



## **Leading Minds Seminars** **Philadelphia 2018**

# **Collaborative Learning that FUELS Your Temperature Sensitive Healthcare Products**

**June 6<sup>th</sup> and 7<sup>th</sup> 2018**

**Normandy Farms, Blue Bell PA  
(just west of Philadelphia)**

Seminar 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 Useful Experiences in Logistics and Storage

No press, no sponsorships, only further FUELS an open dialogue, no pressure, relaxed environment.

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

## Program and Networking

**Day One** – 60% discussion-based program – concentrating on regulatory driven issues, benchmarking approaches and shared best practices.

**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**

### Normandy Farm Hotel and Conference Center Blue Bell, PA

1401 Morris Rd Blue Bell, PA 19422

T +1 215 616 8500 | [www.normandyfarm.com](http://www.normandyfarm.com)

\$149 +tax has been arranged for this event. Please visit the link below and/or mention the special ELPRO/Sonoco ThermoSafe Leading Minds Seminar rate when calling.

#### To Book Your Room Reservation Online:

1. **CLICK HERE** to go to the specialized booking page
2. Click “Add Code”
3. Select “Group Attendee” from the dropdown menu
4. Enter the special code: LMS605

**Booking/Reservation Deadline: May 8, 2018**

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





## Seminar Agenda | Wednesday June 6<sup>th</sup> | Morning

- 08.00** Welcome coffee and registration
- 08.30** Opening remarks chairperson  
*Geoff Glauser*, Consultant – SME – Biological Supply Chain, (BARDA),  
**US Government – Health & Human Services**
- 08.35** **Leading Minds FUELS the Cold Chain – Industry Colleague Team Building** (Ice breaker)
- 08.50** **USP Updates to <1079> Risk Mitigation, <659> Packaging and Storage Requirements, and the Use MKT Calculating Controlled Cold and CRT**  
 - Impact of <1079> changes on day to day practices  
 - Temperature excursion management  
 - Current realities: proper and improper use of MKT  
 - MKT use for CRT versus MKT use for 2 °C..8 °C, –20 °C, –80 °C  
 Speaker: *Chris Anderson*, Director, Quality Systems, **Cardinal Health**, USP Packaging and Distribution Expert Committee Member, USP <1079> Sub-Committee Co-Chair, **U.S. Pharmacopeia**
- 09.30** **Community Forum Discussion: Sufficient Stability Data**  
 - What are regulators accepting for stability data during filing?  
 - What types of studies do they want to see?  
 - How do they accept/not accept use of stability in transport?  
 - Examples of regulators asking for more, what type?  
 - Example from certain countries accepting stability data to ship outside of label claim  
 Moderator: *Geoff Glauser*, Consultant – SME – Biological Supply Chain, (BARDA),  
**US Government – Health & Human Service**
- 10.15** Networking break
- 10.45** **Stability Data In-Practice Part II: Comparing Company Approaches to Using a Stability Budget**  
 - How is the budget determined and set up?  
 - Considering how decisions are made in product development to improve the distribution environment  
 - Types of testing done, all products are unique  
 - Costs and ROI  
 - Net comparison – a list of considerations for evaluating how to set up a stability budget  
 Speakers (Additional speakers TBA):  
*Michael English*, Associate Director, Engineering, **Merck**  
*Matt Pietrangelo*, Sr Manager, Packaging Development, **Alnylam Pharmaceuticals**
- 11.30** **Small Group Breakout Discussions**  
**A) Blockchain: Potential Impact to the Pharmaceutical Supply Chain**  
 - Business benefits: greater transparency of product performance throughout the supply chain of quality control products  
 - Regulatory compliance benefits: meeting DSCSA requirements  
 Discussion Leader: *Dirk Rodgers*, Global Regulatory Strategist, **Systech & Author**, [www.rxtrace.com](http://www.rxtrace.com)  
**B) Stability Budget Temperature Monitoring Protocols**  
 Discussion Leader: *Teresa Parayil*, Global Key Account Manager, **ELPRO**  
**C) Finding Cost-Effective Ways to Ship Controlled Room Temperature (CRT) Products**  
 - How to remain cost effective going from corrugate boxes to passive solutions  
 Group participant: *Lawrence Trey Davis*, Quality Manager II / Supply Chain, Memphis Global Logistics Center, **Baxter Healthcare Corporation**  
**D) Using <659> MKT Calculating Controlled Cold and CRT**  
 Discussion Leader: *Chris Anderson*, Director, Quality Systems, **Cardinal Health**, USP Packaging and Distribution Expert Committee Member, USP <1079> Sub-Committee Co-Chair, **U.S. Pharmacopeia**
- 12.30** Lunch



## Seminar Agenda | Wednesday June 6<sup>th</sup> | Afternoon

**01.30****Last Mile for Cold Chain and CRT Clinical and Commercial**

- Direct to patient distribution in clinical trials for personalized meds
  - What can we learn from clinical trial supply – complete accountability of each shipment, patient compliance
  - Epatient records, anonymous data, collect adverse reports – it's possible if system is in place
  - Hospital perspective – how are they controlling medicines?
  - 3PL stores for virtual pharma company
  - Long term continuous monitoring technology that provides stability budget read-out by end user
- Speaker: *Jeffery M. Carrico, PharmD, BCPS*, Service Chief, Clinical Pharmacy and Investigational Drug Research, **The National Institutes of Health**

**02.15****Interactive Presentation:****Reusable Packaging that Drives Product Integrity While Meeting Environmental Goals**

- How do you qualify the process?
- How do you ensure shippers come back?
- How do you inspect/refurb/clean the systems?
- What makes or breaks a successful program? When should you lease vs. buy?

Moderator: *Vishal Khushalani*, Director of Global Marketing and Business Development, **Sonoco ThermoSafe**

Speaker: *Mark Lovell*, Associate Director of Logistics and Cold Chain, **bluebird bio**  
(Speakers: TBA)

**03.30****Networking break****04.00****Case Study: Achieving a New Level of insight into Temperature Data**

- It's not best to calculate everything – Make it actionable!
  - a. Tracking open shipments to close gaps in supply
  - b. Identifying false excursions and narrowing down why they might happen
  - c. Reducing the false excursion ratio and determining if they are reportable within stability budget scope
- If you cannot measure, you cannot identify gaps in the performance

Speaker: *Sharmila Babu*, Lead, Clinical Supply Capabilities, Clinical Drug Supply, **Biogen**

**04.45****Small Group Breakout Discussions****A) Setting Up Global Risk Analysis for Transportation Validation****B) Active to Passive as Part of a Risk Mitigation Strategy**

Discussion Leader: *Ben VanderPlas*, Global Product Manager, **Sonoco ThermoSafe**

**C) Shipping Clinical Supplies and Products Direct to Patient (DTP) Homes****05.30****FUELS Session – Industry Team Building****05.45****Closing remarks****06.00****Patio Party: Franklinville Terrace (outdoors)****07.00****Dinner: Franklinville Terrace (outdoors)**





## User Groups | Thursday, June 7<sup>th</sup>

The **ELPRO and Sonoco ThermoSafe User Groups Day** will consist of varying formats including a series of small breakout discussions, which will rotate so participants have a chance to join more than one topic. Also groups will be broken into experience level for some discussion topics, to create more focused, detailed discussions.

If you have suggestion of topics or format for the UG day, please email [Courtney.Becker@elpro.com](mailto:Courtney.Becker@elpro.com) (ELPRO UG) and email [Ben.VanderPlas@sonoco.com](mailto:Ben.VanderPlas@sonoco.com) (Sonoco ThermoSafe UG).

### ELPRO User Group | Topics include:

- Sending site – manual vs automated processes. Small groups visit “stations” to experience how different processes and technology can be used.
- In-transit “live” data – how will you use it? Will it actually improve getting your data back?
- 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.
- 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?
- Analytics and trending. What are you measuring? How are outcomes improving business process decisions?  
“Data in Action” – 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?

### Sonoco ThermoSafe User Group | Topics include:

**Site Visit:** The Sonoco ThermoSafe User Group will take place at the Manufacturing Plant and ISC Labs Design & Testing Facility. Transportation will be provided to and from Normandy Farms.

- Visit “stations” in small groups to experience how innovative technologies (green insulation, phase-change, asset tracking, GPS and more) can be used. Discussion.
- Tour ISC Labs – see design engineers in action and interact with them to see what they watch out for? Profile, payload, probing (the 3P’s), and more.
- Experience advanced thermal modeling – review decision engine demo and 3D modeling screenshots
- View manufacturing at the plant – see how products are manufactured, quality tested and delivered to you
- Review reusable options – parcel/bulk, lease vs. buy, other considerations to discuss what’s right for you?



## 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 biotechs, 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](http://www.elpro.com)



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.

[www.thermosafe.com](http://www.thermosafe.com)