



Leading Minds Seminar

Collaborative Learning that FUELS Your Temperature Controlled Pharmaceuticals

November 7th and 8th 2017

Princeton Marriott at Forrestal | New Jersey

Seminar hosted by ELPRO and Softbox



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 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.

LMS 2016 brought together 60 attendees representing numerous global pharmaceutical manufacturers. The feedback was extremely positive.

Format

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

Think industry retreat. Not paintball or karaoke. Instead bringing together the best minds from pharmaceutical manufacturers to solve business critical issues. Call it – collaborative learning.

Fusion of Useful Experiences in Logistics and Storage

Leading Minds Seminars FUELS the cold chain by creating an open dialogue, no pressure, relaxed environment; no press, no sponsorships.

A view back: Best minds of global pharmaceutical manufacturers at the seminar in May 2016



So many events, so little time. Why this one?

ELPRO and Softbox have been involved in developing cold chain systems for decades. Applying our extensive experience, we want to facilitate the right discussions, between the right supply chain partners to ensure successful business outcomes now, and for the long term. Tradeshows serve a purpose, but sometimes you need more than 'information overload'. Rather you need a focused group of people, concentrating on developing a detailed, systematic process approach to find the complete solution that you need.

Program and Networking

Day One – 60% of the program is discussion-based, using problem solving break-outs, as well as presentations. The day concentrates on current affairs, regulations and practical case studies.

Evening Networking – BBQ and Patio Party, set in the beautiful 25 acre Marriott property.

Day Two – Separate User Group meeting(s) to discuss ELPRO and Softbox specific technology and trends in that technology area including implementation challenges and sharing of customer user experiences.

Registration and Hotel

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

REGISTER HERE

Princeton Marriott at Forrestal

100 College Road East, Princeton, New Jersey, 08540

Phone: +1 609-452-7800



Seminar Presentations and Discussion Topics: November 7th | Morning

07.45 Welcome coffee and registration

08.15 Chairs remarks

Tom Grubb, Manager Specialty Products, Cargo Strategy, American Airlines

08.30  **Leading Minds FUELS the Cold Chain – Industry Colleague Team Building (Ice breaker)**

09.00 **Regulatory Inspector Presentation: Quality Control and GDP Best Practices in Today's Global Supply Chains**

- Feedback from site investigations
 - Advice for pharma manufacturers to comply with regulatory requirements
 - A couple years on: How Data Integrity guidance has been implemented, or not
- Ian Holloway, Senior GMDP Inspector, Inspection Enforcement and Standards Division, Medicines and Healthcare products Regulatory Agency (MHRA)*

09.45 **IATA Dangerous Good Regulations Implementation in the Pharmaceutical Supply Chain**

- History and background to evolving regulations for lithium battery shipments
- When to, when not to – use IATA specified labelling for shipments containing lithium batteries
- Considerations for dry ice shipments and sublimation considerations in cargo hold of aircraft
- Complexities in the supply chain
- UN Subcommittee for DG current thinking on future standards of lithium battery shipments for all modes of transport

Paul Horner, Manager Dangerous Goods, IATA

10.30 Morning networking break

11.00  **Problem-Solving Small Group Discussions:**

A Experiences Within the Air Cargo Supply Chain

Paul Horner, Manager Dangerous Good, IATA

B How to Demonstrate Product Quality Throughout the Distribution Environment – Without Shipping It

- What are regulator's expectations for proof?
- Going beyond the shipping validation – what does that really mean?
- Experiences in validating a process at lab-scale, including various environmental testing

Discussion leaders:

Carolyn Williamson, Principal Packaging Engineer, Bristol Myers Squibb

Ian Holloway, Senior GMDP Inspector, Inspection Enforcement and Standards Division,

Medicines and Healthcare products Regulatory Agency MHRA

12.00 **The Future of Cold Chain Packaging Qualification**

- Methods for appraising passive TCP performance:
- Challenges faced by TCP users – How do they create Ambient Profiles?
- Virtual Qualification – Is this the future?

Richard Wood, Technical Director, Softbox Systems

Stefan Braun, Managing Director, SmartCAE

12.45 Lunch



Seminar Presentations and Discussion Topics: November 7th | Afternoon

01.45 Experiences with Transitioning to a New Cold Chain Monitoring Database

- Building system processes, while keeping current processes intact
- Defining roles and responsibilities
- Expectations for impacting overall business processes
- Project management challenges

Sharmila Babu, Lead, Clinical Supply Capabilities, **Biogen**

02.30 Interactive Presentation: Stability Data the Superhero – Using a Budget In Practice

- Circling back on what is a stability budget
- Different approaches, how are you tracking it?
- Do you need to combine data across systems, modes or changes of ownership?
- Connecting data sets from storage and in-transit, to offer a fuller picture on product quality throughout the drug product lifecycle
- Human issues in managing a stability budget – QA vs Logistics
- Long term indicator – a viable solution?

Emanuel Schäpper, Team Leader Key Account Management, **ELPRO**

03.15 Afternoon networking break

03.45 Community Forum Discussion: The Internet of Things (IoT) and the Future of Cold Chain Visibility

- Defining the world of IoT and the wireless technologies in it
- How do you supply chain and Quality leaders see the need for 'live data'?
- Potential ways for how IoT could benefit the Pharmaceutical Cold Chain stakeholders
- Open discussion for possibilities for early adopters

Richard Wood, Technical Director, **Softbox Systems**

Richard Jones, Managing Director, **Softbox Systems**

Cyril Winkler, Team Leader Product Management, **ELPRO**

04.30 Problem-Solving Small Group Discussions:

A Experiences on Managing Re-use and Refurbishment of Re-Usable Temperature Control Packaging in Clinical Trials

Discussion Leader: *Richard Wood*, Technical Director, **Softbox Systems**

B Managing and Analyzing your Data – Combining Diverse Data Sets for Temperature Data Analysis

This discussion group will examine a continuum of technical opportunities, supporting analysis and reporting of Temperature Data. From single system reporting to integration within a data lake, this discussion looks at the basic technical structure needed to expand insights from your temperature data. We'll examine the challenges in combining different data sources and share ideas on the real-world data sets potentially useful in understanding your pharmaceutical cold chain.

Discussion Leader: *Terri Montes*, Informationist, **Knowledgegent**

C Clinical Site Quality Control and Temperature Monitoring Challenges

Discussion Leaders:

Teresa Parayil, Global Account Manager, **ELPRO**

Ed Difilippo, Vice President Sales, **ELPRO**

05.30 Closing remarks

Evening networking, Patio Party and BBQ dinner



ELPRO User Group November 8th

The two User Groups will run concurrently in separate rooms, along the same timetable so participants can go between rooms during breaks.

The ELPRO User Group will shift modes from last year's NJ User Group, and fully adopt the Leading Minds FUELS format of collaborative learning for 2017. Come prepared to discuss and visit sending site and receiving site "stations", to understand different processes and technology available at each step in the supply chain. Each supply chain step will include small group discussions and comparison of individual company approaches; with an outlook to future ELPRO innovations. Let's walk through the cold chain, shall we?

08.30 Breakfast

09.00  **Discussion and Hands-on Technology Workshop**

- Why use a central data repository?
- Sending site – manual vs automated processes. Small groups visit "stations" to experience how different processes and technology can be used. Discussion.
- In-transit "live" data – how will you use it? Will it actually improve getting your data back?

10.30 Break

11.00  **Discussion and Hands-on Technology Workshop**

- Receiving site options, including various ways to upload data to repository. Small groups visit "stations" to experience how different processes and technology can be used. Discussion.
- Deviation processing and reporting (pre-defined workflows, auto notifications) (QA) "Data in Action" – Incorporating stability data into your profiles and monitoring approach, what do you consider allowable excursions?

12.30 Lunch

01.30  **Data In Action Workshop**

- Analytics and trending. What are you measuring? How are outcomes improving business process decisions? Visualizing data in dashboards, identifying trends.
- Combining temperature data from in-transit, warehouses, pharmacy refrigerators. What are the possibilities for batch traceability from manufacturer, through the last mile?

03.30 Close of User Groups





Softbox User Group November 8th

The two User Groups will run concurrently in separate rooms, along the same timetable so participants can go between rooms during breaks.

The Softbox User Group will include a combination of interactive, educational, and practical sessions where all participants will have the opportunity to learn very valuable tips about temperature control packaging:

08.30 Breakfast

09.00 **Introduction to Temperature Control Packaging**

- Materials and design of passive shipping systems
- How materials are used to create packaging systems with different levels of performance and modes of use

10.30 Break

11.00 **Practical session part 1**

- An interactive session where participants will be invited to select the most appropriate Temperature Control Packaging (TCP) system for different shipping challenges.
- Participants will pack and virtually ship their selected TCP systems.

Lunch

01.30 **Practical session part 2**

- TCP systems will be received from international transit and shipping data analysed with a summary review of what we have learnt.

03.30 Close of User Groups





About the Seminar Hosts



More than 30 years, ELPRO has been a leading Swiss manufacturer of innovative monitoring solutions and data loggers for documenting environmental conditions in cold chain transportation, production facilities and warehouses. ELPRO partners with clients to develop solutions that integrate ELPRO's high-quality measurement components into their business processes. Clients include biotech, diagnostic manufacturers, and top 20 pharmaceutical companies. As the inventor of the LIBERO PDF Logger, ELPRO supports pharmaceutical and healthcare companies around the world in simplifying their cold chain while having less manual work thus reaching quicker release times. ELPRO's US subsidiary has been established in Marietta, OH since 2003 with a full turnkey support and technical staff.

www.elpro.com



Softbox Systems is an award-winning temperature control packaging innovator with over 20 years' experience. We offer consistent quality to our clients from our strategically located global manufacturing sites throughout Europe, North America, Latin America and Asia Pacific. We have formed long standing partnerships with the world's leading biotech, pharmaceutical, clinical research and logistics companies, and apply innovative thinking to overcome the challenges that our clients face in maintaining the Cold Chain when shipping temperature sensitive products.

www.softboxsystems.com