Leading Minds **Seminars**

Temperature Controlled Distribution of Biologics

September 11th 2018
The Alexandria at Torrey Pines, San Diego

Seminar hosted by

ELPRO BIOCOM

About the Seminar

Southern California's Life Science community is a leader in novel drug discovery, genomics research and extensive clinical trial research. These innovative R&D activities often involve highly-sensitive materials and highly valuable clinical and commercial products that need to be protected against thermal stress.

This seminar will discuss quality and logistics initiatives that companies are using to protect life-saving medicines throughout their lifecycle from APIs, to clinical trial supply and through commercial distribution for today's next gen therapeutics, diagnostics and biologics.

Leading Minds Format

Leading Minds Seminars are unique in format and intent: we call it FUELS.

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

Experience sharing and problem solving are at the core of the seminars. Seminar programs are 65% discussion based.
Step in, sit down, benchmark with other practitioners. Collaborative and community-based learning at its best!

Registration

Register HERE

Cost

- ELPRO Leading Minds Network Members (Industry): $0 (Use special discount code "ELPRO" when registering)
- Biocom Members (Industry): $0
- Biocom Non-Members (Industry): $250

Location

The Alexandria
10996 Torreyana Road
San Diego, CA 92121
www.thealexandria.com

Accomodation

*There is no overnight accommodation at the Alexandria. For bedroom accommodations, nearby hotels include:

Hilton La Jolla
10950 N Torrey Pines Rd
La Jolla, CA 92037
+1 (858) 558-1500

Sheraton La Jolla
3299 Holiday Ct
La Jolla, CA 92037
+1 (858) 453-5500

Sponsored by

For any exhibition enquiries, please contact Angela Wieszchowski at Biocom: angelaw@biocom.org

Seminar Agenda | Tuesday September 11th | Morning

08.00 **Welcome coffee and registration**

08.30 **Opening remarks chairperson**
Kevin Hickman, Manager, Supply Chain Distribution, **Gilead Sciences, Inc.**

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

08.50 **Community Forum Discussion: Approaches and Trends to International Regulatory Compliance**
- Industry observations and major concerns from FDA and other regulatory agencies in recent years
- Stability label claim challenges in some countries – regulatory hurdles
- USP updates to <1079> and <659> Using MKT for Cold and CRT

Regulatory authority speakers invited

09.30 **Community Forum Discussion: Strategic Logistics Collaborations**
- Logistics day to day issues
- Quality controls
- Temperature monitoring considerations

Discussion leaders:
Kevin Hickman, Manager, Supply Chain Distribution, **Gilead Sciences, Inc.**
Saya Mehta Godwin, Director, Supply Chain and Logistics, **Heron Therapeutics**

10.20 **Networking break**

10.50 **Interactive Session and Small Group Exercise: Managing Risk Through Customized SOPs**
- In-transit intervention strategies: Best practices for irreplaceable biotech products
- Reducing supply chain risk: Defining actual and consequential appropriately
- Mapping contingency options activity – could we explain this a little more clearly?
  Putting your current contingency plans on paper. Are they optimized? Ideal?

Discussion leader: *Jeff Walsingham,* Corporate Healthcare Strategy, **UPS**

11.30 **Small Group Breakout Discussions**

A) Process Considerations for Cryogenic Shipping of Cell-Based and Other Biologics
Ultra-low shipping can be challenging, especially for newer applications in personalized cellular therapies and regenerative medicines. This discussion will examine considerations for liquid nitrogen safety, label adhesion and primary container integrity at cryogenic temperatures, and the importance of relationships, documentation, and training with logistics partners.
Discussion Leader: *Craig Vermeyen*, Sr. Manager, Packaging Engineering, **Kite Pharma**

B) GDP and GMPs for Temperature Sensitive APIs: Considering New 2018 FDA Guidance In-Practice
- Who is ultimately responsible for the quality control of APIs? Biopharma, courier or CMO?
- Best practices for meeting the standards through quality agreements.

Discussion leader: *Robert Cook,* VP Operations, **Argonaut Manufacturing Services**

C) Using Stability Data in Your Temperature Control Chain to Reduce Cost and QA Time
False excursions happen all the time due to handling errors at healthcare sites. This discussion will discuss how to avoid them; and also, how to use stability data to manage Time of Refrigeration (TOR) and stability budget allowances. Let's share experiences on what regulators are accepting.
Discussion leader TBC

12.30 **Lunch**

Seminar Agenda | Tuesday September 11th | Afternoon

01.30 **Community Forum Discussion: Controlled Room Temperature Shipping**
- CRT vs. Ambient. Clarity on definitions.
- Educating internal departments and external partners
- Discussion - how to ship CRT and validate system according to regulatory requirements
- Shipping outside US
- CRT warehouse facilities maintain processes differently
- Best practices for CRT based on stability data
- CRT raw materials and APIs

Invited: *Jerry Ferracamo,* Product Development Manager, **Inmark**

02.10 **Interactive Presentation: Ensuring Data Integrity in the Clinical Supply Chain in a Biologics World**
- Considering USP and global regulations for clinical supply, MKT use and data integrity
- Using stability data for clinical shipment strategies including widening shipping ranges and using multi-level monitoring – what is an allowable excursion?
- Better control of healthcare clinical site processes, including more efficient alarm handling
- Handling ultra-cold temperature shipments and their data monitoring challenges
- Steps to gaining greater visibility into lanes and partner performance using temperature data including dashboard views for teams

Jeroen van Loo, Global Account Manager, **ELPRO**

02.50 **Networking break**

03.20 **Small Group Breakout Discussions**

A) Qualifying Thermal Blankets for Cost-Effective CRT Shipping
Thermal blankets can be an attractive protective solution for lower cost CRT products. However, does the data prove sufficient temperature control? What are the transport considerations and challenges by handlers in the supply chain? Are there best practices for PQ/OQ testing?
Discussion Leader: *Carmichael Galang,* Senior Cold Chain Project Manager, **Bayer AG**

B) Quality Control Practices in Facilities Storing Biologics
Today's temperature sensitive healthcare products come in a wide variety of shapes, sizes and of course temperature. This discussion will discuss challenges staying current with biopharma company's requirements in a storage facility for CRT products and ultra-cold shipments; while ensuring the facility is GxP compliant. Preventing cold storage humidity and ice is critical. Is there standard monitoring equipment to ensure mechanical equipment is in working order?

C) Import Export & Customs Acceptance and Best Practices
Shipping tightly controlled biologics materials and products can be a tricky business at the borders. With no time to waste, customs practices and documentation must be in place. There is no free flow of goods in the pharmaceutical world. This discussion will focus on common errors and experiences shipping small parcels and bulk ingredients internationally.

04.20 **Personalized Medicines and Healthcare Last Mile Challenges**
- Challenges with new shipments on dry ice and LN2
- How to design product packaging being controlled by patients
- Monitoring irreplaceable personalized medicines through until patient consumption.
- Evaluating real-time monitoring cost, vs. operational advantages- vs. other monitoring approaches.
- How does the patient know it's safe to use?
- Educating the last miles – pharmacies hospitals how to handle temperature-controlled shipments

Speaker TBC

05.00 **Closing remarks**

05.15 **Patio Party (outdoors weather permitting)**

07.00 **Seminar end**

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.

www.elpro.com