile), including the shipping information added during the SmartStart process (e.g. study number, tracking number). When sending to liberoMANAGER, an "open shipment" with all available information is automatically triggered, so that Lundbeck can track and check whether monitoring data of all sent loggers have been sent back to the database.

Ease of use at the destination
No software installation is required to access the data from LIBERO CS. A PDF report (with embedded data) is generated automatically as soon as the LIBERO CS is connected to a USB interface. The generated PDF/A complies with ISO standard 19005-1 Document Management for long-term preservation of electronic documents and FDA 21 CFR Part 11. The PDF/A report has embedded raw data in a secured region of the file is unique and ELPRO patented. The personnel at the receiving location can see the OK or ALARM status on the logger display based on the symbols recommended by the WHO and can immediately release the goods for use.

Excursion evaluation
By configuring the LIBERO's with the stability budget, the device can automatically and continuously calculate the alarm status. With this process, the number of temperature excursions can be reduced to an absolute minimum, thus avoiding time-consuming analyses.

Process monitoring in liberoMANAGER (SaaS)
In the archive of liberoMANAGER, all shipments are listed and the original LIBERO PDF reports are saved after a successful check of the data integrity.
Using the authorization concept, worldwide access to the data can be restricted and monitored. Users can access the data relevant to them at any time using a web browser and edit information about the program with the appropriate authorization. Every action is documented in an audit trail and thus complete traceability is guaranteed. In addition, it is ensured that the LIBERO PDF report relevant for GxP conformity cannot be manipulated.

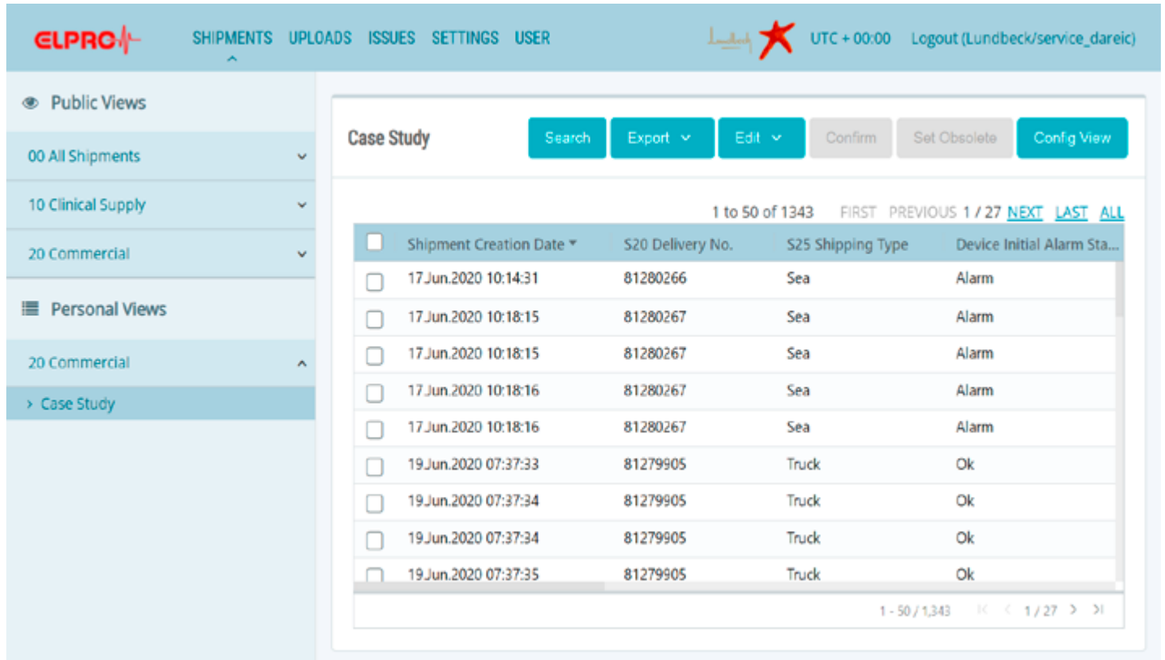
Continuous improvement
The sponsor of the clinical trial has access to the current status at all times. "Open" shipments can be tracked and the performance of third parties monitored. In addition, targeted analyzes can be worked out with the collected data and important trends identified, which enable a positive change of strategy, cost-saving process improvements such as changing the means of transport, use of alternative packaging and/or choice of route.

Commercial Supply Chain

The goal for commercial was maximum efficiency through the highest possible degree of automation with the lowest possible susceptibility to errors.

Process optimization with SAP
The number of data loggers in the shipment is shown on the delivery papers. A LIBERO CB prepared by ELPRO with a technical configuration is started and the device ID is read into SAP using a scanner. As soon as the shipment has been created, an XML file is automatically sent to liberoMANAGER software in the background via the API interface, which automatically creates an open shipment file for each product/batch/handling unit combination.

Assessment per product reduces goods in quarantine
The recipient of the goods can read the LIBERO using a standard USB interface without the necessity installing software. The LIBERO automatically generates a PDF report that is sent by email to liberoMANAGER where it is archived after it goes through a number of data integrity checks. Then the system generates an automatic assessment report for each product/batch/handling unit combination with the corresponding temperature profile and sends the notification to the original sender. This ensures that in the case of multiple shipments, the maximum stability budget per product is available during the assessment and, in the event of a temperature deviation, only the goods in quarantine are those that are actually critically affected.



Minimum time in Quality Assurance
Due to the product specific evaluation, the number of temperature deviations, and time for QA to evaluate them, can be reduced to a minimum. If the temperature is nevertheless exceeded, the responsible quality assurance will be notified automatically by liberoMANAGER. In such a case, the employee can analyze the monitoring data directly in the liberoMANAGER and carry out a reassessment. After confirmation of this reassessment with the final status, liberoMANAGER automatically sends a notification to the receiving location. The processing time and thus the time where the goods have to be stored in quarantine is reduced to a minimum.

Flexible despite standardization
It is also worth mentioning that, despite the use of only one LIBERO data logger with a standard configuration and thus the simplest handling and warehouse management, the system approach is flexible enough to take special regulatory requirements into account for certain regions. For example, the LIBERO must show the alarm status for the SFDA on the device display in order to gain access to Saudi Arabia. This information is intentionally hidden in the standard system so that the receiving location has to send the LIBERO PDF report to liberoMANAGER before the product release, thus ensuring a complete archive. To avoid unauthorized changes, the LIBERO data logger is protected with a configuration password.

Easy Project Management

ELPRO's cloud SaaS database, liberoMANAGER, can be customized to fit existing processes and support immediate decision making so there are no supply chain delays. Different users have different access rights to the system. When there is an alarm, a notification is sent to the correct person depending on who needs to be notified.

liberoMANAGER acts as a project manager by sending automated notifications to the correct, relevant contacts in case of:

- Alarm (temperature excursion)
- Issue with API Interface
- Device Error
- Approved Reassessment
- Clinical Study Report

Several different people can be included in a combined notification, creating efficient workflows in the entire supply chain organization.

CS_Lundbeck_V4E

Images with permission by (c) Lundbeck

Summary: Harmonization Does Not Mean Giving Up Individualization

After implementing the adaptable LIBERO Cloud solution across the entire organization, Lundbeck realized immediate and long-term cost-saving benefits including:

- Streamlined qualification of hardware and software
- Reduced implementation efforts (less resources, people to have in one system)
- Less maintenance efforts (e.g. requalification after systems updates)
- Significant continuous improvement costs savings by measuring KPIs across departments, including:
  - Performance of service provider (logistics or warehousing)
  - Performance of packaging
  - Performance of qualified transport lanes
  - Performance of LIBERO data loggers

"We have new ideas collaborating with ELPRO for future. They have supported our goals to improve our supply chain. Together with ELPRO, we are confident we will keep working out the best solutions" MIKKEL PIND, SPECIALIST GDP, LUNDBECK

Lundbeck can continue to focus on the core business of R&D because they know the vital temperature data and associated information are safe and taken care of within the LIBERO Cloud cold chain monitoring system. Because the data is accessible at all times from any location in the world, clinical trial delays at hundreds of sites have been reduced, with QA in control to make swift, critical decisions on releasing a product for use.

Lundbeck's commercial supply chain can finally create a complete audit trail by requiring upload of data to be able to release the product, no more chasing missing reports. ELPRO is happy to partner with Lundbeck to provide a platform that allows their clinical trial supply team to create an efficient and GDP compliant supply chain with the ELPRO LIBERO Cloud solution they have implemented.

Additional Information

Would you like to learn more about the case study, or do you have questions about your own project? Then contact our experts online using the contact form or by e-mail at online@elpro.com.

Leading Minds **Network**

More best practice content and industry benchmarking opportunities are found at the Leading Minds Network leadingminds.elpro.com.