Collaborative Learning that FUELS Your Temperature Sensitive Healthcare Products

May 29th Seminar, May 30th User Groups
Chauncey Hotel, Princeton New Jersey
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 Useful Experiences in Logistics and Storage

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

Program and Networking

Day One – Discussion-based program concentrating on regulatory driven issues, increasing global operations, new technology and systems and moving industry best practices and common approaches forward.

Evening Networking – BBQ and Patio Party

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

Registration and Hotel

Register for seminar HERE

CHAUNCEY HOTEL & CONFERENCE CENTER
660 Rosedale Road
Princeton, NJ 08541
Phone 609-921-3600
acc-chaunceyconferencecenter.com

Accommodation
A special rate has been arranged for Leading Minds Seminar attendees at Chauncey. Please follow this link to book.

A view back: Best minds of global pharmaceutical manufacturers from a previous Leading Minds Seminar.
Seminar Agenda | May 29th

8.00  Welcome Coffee and Registration
8.30  Opening remarks Chairperson | Geoff Glauser, Consultant - SME - Biological Supply Chain, (BARDA), US Government - Health & Human Services
8.35  Leading Minds FUELS the Cold Chain – Industry Colleague Team Building
9.00  Community Forum Discussion: Where Does the Buck Stop?
Quality Decision Making Through the Supply Chain to Last Miles including Pharmacies
> Who has ownership (and liability) at which points in supply chain?
> Excursion handling at different points through the supply chain – how can each stakeholder be sure they are passing along a quality product?
> The visibility of stability data amongst supply chain stakeholders
> Company approaches to deciding how and when to use stability data in the supply chain
> New approaches from manufacturers
Moderator: Geoff Glauser, Consultant - SME - Biological Supply Chain, (BARDA), US Government - Health & Human Services
Panel: Thomas Scalone, Director North American Logistics, Celgene
Wholesaler perspective TBC, Pharmacy/Mail order perspective TBC
9.50  Community Forum Discussion: Continuous Monitoring vs. Risk-Based Approaches as Supply Chains Get Closer to the End-Users
> Developing robust qualified systems, seasonal profile and data sets to demonstrate quality control
> Impact of DtP (Direct to Patient) and dealing with healthcare customers that are more educated and asking questions
> Is there room for monitoring and visibility improvement in the last miles?
> Total cost review of materials, assemble, conditioning, shipping, monitoring, and qualification efforts
Moderator: Lisa Moher, Head of North American Distribution, Sanofi
10.40 Networking Break
11.10 Visibility, Automation and Control: ELPRO’s Technology Outlook and View on Market Trends
> SmartSensor case study: Contactless and real-time monitoring
> Automated monitoring processes and sophisticated workflows: liberoMANAGER
> Vision “One System” for end-to-end monitoring
> Future wireless technology, networks, and Smart labels
Speaker: Martin Peter, VP Strategy, ELPRO
11.40 Community Forum Discussion: Value and Viability of Data to Realize Supply Chain Visibility, Efficiencies and End to End Control
> What is IoT? What is Blockchain?
> What do you want to measure? Value of temp, location, container openings, etc.
> Automating shipment receipt/release using automated technology – or is that not ideal?
> Deciding when to use real-time, and when it’s not justified. What is the cost threshold?
> Comparing manufacturer considerations and examples
> Logical extension of standard temperature monitoring – future outlook
Moderator: Bill McGillian, Associate Director, Supply Chain Management, Merck
Panel: Gordon Johnson, Global Head of Optimization, DHL Global Forwarding, Martin Peter, VP Strategy, ELPRO
12.30 Lunch
1.30 Small Group Breakout Discussions
A) Clinical Trial Supply and Challenges at the Clinical Sites
> Oversight and ownership of the process for managing product and excursions at the clinical trial site
> Challenges in getting the data back from the sites for analysis
> What works? What doesn’t work? What are we missing?
> How does the trend towards Direct-to-Patient change the equation?
Discussion leader: Doug Meyer, Associate Director, Clinical Drug Supply, Biogen
Seminar Agenda | May 29th

B) Stability Budget: Evaluating Methods, including How to Build Stability Budget into Loggers for a Proactive Approach
C) Evaluating Risks in the ‘Last Miles’ Including Mail Order Pharmacies

2.20 Sonoco ThermoSafe Future Technology Outlook and Market Trends (10 minutes)
> Sustainability – Return, Reuse, Recycle, and Biodegradable
> Integrated Data Services – Internal/External Temperature, Location, and More
> “One Touch” Solutions – Preconditioned Bulk and Active Parcel
> Value Added Services – JIT Programs, Reclamation Services, and Engineering Consulting

2.30 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?
Panel: Mark Everitt, Qualification Engineer, AstraZeneca
Michael English, Director Engineering, Merck
Carolyn Williamson, Parenteral Supply Chain (former BMS)

3.20 Networking Break
3.50 Small Group Breakout Discussions
A) Qualification of Single-Use vs. Reusable Shippers
> Two independent industry groups are working to define a standard approach for single-use qualification.
> Is there an opportunity for one standard?
> How should the qualification of a reusable solution differ from a single-use qualification? Discuss a recent USP Stimuli article sharing best practices for the qualification of a reusable temperature-controlled packaging solutions.
Discussion leader: Ben VanderPlas, Manager, Engineering & Product Management, Sonoco ThermoSafe

B) Cell and Gene Therapy Supply Chain – Shipping Ultra Low Temperatures
Several products approved for cell therapies, getting track n trace info is critical. Vibration effect on cells, temp impact, the inbound and return are two different things (after gene manipulation) - different temp handling?
Does this affect many big manufacturers, or address from clinical perspective?

C) Chocolate Challenge: How Melty is your Chocolate?
Join this hands-on exercise to see just how valuable temperature data is when something very important is on the line – Swiss chocolate! Participants will use liberoMANAGER SaaS software at small-group PC stations to program a logger with shipment criteria; read and generate a shipment report; and assess a shipment adding stability data
Group leader: Teresa Parayil, Global Account Manager, ELPRO

4.40 Community Forum Discussion: Serialization Implementation Status:
Considerations for Temperature Control Supply Chains
> Current situation and outlook -when will this key driving force to patient safety be ready?
> DSCSA Saleable Returns Verification requirement phases in November 2019: Already Warning Letters reflect need for wholesalers to report suspect or illegitimate products
> SSCC barcode Serialized Shipping Container Code – considering how it could contain more information including shipping information or a temperature profile
Moderator: Geoff Glauser, Consultant - SME - Biological Supply Chain, (BARDA), US Government - Health & Human Services
Panel: Thomas Scalone, Director, North American Logistics Operations, Celgene
Wholesaler perspective TBC

5.10 Closing remarks
5.30 Cocktail Reception and Networking Games
7.15 Dinner
May 29

You’re invited to a

Patio Party

Cocktail Reception and Networking Games | 5.30 pm
Dinner | 7.15 pm
Location | Outdoors, Chauncey Garden Pavilion (partial grass lawn)

Join your industry colleagues, ELPRO and Sonoco ThermoSafe for a relaxing, slightly competitive evening.
ELPRO User Group | May 30th

The User Group is designed to explore ELPRO data monitoring and management technology in-depth. The workshop-style day is ideal for temperature control practitioners using ELPRO systems, or not. The discussions will benefit anyone wanting to improve their operations, update their systems and to benchmark with other cold chain practitioners on the topics of data management, including:

**Breakfast and coffee**

**7.45**

*Adding Automation to Your Cold Chain Monitoring: Using a Central Database*
- Automated workflows for communicating with site and project managers
- Assessment and approval of alarms/excursion handling, and shipments not just loggers
- How to keep traceability between the logger ID and the pallet ID when using 3rd party LSPs

**8.45**

**Break**

**10.15**

*Smart Sensor Technology Case Study*
- Integration of real-time devices into liberoMANAGER: LIBERO G and NB-IOT
- Implementing automated workflows for process improvements
- Geofence and real-time Pilot results

**ELPRO Product Roadmap**
- Bluetooth functionality LIBERO CE/CL/CH for ultra-low temperature shipments and equipment monitoring

**10.45**

**Break**

**12.00**

*Lunch*

**1.00**

*Thermal Mapping Warehouses and Cold Rooms*
- Thermal mapping strategy and analysis of warehouses and cold rooms vs. Facility qualification
- What drives monitoring placement points – the layout of the warehouse; or the hot and cold spots based on the mapping?

**Interactive Small Group Exercise: Using liberoMANAGER Database in Practice**
- Participants will use liberoMANAGER SaaS software at small-group PC stations to store, search and analyze temperature data.

**2.30**

*Close of meeting*
Sonoco ThermoSafe User Group | May 30th

7.45  Breakfast and Coffee

Next Generation Think Tank
When you think about the future of temperature controlled distribution, what do you envision 10 years from now? Let’s discuss by sharing real world experiences, diving into current challenges, strategizing best practices, and examining how requirements both near and long-term will affect the pharmaceutical supply chain moving forward. How do we solve these challenges? What is on your wish list?

8.45  Break

Connected Healthcare and IoT – Keeping Up with Technology Trends
The rapid development of data gathering technology, going beyond temperature alone, paired with numerous means of communication has quickly become a powerful tool ripe for the integration into the supply chain of temperature sensitive products. How can we embrace these technologies and develop alerts and services to act before a temperature excursion occurs? We can find ways to reduce waste and increase visibility across the supply chain. This session will focus on how real-time data can and will make a significant impact across the pharmaceutical supply chain over the next few years.

10.15  Break

10.45  Connected Healthcare and IoT – Keeping Up with Technology Trends

12.00  Lunch

1.00  Technology & Services - Risk Mitigation, Removing Costs from the Supply Chain, and more ...
In the temperature controlled supply chain there is never one “right” solution. There are many tradeoffs and variables to consider when selecting the strategy by which you purchase and design a temperature controlled packaging solution. Let’s review and learn about some of our latest innovations including real-time telemetry, pay-per-use reusable solutions, and get a glimpse of our current development projects. How can these innovations optimize the total cost of ownership within your network?

2.30  Close of Meeting

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

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.

Join us on Wednesday October 16\textsuperscript{th} at the IQPC Global Forum where we’ll be hosting our next Professional Course.

To learn more, visit: thermosafe.com/tapcertification
For over 30 years, ELPRO is widely recognized as the global knowledge leader in innovative, Swiss engineered environmental monitoring solutions and data loggers for pharma, healthcare and life science. ELPRO partners with clients to develop solutions that integrate ELPRO's high-quality measurement components into their business processes. Clients include biotechs, diagnostic manufacturers, and the top 20 pharma companies. As the inventor of the LIBERO PDF Logger, ELPRO solutions have the lowest total cost of ownership and assist pharmaceutical and healthcare companies around the world preserve and manage stability budgets and simplify their cold chain by reducing manual work, resulting in quicker release times.

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.