ELPRO

CASE STUDY

Lundbeck

A cold chain monitoring solution that streamlined end to end processes ensuring successful clinical trial progression and cost-effectiveness

we prove it.

Reducing costly time delays

Project Partner

Lundbeck is a global pharmaceutical company highly committed to improving the quality of life of people living with psychiatric and neurological disorders. For this purpose, Lundbeck is engaged in the research, development, production, marketing and sale of pharmaceuticals across the world. The company's products are targeted at disease areas such as depression, schizophrenia, Parkinson's disease and Alzheimer's disease.

Project

As a large R&D organization with clinical sites around the world, Lundbeck needed a cold chain monitoring solution that streamlined end to end processes communicating temperature data that would ensure successful clinical trial progression and cost-effectiveness. In addition, it was their priority to meet new GDP requirements to demonstrate control during transport by collecting data and having an auditable database.

Previous data loggers were often returned from sites to the Lundbeck QA team for evaluation. This caused a lot of unnecessary time for receiving sites as well as QA to evaluate excursion data after they were sent back. This lengthy process delayed decisions on-site that potentially could have delayed a clinical trial. The previous data loggers created different report formats in different systems, depending on what data logger the supply chain partner was using, preventing common processes and comparison of historical data.

Lundbeck was looking for a new solution with these requirements:

- Easy for receiving sites to read alarm / no alarm
- Multi-level alarm feature to make use of available stability data
- Simple process to get data from receiving site to QA
- No need to physically send back data loggers to origin
- Central, traceable database and archive accessible from any location
- No software needed nor individual log-ins for each site, rather central QA controlling the database

The Solution: Programmable Data Loggers

Lundbeck chose the single-use LIBERO Ti1-S multi-level PDF Logger that has 6 alarm ranges and generates an automatic 1 page PDF report with embedded data. The time it takes to handle temperature deviations at clinical sites has been considerably reduced because the logger evaluates the temperatures occurred during the shipments towards the stability data of the product that is programmed into the logger. The easy and quick process of retrieving data from the logger via PDF file on any USB connection is also an added benefit. Once the PDF Logger is plugged into a computer, a report is automatically generated and can easily be emailed to the liberoMANAGER, a web based database service provided by ELPRO. liberoMANAGER forwards any alarms to Lundbeck's QA team.

Programmable Data Loggers

For Lundbeck it was important the data loggers were programmable to be able to use stability data and have the flexibility to allow excursions above / below certain alarm levels for a limited time. Having to only stock one type of logger for any kind of shipment requirement was a big additional benefit.

Safe and simple process at sending site

The ELPRO Cold Chain Monitoring Solution offers SmartStart is used to apply predefined configuration profiles including the product-specific stability data to each LIBERO PDF logger and at the same time add shipment-specific information at the point of packing. Lundbeck's SmartStart is a self-sustainable executable (.exe) file that can easily be downloaded and run from a secure hosting area offered by ELPRO to all Lundbeck depots. This way Lundbeck is in full control what temperature profiles are applied to the loggers as SmartStart does not allow access or change of any critical settings like temperature limits or logging intervals. SmartStart automatically generates a report with all the details of the customized loggers (e.g. logger ID, chosen profile) including shipment information added during the SmartStart process (e.g. shipment no, destination). When sent to liberoMANAGER, an «Open Shipment» is triggered with all available information, so Lundbeck can follow up and check if data from all sent loggers has been sent back to the database.

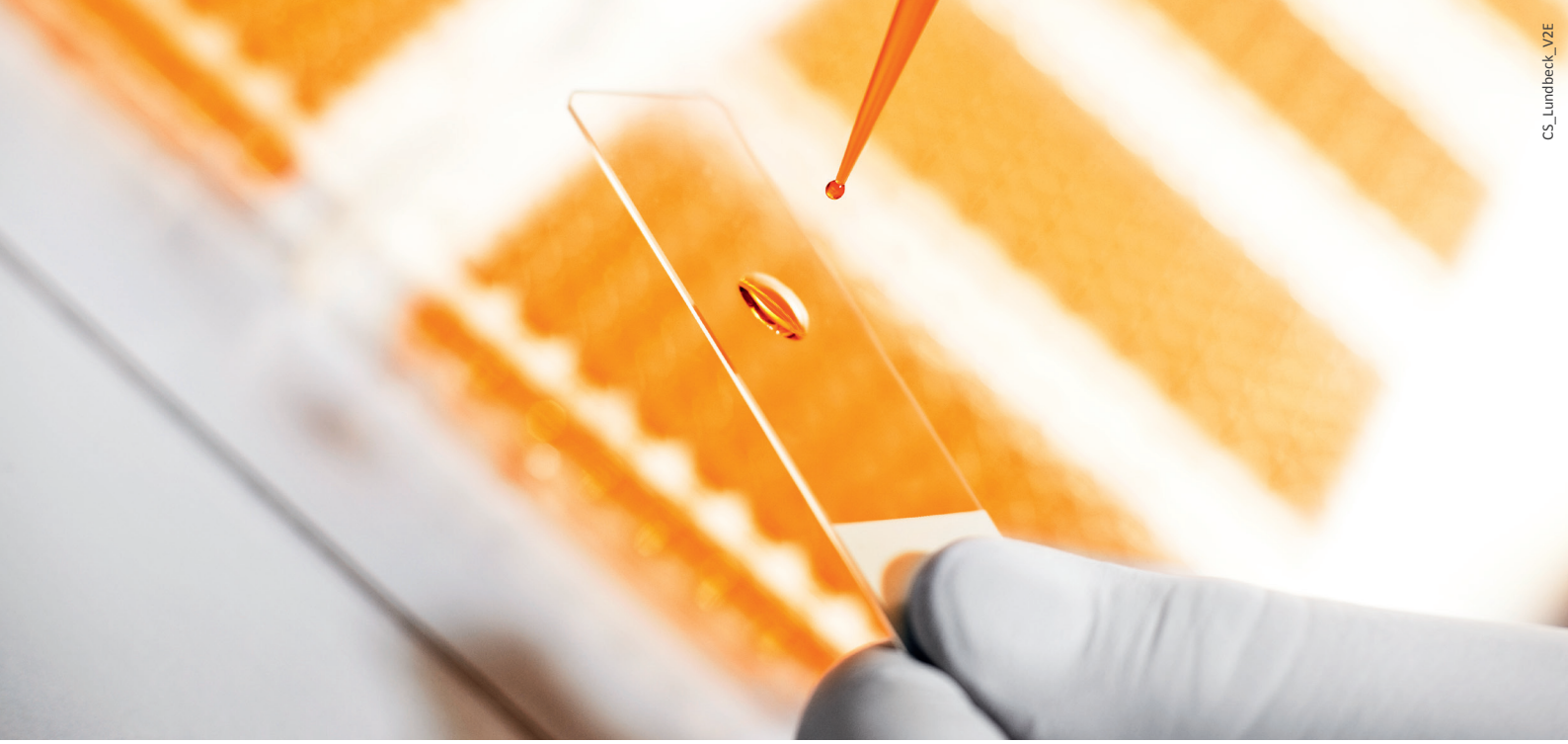
Ease of use at destination site

There is no software or equipment needed to retrieve the data from LIBERO PDF loggers. A PDF report (with embedded data) is automatically generated when connected to any USB interface. The PDF/A that is generated complies with ISO standard 19005-1 Document Management for the long-term preservation of electronic documents and FDA 21 CFR Part 11. Personnel at the receiving site can immediately release a product based on the easy-to-read display showing an OK or ALARM status with WHO recommended icons or based on the more detailed PDF report.

The Data Management Process

All PDF reports regardless of their alarm state are emailed to liberoMANAGER where the data is checked for integrity and that no duplicates are filed. If there is no alarm the PDF reports are automatically archived in the liberoMANAGER database, cutting down QA's workload to review and make decisions on temperature data of shipments that did not exceed the stability data that was assigned to them. In case of an alarm shipment, liberoMANAGER automatically generates an alarm email to Lundbeck's QA team so they can follow up on the shipment, document their findings and make a final release decision in liberoMANAGER storing all relevant information in one place.

«Our partners at ELPRO are always helpful sorting out issues regarding setting up the right configuration, dealing with email transfer problems and development of new features of the data monitoring system that will benefit Lundbeck.»
Lisbeth Nielsen, Senior Clinical Supply Technician, Lundbeck



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With liberoMANAGER, Lundbeck is able to collect all temperature data in an easily accessible platform, ensuring a GDP compliant traceable clinical supply chain. Because they can track «open» shipments in the database, it's possible to monitor the performance of the parties they work with along the supply chain. A central database also enables Lundbeck to search and be able to analyze depot activity, ongoing excursions and identify important trends that enable a positive change in strategy, cost-saving process improvements such as changing mode of transport or using alternative packaging.

liberoMANAGER was easy to implement as there were no specific hardware or software requirements for Lundbeck to consider. ELPRO offers liberoMANAGER as a web based application on a Software as a Service (SaaS) platform taking care of operation, maintenance and backup of the database. The SaaS cloud platform is fully GAMP 5-validated system operated in a highly secure and redundant (ISO 27001) data center in Zurich, Switzerland.

Customer Benefit

Lundbeck can focus on their core business of R&D because they know the vital temperature data and associated information are safe and taken care of within the ELPRO 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. At the same time, Lundbeck has detailed visibility into when temperature excursions happen and investigate quickly and judiciously. 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 Cold Chain Monitoring Solution they have implemented.