**Master Class Registration & Breakfast**

**8:15 am**
**Master Class Registration & Breakfast**

**9:00 am**
**Part 1:**
Temperature-Controlled Clinical Trial Materials (CTMs) Packaging Essentials: An Introduction to Thermodynamics, Packaging System Options, Risk Based Approaches Used for Distribution; An Introduction to GDP Regulations & Guidance and How They Apply to CTMs, Qualification VS Validation, Fundamentals of Quality Agreements, SOP’s & Building Relations with All Supply Chain Stakeholders and How To Apply It In Your Day to Day Operations

**Part 1:**
Supply Chain Quality Management Systems (GDP QMS)

Learning Objectives- Upon completion of this course you will be able to:
1. Define the framework for the supply chain management system
2. Incorporate agency observations into metric review process with current data from regulatory agencies such as FDA and EMA
3. Describe the current USP GC guidance covering the drug supply chain
4. Document network strategies and create a gap assessment to list risk management opportunities on your supply chain management system

**10:00 am**
**Mid-Morning Networking Break & Refreshments**

**10:30 am**
**Part 2:**
Part 1 Continued

**Part 2:**
GDP Essentials: An introduction to GDP Regulations & Guidance and How They Apply to CTMs, Qualification VS Validation, Regulatory Fundamentals of Quality Agreements, SOP’s & Building Relations with All Supply Chain Stakeholders

**Part 2:**
Developing a Supply Chain Strategy

**12:00 pm**
**Working Lunch**

**Part 3 (12:30 PM - 1:30 PM):**
Lunch Discussion: Current Regulatory Guidance

**Part 4 (1:30 PM - 3:00 PM):**
Supply Chain Temperature Issues

**3:00 pm**
**Afternoon Networking Break & Refreshments**

**3:30 pm**
**Part 2:**
Part 2 Continued

**Part 5:**
World Wide Regulatory Review of Supply Chain Requirements

**5:00 PM**
**End of Master Classes**
**Workshops**

**Tuesday, March 1st, 2016**

**Registration for Workshops A & B with Morning Coffee and Light Breakfast**

**Seven East**

**WORKSHOP A:**

**Packaging Design Essentials 101**

Join us to review packaging fundamentals & gain a better understanding of related industry best practices and packaging technologies.

**What you will Learn:**

- Identify the differences between types of packaging materials and systems
- Review packaging materials and systems - Performance, applications and costs
- Implement a risk based approach - Identifying a risk assessment tool that can guide your organization through the level of control to build into the system
- Gain a better understanding of how product stability affects package design
- Review Quality Agreements and SOP fundamentals
- Find the right partner and build stronger relations with all supply chain stakeholders

**Jeff Sullivan**, VP, Engineering & Customer Solutions, **American Aerogel**

**Jim Bacon**, VP, Partner Client Solutions, **American Aerogel**

**Seven West**

**WORKSHOP B:**

**Drug Product Stability Budget**

Join us to learn about the concept of Stability Budget and gain better understanding of its implementation for handling, storage and distribution of temperature controlled (bio)pharmaceuticals.

**What you will Learn:**

- How long can a pharmaceutical product be exposed to temperatures outside the recommended storage conditions
- How can product discard be prevented in cases of temperature excursions
- How to establish and manage the allowed time out of storage of a (bio)pharmaceutical product
- The science behind the establishment of a stability budget for products that need to be maintained under controlled temperature conditions
- How may stability budget be implemented for good distribution practices (GDP)

**Rafik H. Bishara, Ph.D.**, Technical Advisor, & former Director, Quality Knowledge Management & Technical Support, **Eli Lilly and Company**

**Seven Central**

**Registration for Workshop D with Mid-Morning Refreshments**

**Seven East**

**WORKSHOP D:**

**Pushing What is Possible in Temperature Controlled Transportation**

The world of Temperature Controlled Transportation is constantly changing: new regulations, innovative technologies and stronger business constraints constantly challenge healthcare shippers to revisit and improve their long established cold chain practices and invent more effective solutions to transport their temperature sensitive goods. This workshop focuses on some of the most promising ideas and solutions from the perspective of UPS Cold Chain Experts.

**What you will Learn:**

- How to build and maintain a Quality Management System compliant with the latest GDP regulations
- How to improve the quality of executions and minimize excursions
- How to successfully adapt your cold chain processes to new demands (CRT / Cryogenic), New Markets (Brazil / Saudi Arabia), New Modes (Ocean Freight)
- How to leverage synergies between packaging and transportation
- Our most recent thoughts about the future of Transportation and Cold Chain

**Tim Fosnough**, Global Director, Freight Forwarding - Healthcare, **UPS**

**Wanis Kabbaj**, Director, Global Strategy, Healthcare Logistics, **UPS**

**Seven Central**
Workshops

Tuesday, March 1st, 2016

Please choose Intermediary or Advanced Workshops

INTERMEDIARY WORKSHOPS

Registration for Workshop E

**WORKSHOP E:**

**Developing your Temperature Sensitive Logistics Strategy - Supply Chain Mapping & Transport Qualification**

The number of new complications and eroding obstacles to the many facets of the supply chain will continue to grow along with the industry. Combating these challenges and formulating cost efficient and practical solutions will continue to be a top priority. Today’s complex global supply chain requires firm understanding of logistical planning and global regulatory requirements.

What you will Learn:

- Discuss roles and responsibilities
- Determine the strengths and weaknesses of transportation routes and shipping lanes
- Analyzing of your temperature controlled products and their requirements
- Strategy for Single & Multicriteria Shipping
- Explore your questions about Transport Performance Qualification (PQ) and how it works
- Risk Management in the supply chain through Critical Control Point analysis, mitigation and contingency planning
- Track and analyze the right supply chain data
- Logistics considerations for high value products

Please refer to our mobile app for speaker details

ADVANCED WORKSHOPS

Registration for Workshop G with Afternoon Refreshments

**WORKSHOP G:**

**The Partnering Strategy - The Core Team Approach Revisited**

In this workshop we’ll discuss the barriers that create indecision in your internal Cold Chain Strategy & review a proven best practice to create collaboration within & external to your organization. Balancing your requirements and the capabilities of the supplier or service provider with the increasing regulatory requirements requires focus, alignment and engagement. We’ll have an interactive discussion of your successes and challenges to help you develop a custom strategy that encourages transparency and generates an innovative environment of continuous improvement.

What you will learn:

- Develop collaborative relationships, both internal and external
- Identifying the Trust / Competency factors of Partner Providers
- Taking a lead role in the decision process by having a well-defined set of criteria
- Building the Core Team – using the team to create flexibility, discipline, and balance
- Ownership and accountability during development, testing / approval, and execution
- Key drivers that define success

**Jim Bacon**, Former Senior Director, Demand Planning & International Customer Operations - U.S. Office, Grifols, Inc.
Main Conference

Wednesday, March 2nd, 2016

8:00am  Coffee and Networking in Exhibition Hall
8:45am  Welcome Remarks by IQPC
8:50am  Opening Remarks by Chairman
9:00am  KEYNOTE: Health Canada’s Strategy for the Pharma Supply Chain
Anthony Lostracco, Compliance Specialist, Health Canada

9:45am  KEYNOTE: European GMP/GDP Updates & Experiences and Trends from the Real World
Ian Holloway, Senior GMP Inspector, MHRA

10:30am Morning Networking Break in Exhibit Hall

Join your peers to browse the 2016 Solution Hall where you’ll be able to find all the latest packaging/container, transportation, logistics, temperature monitoring, security and data management solutions. The ideal place to meet existing and new partners.

11:15am Ensure Compliance with Guide-0069 Throughout a Complex Distribution Model and a Wide Range of Products
Rania Al-Ammar, Regional Director, Commercial Quality, Hospira, a Pfizer company

12:00pm Ambient/CRT Supply Chain Challenges - Transportation Vs. Packaging Validation Strategy for the Canadian Market
Irina Burcescu, Director, Regulatory & Supply Chain, Shoppers Drug Mart - Specialty Health Network
Claude Jolicoeur, Director of Regulatory Affairs, Corporate GMP Officer, McKesson Canada Corp.

12:50pm Networking Strolling Lunch
Stay tuned for Roger’s presentation on end-to-end Cold Cargo & Fleet Management Solutions directly preceding the Luncheon.

Main Conference

DAY 1

TRACK A  Regency Salon ABC

1:50pm Serialization and Traceability Best Practices
Lisa R. Ray, Distribution CoE and Process Ownership, Eli Lilly and Company
Austin Walker, Quality Assurance Director, Eli Lilly and Company

2:30pm Session Transition

2:35pm Creating a Strategy for Shipping Qualification, Control and Monitoring for Global Distribution of Temperature Controlled Products
Mandy Vanderslot, Project Leader, Supply Chain Realization, APOTEX

3:15pm Afternoon Networking Break

4:00pm Case Study Follow Up, One Year In - Effectively Benefitting from Ocean Freight
Natasha Harper, APFF, CCS, CTCS, Transport and Customs Specialist, Sandoz Canada Inc.

4:40pm Session Transition

4:45pm USP General Chapter: Good Distribution Practices
Mary Foster, Chair, Packaging and Storage Expert Committee, United States Pharmacopeia

5:30pm End of Conference Day 1

5:30pm - 8:00pm 14th Annual Networking Drinks Reception in Exhibition Hall
Join your peers to browse the 2016 Exhibit Hall where you’ll be able to find all the latest packaging/container, transportation, logistics, temperature monitoring and data management solutions.

Join our LinkedIn Group #ColdChainCanada www.coldchainpharm.com
# Main Conference

**Thursday, March 3rd, 2016**

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<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker Details</th>
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<tbody>
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<td>8:00am</td>
<td>Coffee and Networking in Exhibition Hall</td>
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<tr>
<td>8:50am</td>
<td>Opening Remarks by Chairman</td>
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<tr>
<td>9:00am</td>
<td>Increasing Productivity and Overcoming Infrastructure Challenges Through Third Party Relationship Management</td>
<td><strong>Luiz Alberto Barberini</strong>, External Manufacturing Organization Latin America, <strong>Bayer Consumer Care</strong></td>
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<tr>
<td>9:45am</td>
<td>Developing and Successfully Implementing Effective Thermal Packaging Solutions</td>
<td><strong>Paul Derksen</strong>, Sr. Project Manager, <strong>Canadian Blood Service</strong></td>
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<td><strong>Kai Goellner</strong>, Product Development Engineer, <strong>Pelican BioThermal</strong></td>
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<tr>
<td>10:30am</td>
<td>Morning Networking Demo Drives &amp; Networking Break In The Exhibit Hall</td>
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| 11:15am-12:05pm | Interactive In-Depth Discussion Lounges                                                    | **COLD CHAIN MANAGEMENT**<br>Minimizing the Impact of Harsh Winters While Keeping Costs Under Control<br>Please refer to addendum for updated information on this session<br>**Shamilla Gounder**, Manager, Quality & Compliance, **Sunovion Pharmaceuticals**<br>**PACKAGING**<br>Benefiting from Experience & Lessons Learned - Pack-out Qualification Study<br>**Irina Burcescu**, Director, Regulatory & Supply Chain, **Shoppers Drug Mart - Specialty Health Network**<br>**RISK MANAGEMENT**<br>A Risk Assessment Approach Based on Lanes and Products - What is the Best Solution for a Given Product?<br>Please refer to addendum for updated information on this session<br>**Eric Hiser**, Vice President of Technical, **International Safe Transit Association (ISTA)**<br>**GDP STANDARDS**<br>ISTA Processes & Standards for Pharma GDP<br>**Eric Hiser**, Vice President of Technical, **International Safe Transit Association (ISTA)**
| 12:05pm-12:55pm |                                                                                             | **QUALITY PRINCIPALS**<br>Stability Budget and the GDP - Creating and Using a “Stability Budget” for Your Handling, Storage and Shipping Processes<br>**Rafik H. Bishara**, Ph.D., Technical Advisor, and former Director, Quality Knowledge Management and Technical Support, **Eli Lilly and Company**<br>**SERIALIZATION & TRACEABILITY**<br>Building Upon the GS1 Standards for Serialization; An Update of the State of the Industry and How to Pave the Way for Your Company’s Global Compliance Efforts<br>Please refer to addendum for updated information on this session<br>**EU GDP REQUIREMENTS**<br>Results of GDP Inspections Based on the New EU GDP Guidelines<br>**Ian Holloway**, Senior GMP Inspector, **MHRA**
| 12:55pm  | Networking Lunch                                                                            |                                                                                 |
| 2:00pm   | Networking Break In the Exhibit Hall & Passport Card Prize Drawing                           |                                                                                 |
| 2:45pm   | A Pharmacist’s Perspective on Vaccine Cold Chain & Logistics                                | **Dr. Tarek Kilani**, Head of Pharmacy & Continuing Medical Education Coordinator, **EMIRATES FRENCH HOSPITAL** |
| 3:05pm   | CEIV Pharma: Raising the Standard of Pharmaceutical Logistics                               | **Ronald Schaefer**, Project Lead, **CEIV Pharma**, **IATA**                       |
| 3:50pm   |                                                                                            |                                                                                 |
| 4:35pm   | Close of Conference                                                                        |                                                                                 |

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