



Leading Minds Seminars



## Collaborative Learning that FUELS Your Temperature Sensitive Healthcare Products

13<sup>th</sup> November afternoon – User Groups (optional)

13<sup>th</sup> November evening – Welcome Reception and Dinner

14<sup>th</sup> November – Full day Seminar

Park Plaza Victoria Amsterdam, Netherlands

Hosted by





## Format

Leading Minds Seminars are unique in format and intent: we call it FUELS. Experience sharing and problem solving are at the core of our seminars. LMS programs are 65% discussion based. Step in, sit down, benchmark with other practitioners. We call it – collaborative learning.

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

**All pharmaceutical manufacturers are invited, complimentary (no fee) attendance. Teams welcome.**

## Programme and Networking

**13<sup>th</sup> November afternoon** – Concurrent, separate User Group meetings (ELPRO and Sonoco ThermoSafe)

**13<sup>th</sup> November evening** – Welcome reception and dinner

**14<sup>th</sup> November full day Seminar** – Discussion-based programme concentrating on regulatory driven issues, business critical topics and shared best practices

## Registration and Hotel

**Register for seminar [HERE](#).**

### **PARK PLAZA VICTORIA AMSTERDAM**

Damrak 1–5  
Amsterdam 1012 LG  
Netherlands  
Reservations: +31 20 717 6888 (Direct Hotel Reservations)

### **Accommodation**

**Please follow this link to book.**



The seminar venue is 2 minutes walking distance from Amsterdam City Center train station. Making these educational days a short train ride away from many European cities!



# User Groups | 13<sup>th</sup> November

13.30–18.00 | Two User Groups will run concurrently in separate rooms.

## ELPRO User Group

The User Group will discuss day-to-day applications, use and workarounds with LIBERO PDF loggers and liberoMANAGER SaaS database, as well as future product roadmap plans.

- > Project Move IT Case Study: Using liberoMANAGER to automate processes to realize an efficient, state of the art monitoring solution with the lowest cost of ownership
- > Pushing stability budget forward: Monitoring, assessing and releasing batches and products; not just loggers
- > Automated workflows and notifications for communicating with site and project managers
- > Using dashboards for performance KPIs of routes, sites, packaging and partners
- > Smart Sensor Technology Case Study: Geofence and real-time pilot feedback
- > Group Discussion: Requirements for wireless real-time Monitoring today and future

## Sonoco ThermoSafe User Group

Join a panel of experts from Sonoco ThermoSafe's Engineering team for an interactive ISC Labs Clinic. We'll discuss practical, day-to-day issues and wider strategic concerns surrounding everything to do with temperature-controlled shipping. Take the opportunity to use our expertise to help you solve your TAP challenges.

- > Q&A with panel of experts from the Engineering team at ISC Labs
- > Open discussions on the challenges and issues customers are experiencing
- > Solutions to take back and put into practice
- > Hands on practical advice
- > No problem too big or too small to discuss
- > One to one appointments also available



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



Past Leading Minds Seminar discussion group.

*You're invited to*

*Welcome Reception  
and Dinner*

**Date** | 13<sup>th</sup> November, 19.00

**Join your industry colleagues, ELPRO and Sonoco ThermoSafe for a relaxing, entertaining evening.**



# Seminar Agenda | 14<sup>th</sup> November

**8.30**

Registration and Coffee

**9.00**

Welcome Remarks

**9.05**Opening remarks from the Chairperson | **Henry Moran**, Director, **ASC Associates Ltd.****9.10****European Regulatory Insight: Temperature Control Distribution 2020+**

- > Learnings from inspection findings
- > Certain countries where temperature control expectations are unique
- > Comments to Brexit and global pharmaceutical trade

Speaker: **Riekert Bruinink**, Bruinink Pharma Consultancy, **formerly Dutch Healthcare Inspectorate****9.50** **Community Forum Discussion: Impact of Brexit on Pharmaceutical Trade**

- > How will Brexit disrupt the supply of medicines to the UK and EU patients?
- > What about the Falsified Medicines Directive?
- > Will our medicines be safe?
- > Will the cost of reverse logistics be impacted?
- > What tariff or tax implications could drive up logistics costs?

Discussion leader: **Henry Moran**, Director, **ASC Associates Ltd.****10.30** **Community Forum Discussion: Quality Control in Last Miles Clinical and Commercial**

- > Impact of Direct to Patient Distribution on clinical last miles
- > Quality control at healthcare sites
- > Site challenges with cell and gene therapies
- > Last mile quality control from a pharmacy and patient perspective

Panel: **Dr Samantha Carmichael MRPharms**, Lead Pharmacist Clinical Trials/R&D, **NHS** (Greater Glasgow & Clyde)  
**Hok Tjiok**, Pharmacist and Owner, **E-Pharma****11.10**

Break

**11.40** **Small Group Breakout Discussions****A) 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 MYTIGATE regarding network design, quality documentation and proof towards health and certification authorities

Session leader: **Prof. Dr. Yvonne Ziegler**, Professor Aviation Management, **University of Frankfurt****B) Biologics Part I In-Transit: Addressing the Rise in Frozen Shipments and Options Available Avoiding Dry Ice**

Session leader: TBC

**C) Last Mile E-Pharmacies: Real Life Challenges Speaking With and Supporting Patients With Temperature Sensitive Medicines**

- > Sources of information for the patient, what is confusing, what is helpful
- > How can e-pharmacies and pharma work together to better help patients?

Session leader: TBC

**12.20****Future Outlook Technology and Market Trends – Data Management**Speaker: **ELPRO****12.30****Community Forum Discussion: Real Time Monitoring and IoT: Evaluating Opportunities for Realizing End to End Visibility**

- > Deciding when to use real-time, and when it's not justified. What is the cost threshold?
- > Comparing manufacturer considerations and examples
- > Inventory optimization and replenishment across a network of warehouses
- > Besides temperature and location, what other data points do you need, and why?

Panel: **Gino Vleugels**, Senior Manager EMEA Temperature Control, **Johnson & Johnson**  
**Ruud van der Geer**, Assoc. Director Supply Chain Management EMEA, **MSD****13.10**

Lunch



# Seminar Agenda | 14<sup>th</sup> November

**14.10****Performing and Managing Commercial Shipments (4PL) and Challenges/Obstacles on the Road and in the Air**

- > Background on J&J and the operation in Leiden, NL
- > Working from a tender and 4PL
- > Planning and tracking E2E
- > Shipping Route Verifications

Speaker: **Jeroen Klein**, Supervisor Warehousing and Logistics, **J&J (Janssen Biologics)**

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**14.50****Case Study: Implementing a New Temperature Data Management System to Improve Global Cold Chain Operations**

- > Strategy, transition and decision criteria for moving to a new system
- > First steps into identifying areas for improvement in supply chain operations
- > Tracking open shipments and supply chain partner's performance
- > Automating processes to create more efficiency in QA investigations
- > Creating lane qualification reports from the temperature data
- > Cost savings realized so far
- > Challenges in implementing a new system

Speaker: **Cecile Crespy**, Senior Supervisor Quality Assurance, **Baxter**

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**15.30**

Break

**16.00** **Community Forum Discussion: Reusable Shipping Systems – Case Studies, Different Implementation Models, and Challenges to Overcome**

- > Discuss the challenges to implement a successful reusable program
- > Understand where others have identified opportunities within their distribution network
- > Performance and quality are essential but would you pay more? Are there opportunities to reduce cost?

Moderator: **Andrew Heholt**, Director of Business Development, **Sonoco ThermoSafe**

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**16.40****Future Outlook Technology and Marketing Trends – Temperature Controlled Packaging**

Speaker: **Sonoco ThermoSafe**

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**16.50** **Small Group Breakout Discussions****A) Biologics Part II In-Storage: Ultra-Cold Storage of Biological Materials Case Study and Discussion**

- > How to ensure GMP compliance when storing and handling biological samples
- > Central monitoring freezers and biological assets
- > Risk management of biological materials (storage and transport)

Session leader: **Hussein Ismail**, Managing Director, **Birka BioStorage**

**B) Security for Wireless Monitoring**

- > Hardware security – how is the hardware secure against tampering and hacking
- > Authentication of hardware
- > How would firmware updates be handled for hardware devices (multi-use) and testing
- > Ensuring secure updates
- > Secure software and integration

Session leader: **ELPRO**

**C) New EU Medical Devices Regulations: Impact to Products that Require Temperature and Quality Control**

Session leader: TBC

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**17.30**

Close of seminar



## Continue the conversation here

You may have noticed ELPRO is big on education.

**As a trusted global leader in our industry for over 30 years, we continue to innovate and discover new ways to help you solve problems. We keep our ears to the ground and conversations going.**

Join ELPRO's Leading Minds Network to receive our monthly newsletter, links to new white papers and invitations to relevant (free) industry events.

If environmental monitoring and data management is a concern in your pharmaceutical or healthcare laboratory, facility, or supply chain – stick with us – we have something to say.

**Read on!** [leadingminds.elpro.com](http://leadingminds.elpro.com)



**How Lundbeck Stopped Wasting QA Resources in Clinical Supply**



**Lithium Battery Regulations Causing a Kerfuffle**



**CRT Policy – Can Regulator's Trust Your Processes?**



# Education and Training TAP Certification Program

To expand the knowledge of our customers and partners in the temperature assurance packaging (TAP) realm, we are pleased to offer our TAP Certification Program. ThermoSafe's Temperature Assurance Packaging Certification Program will help participants to understand the fundamentals and advanced concepts of temperature assurance packaging so they can:

- > Evaluate different TAP solutions as they relate to the needs of their company
- > Contribute knowledgeably to conversations regarding temperature assurance packaging
- > Guide their organizations in implementing TAP solutions



## Fundamentals Course:

This self-paced, online course offers participants a systematic approach to developing a foundational understanding of Temperature Assurance Packaging.



## Professional Course:

This one-day, live and interactive course is conducted by a diverse team of industry experts to provide hands-on instruction with a case-study based learning environment.

**To learn more, visit:**

[thermosafe.com/tapcertification](https://thermosafe.com/tapcertification)



