Leading Minds **Seminars**

Collaborative Learning that FUELS the Distribution of Your Temperature Sensitive Healthcare Products

November 6th and 7th 2018
Sheraton Skyline Hotel, London Heathrow

Seminar hosted by

ELPRO SONOCO THERMOSAFE

Why

It takes a village. Global supply chains are a sum of moving parts, orchestrated by teams of people and supply chain partners. There are no quick fixes in the cold chain; only structured, collaborative approaches.

Leading Minds Seminars bring together serious-minded practitioners to solve these very real, very challenging operational hurdles in the pharmaceutical cold chain. Learning from your peers in other pharma companies, ensures you're on track, implementing the right, most cost-effective best practices.

Unique Format

Leading Minds Seminars are unique in format and intent. LMS programmes are 65% discussion based. Experience sharing and problem solving are at the core of our seminars. We call it – FUELS.

Fusion of **U**seful **E**xperiences
in **L**ogistics and **S**torage

Life science manufacturers, laboratories, CROs, Pharmacies, Distributors are invited, complimentary (no fee*) attendance (non-sales titles). Teams welcome.

*All registrations subject to approval.

Programme and Networking

6th November (14.00 – 17.30)
ELPRO User Group discussing data monitoring and management technology, and future product roadmap based on customer requirements.

6th November evening (19.00 – 22.00)
Welcome networking reception and dinner.

7th November – Seminar
Discussion-based programme concentrating on regulatory driven issues, business critical topics and shared best practices.

Registration

Register for seminar HERE

Venue and Accommodation

Sheraton Skyline Hotel, London Heathrow
Bath Rd, Hayes UB3 5BP, United Kingdom
Phone: +44 20 8759 2535

Seminar participants receive a special rate of £143.50, for a double bedroom, inclusive of 20% VAT and full English breakfast.
Please book via this link to ascertain this rate.

A view back: Best minds of global pharmaceutical manufacturers from a previous Leading Minds Seminar.

Seminar Agenda | Wednesday 7th November | Morning

09.00 **Registration and Coffee**

09.30 **MHRA Regulatory Perspective Presentation and Q&A**
- Inspectorate feedback – audit lessons
- How can manufacturers balance risk-based approaches using stability data?

Ian Holloway, Senior GMDP Inspector, Inspection Enforcement and Standards Division, **Medicines and Healthcare products Regulatory Agency (MHRA)**

10.10 **Community Forum Discussion: Stability Data in the Supply Chain**
- New 2018 EMA Guidance – storage conditions, label claim and controlling facilities to local climate zone define by WHO
- Sharing examples of what regulators are accepting for stability data usage and what type of studies they want to see

Panelists: *the Audience*

10.30 **Interactive Discussion: Assessing Shipping Lanes and Extreme Excursions Using Temperature Data**
- Reviewing lane assessment examples
- Discussing acceptable excursion rates; and is there a difference between deviation and excursion?
- Focusing on the significance of extreme excursions (intensity and duration) to prioritize corrective actions
- Year to year analysis and cross-mode/cross-shipping system comparisons
- In-practice use of multi-level data loggers

Philippe De Herdt, Quality Systems Senior Manager, **Zoetis**

11.10 **Networking break**

11.40 **Discussion Session: Qualification of Shipping Lanes vs. Monitoring All Shipments**
- What is qualification?
- How do you qualify a transport lane from the temperature management viewpoint?
- Temperature monitoring vs. temperature control
- Risk management
- Deviation management

Discussion leader: *Stephen Mitchell,* Compliance and Quality Manager, Global Logistics, **GlaxoSmithKline**

12.20 **Small Group Breakout Discussions**

A) The Future of Data in the Cold Chain – Requirements vs Wishes.
Real-time data – What is Most Useful, Practical and Affordable?
Discussion Leader: *Simon Kaufmann*, Product Development Director, **ELPRO**

B) Reusable Packaging that Drives Product Integrity While Meeting Environmental Goals
- How do you ensure shippers come back?
- How do you inspect/clean/refurbish the systems?
- What makes or breaks a successful programme?
- When should you lease vs. buy?
- Explore real-world success stories

Discussion leader: *Ben VanderPlas,* Engineering & Product Manager, **Sonoco ThermoSafe**

13.00 **Lunch**

Seminar Agenda | Wednesday 7th November | Afternoon

13.50 **Is There Flexibility in How CRT is Shipped? Finding Compliant and Cost-Effective Ways to Ship**
- How to remain cost effective going from corrugated boxes to passive solutions
- How are manufacturers deciding on temperature range during product development – should the focus be earlier in the lifecycle? Could better decisions on stability profiles smooth the distribution environment?
- Balancing your regulatory filing label claim, with actual temperatures being shipped to
- Looking at differences between shipping CRT in Europe vs. US; and US domestic vs. international. Do local regulations affect practices?

Rognvald Lamb, Director, Transportation Services, Clinical Supply Services, **Catalent**

14.30 **University of Frankfurt Risk Management Initiative: Identifying Threats in the Temperature Sensitive Healthcare Supply Chain and Mitigation Strategies**
- Aligning risk approaches in collaboration between academic institutions, pharmaceutical manufacturers, logistics service providers, air carriers, ground handlers and transport associations
- Co-creating a new web-based IT tool regarding network design, quality documentation and proof towards health and certification authorities

Prof. Dr. Yvonne Ziegler, Professor Aviation Management, **University of Frankfurt**

15.10 **Networking break**

15.30 **Small Group Breakout Discussions**

A) Presentation and Discussion: Transportation of Temperature Controlled Medicines via Rail Across the Globe
- Infrastructure requirements and concerns in a global rail network
- Partnerships with rail companies
- Qualifying the processes and equipment
- Early CAPAs and areas for improvement in this new mode
- Discussion of other company approaches

Richard Peck, Global Head of Process Controlled Transportation CoE, **AstraZeneca**

B) Examining the Changing Last Miles in Clinical Supply
- The changing landscape of clinical trial supply
- The challenges of monitoring in a DtP supply chain
- Using stability budget to monitor patient kits ensuring on-time trials
- Long term continuous monitoring technology read-out by end user

Emanuel Schäpper, Team Leader, Key Accounts, **ELPRO**

16.10 **Risk Mitigation Strategy: Discuss Active to Passive and other opportunities to maintain or improve performance and quality while reducing risk and cost.**
Discussion leaders:
Mark van Bakel, Business Development Manager – Europe, Temperature Management Solutions, **DHL Global Forwarding**
Chris Day, Director of Leasing Services, **Sonoco ThermoSafe**

16.50 **Closing remarks**

16.55 **End of day**

User Group | Tuesday 6th November | 14.00 – 17.30

The purpose of the User Group is to discuss day-to-day applications, use and workarounds using ELPRO technology, specifically LIBERO PDF loggers, liberoMANAGER SaaS database and future product roadmap plans and customer requirements. This will be a unique opportunity for ELPRO customers to speak with other's using the system. (Non-customers also invited.) Small group discussions will be used to exchange ideas and compare individual approaches.

- **Why use a central data repository?**
- **Examining practical processes at each step in the supply chain including automation options for:**
  - Processes at sending site (information added during configuration, open shipment, etc.)
  - Processes in-transit (missing logger notification)
  - Processes at destination (Read out and upload options; Assessment and Approval of alarms: one colleague for both steps or two colleagues/two distinct steps?
- **Discussing practical processes including automation options for:**
  - Processes for Quality (excursion handling and communication to the site)
  - Processes for Logistics and Operations (dashboard, process improvements, etc.)
- **Case Studies**
  - How to handle multi-step shipments with different products and stability data
  - Continuous long-term monitoring applications. LIBERO ITS
  - Discussing the number of loggers used per shipment (e.g. one per pallet or product vs. one per shipment)
  - How to keep traceability between the logger ID and the pallet ID when using 3rd party LSPs
- **Future monitoring and data management technology**

Discussions at a previous Leading Minds Seminar.

About the Seminar Hosts

For 30+ years, ELPRO has been a leading Swiss manufacturer of innovative environmental monitoring solutions for the pharmaceutical, life science, biotech and health care industries. As the knowledge and innovation leader in the industry, ELPRO offers state-of-the-art data loggers, SaaS platforms including data analytics, and a team of GxP experts to support the system integration into your business processes. ELPRO's LIBERO PDF Loggers measure temperatures from -200 °C..+200 °C. They do not require any hardware or software to install or validate; simplifying end-to-end cold chain data handling. ELPRO is consistently dedicated to quality, which resonates throughout all facets of our operations – technology, service and customer support. ELPRO is ISO 9001 certified, operates SCS/NIST accredited laboratories, and complies with the GAMP5 guidelines, therefore supporting customers to fully comply with GxP guidelines. ELPRO's sales and technical support offices are located in Switzerland, US, Canada, UK, Germany, the Nordics, Benelux and Singapore.

www.elpro.com
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Sonoco ThermoSafe, a unit of Sonoco (NYSE:SON), is a leading global provider of temperature assurance packaging for the safe and efficient transport of pharmaceuticals, biologics, vaccines and other temperature sensitive products. Sonoco ThermoSafe shipping solutions mitigate risk for our customers and ensure product efficacy throughout the extremes of a supply chain. With operations in North America, Europe and Asia, Sonoco ThermoSafe has a vast product offering featuring industry-leading technology that encompasses refrigerated, frozen or controlled room temperature applications. In addition, Sonoco ThermoSafe's ISC Labs® design and testing services deliver individualized and innovative packaging solutions along with qualification and validation services to meet all regulatory requirements.

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