Leading Minds **Seminars**

Temperature Controlled Distribution of Biologics

September 10th 2019, The Alexandria San Diego

About the Seminar

Southern California's Life Science community is a leader in novel drug discovery, genomics research and extensive clinical trial research. But what about outside of the laboratory and clinical trial walls? What level of consideration and investment is being allocated to the protection of in-process, clinical, active ingredient and finished good during distribution?

The distribution environment is challenging, even more so when handling high-value temperature-sensitive products. To preserve the safety and efficacy of these products through each stage of products in-transit, they must be adequately and compliantly protected against thermal and physical stress.

Leading Minds Format

Leading Minds Seminars are unique in format and intent: we call it FUELS. **F**usion of **U**seful **E**xperiences in **L**ogistics and **S**torage. Experience sharing and problem solving are at the core of our seminars. Our Seminar programs are 65% discussion based. Step in, sit down, benchmark with other practitioners. Collaborative and community-based learning at its best!

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Draft Agenda – List of Topics | 10th September

8.00 Welcome Coffee and Registration
8.30 Welcome Remarks
8.35 Opening remarks Chairperson
Kevin Hickman, Senior Manager, Supply Chain Distribution, **Gilead Sciences, Inc.**

8.40 FDA feedback to lane studies and recent 483 observations related to temperature control shipping

9.00 GDP Regulations and Industry Standards Updates Across the Globe
- ISPE guidelines for qualification and storage of equipment and facilities
- New EU Medical Device legislation – cold and frozen consumables/reagents. Why should medical device companies care about temperature control?
- Brexit impact, changes to label process?
- China evolving regulations requiring data loggers in clinical and commercial

9.40 Preparing for commercialization – what will you put in the BLA?
- What type of data do you need for quality assurance, and for your prospective buyer?
- Do you have a trained supply chain professional ready?
- Evaluating transport partners
- Stability studies sufficient to protect product integrity and product investment
- Will you monitor by pallet, unit, etc.
- What will you do with the data when you get it? What information is really useful? Are some excursions acceptable?

Session leader: **Bob Seevers,** Senior Advisor, **Pearl Pathways** & Member, *USP <1079> Packaging and Distribution Committee*

10.30 Networking break

11.00 Small Group Breakout Discussions

A) Commercial Supply Chain Considerations Including Serialization Status
- Drug Supply Chain Security Act (DSCSA)
- Saleable Returns Verification requirement phases in November 2019: Already Warning Letters reflect need for wholesalers to report suspect or illegitimate products

B) BioPharma Supply Chain 101
- Proper paperwork and being prepared with correct documentation
- How to map and qualify a lane
- Auditing vendors: Importance of on-site visit from SME
- Contingency plans per lane
- How to upgrade shipping studies and how should I do thermal Cycling?
- What has to validated? Don't re-invent the wheel!
- Are all suppliers approved and is all documentation in place?

Session leader: **Heather Lane**, Senior Supply Chain Specialist, **Heron Therapeutics**

12.00 Lunch

12.50 **Community Forum Discussion: Biopharma and Logistics Partners**

Agreements, SOPs and Quality Control

- Identifying shipping requirements with your partner, eg. CRT definitions
- Communication and intervention in case of long FDA or other hold (delay in shipment?)

Packaging:

- Having a standard cargo box. Which size runs best through the system of the forwarders?
- Does partner have qualification documentation for pre-qualified system?
- How do you know when gel packs are properly conditioned?
- Educating the customer on passive logistics

Temperature monitoring:

- Selecting the right monitor for immediate data access vs. via logistics partner
- Redundancy in monitors across partners

Global logistics challenges

- What type of cooling units or refrigerators are your partners using?
- Considerations for sharing loads or mixed loads
- Concerns around biologics handling in-transit – how xray or other factors affect these sensitive products?

Moderator: **Denise Valentino**, Director, Global Trade Compliance & Logistics, **Neurocrine**

1.40 **Temperature Data for Quality Control and Compliance**

- What is an excursion, vs deviation – and what are acceptable levels?
- Focusing on significant excursions to prioritize corrective actions
- Dealing with human error and false/positive excursions
- Tactics to reduce excursion handling time
- Lane assessment data and practices
- Using software for audit trail requirements, product release processes and future analysis on shipments if necessary

Speaker: **Laurie Rockwell**, Global Account Manager, **ELPRO**

2.20 Networking break

2.50 **Community Forum Discussion Temperature Controlled Packaging Considerations and Systems**

- Deciding which packaging and materials fit your needs
- Passive system logistics challenges, and opportunities
- Active vs passive
- Considering the qualification requirements and how to possibly harmonize those efforts
- How to work with packaging partners to meet qualification requirements as supply chain and networks grow internationally
- How to design product packaging being controlled by patients

Moderator: **Kevin Hickman,** Senior Manager, Supply Chain Distribution, **Gilead Sciences, Inc.**

3.40 **Healthcare Temperature Controlled Logistics**

- Qualification and validation (DQ, OQ, PQ) of packaging systems
- Ambient profiling and lane risk assessment
- Risk mitigation and contingency planning

Speaker: UPS

4.20 – 6.30 Patio Party Networking

About the Seminar Hosts

BIOCOM

Biocom is the largest, most experienced leader and advocate for California's life science sector. We work on behalf of more than 1000 members to drive public policy, build an enviable network of industry leaders, create access to capital, introduce cutting-edge STEM education programs, and create robust value-driven purchasing programs.

www.biocom.org

ELPRO

ELPRO, a Swiss engineering firm, has been a partner to biopharma companies for three decades developing compliant data monitoring systems for facilities and products in-transit. ELPRO's data loggers and software protect your biotech assets from lab to supply chain: growing and adapting as your products move through trials and into market. ECOLOG Monitoring Solutions for Rooms and Equipment allows great flexibility to access your facility remotely via internet browser to see temperature, CO2 RH, Pressure differential or any 4-20mA signal. LIBERO PDF multi-alarm data loggers monitor shipments to control a wide-range of biotech applications (-200°C...+200°C) including clinical trial kits, ultra-low shipments and APIs. Ask us about new developments in real-time monitoring and wireless monitoring. ELPRO's USA main office is in Marietta, Ohio since 2003 with a full technical support staff; and offices in San Diego and San Francisco.

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