

Canada's #1 event covering  
all temperature ranges &  
life science products...

13th Annual Cold Chain



# GDP & TEMPERATURE MANAGEMENT LOGISTICS Summit - CANADA



Temperature Control Logistics,  
Quality & Security Practices  
for your Commercial and  
Clinical Supply Chains

February 23-26, 2015

Hilton Montreal  
Bonaventure

Montreal,  
Quebec

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# Welcome to your Industry's #1 Canadian event...

Tailor made to be more inspiring, practical and innovative than ever before.



Dear Life Science Professionals,

We are excited to bring back the **13th Cold Chain GDP & Temperature Management Logistics Summit - Canada**, February 23-26, 2015 to Montreal!

Temperature control and sensitive handling are fundamental requirements of most life sciences products today. The Canadian Summit will examine the modern cold chain – including all temperature range products and their regulatory requirements – as well as an expanded focus on Supply Chain Integrity.

As supply chain complexities continue to increase, the Canadian market is facing costly challenges resulting from **evolving regulations, changing requirements and challenging regional weather conditions**.

To address key regional and global market concerns, the Canada Summit will be taking a closer look at:

- Maintaining regulatory compliance: domestic & international regulatory **GDP updates**
- **Biotech and small pharma temperature** controlled supply chain challenges
- **Lane validation & temperature mapping** - Standardization of "risked based controls"
- Cost effective and quality based strategy for commercial **clinical supply chain**
- Reinforcing your cold chain's **risk management** process
- Cost effective **CRT & ambient** temperature monitoring and control
- **Green and reusable packaging** as a cost effective option
- **Temperature-Sensitive Packaging Essentials:** An Introduction to Thermodynamics, Packaging
- Systems & Temperature Monitoring Device Technologies and Applications
- **GDP Essentials:** An introduction to GDP Regulation & Guidance, Transport Qualification,
- **Air Cargo Processes**, Fundamentals of SOP's and Quality Agreements
- Important considerations for **product serialization**
- Reducing/eliminating **import delays**

*Don't miss the chance to network at the largest Canadian event addressing quality distribution & management of temperature controlled medicines in Canada. The industry's top choice for best practice discussions and to see some familiar faces!*

Join us and take full advantage of NEW 2015 Networking opportunities:

- **Even bigger exhibit hall!** Take full advantage of increased 'browsing' time and activities in the exhibit hall. See first-hand the latest innovative solutions available in Canada for distribution of temperature control life science products
- **New 4 day conference format:** Our new format allows industry attendees to experience the **full 4 days** of activities packed with valuable information, learning and networking opportunities
- **Biotech Focus:** Learn from leading organizations and their lessons learned in establishing a **compliant** supply chain for small pharma and biotech organizations

On behalf of the IQPC event team and conference advisory board, we look forward to seeing *you* Montreal!

Sincerely,



Claudia Rubino  
Divisional Director



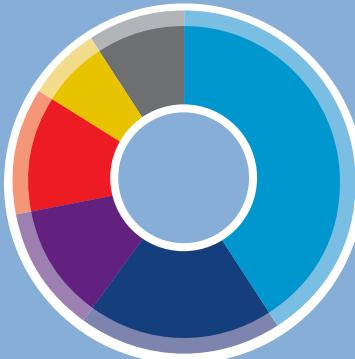
Join us on social media!



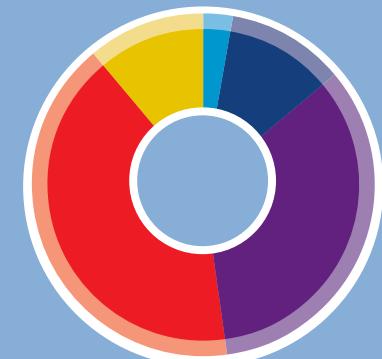
@ColdChainCanada #13CCCAN

## GET TO KNOW THE AUDIENCE

### Attendee Industry Breakdown



### Attendee Seniority



### Attendee Geographical Breakdown



### Table of Contents

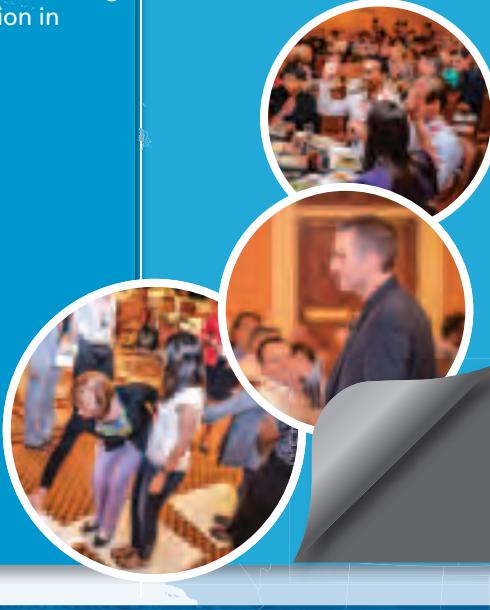
Week Snapshot & Industry Trends.....	3
Speakers & Advisory Board.....	4
Pre-Conference Training Masterclasses .....	5
Pre-Conference Workshop .....	7
Benefits of Attending as a Team .....	9
Main Conference Day One .....	10
Main Conference Day Two .....	13
Sponsors & Exhibitors.....	16
Pricing & Registration .....	19



# YOUR WEEK'S SNAPSHOT

## FEBRUARY 2015

23	Monday	24	Tuesday	25	Wednesday	26	Thursday
<b>2 Pre-Conference Master Classes</b> 1. Temperature-Sensitive Packaging Essentials: An Introduction to Thermodynamics, Packaging Systems & Temperature Monitoring Device Technologies and Applications 2. GDP Essentials: An introduction to GDP Regulation & Guidance, Transport Qualification, Air Cargo Processes, Fundamentals of SOP's and Quality Agreements	<b>Site Tour - ATS Facilities</b> <b>6 Workshops</b> A. CEIV Pharma: Raising the Standard of Pharmaceutical Logistics B. Creating Value through Designing and Implementing a Shipping Lane Qualification for High-Value Pharmaceutical Products C. Quality Assurance Systems and Statistical Process Controls for Good Distribution Practices (GDP) D. Quality Assurance Systems and Statistical Process Controls for Good Distribution Practices (GDP) E. The Implications of Non-Temperature Hazards in the Design and Distribution of Temperature Controlled Packaging F. Collaboration in the Cold Chain – The Core Team Approach	<b>Main Conference &amp; Exhibit Hall</b> 13th Annual Networking Drinks Reception in Exhibit Hall	<b>Main Conference &amp; Exhibit Hall</b>				



## 2015 TOPIC HIGHLIGHTS Addressing your Business Critical Challenges

- Regulatory developments:** Domestic & International GDP updates
- Roles and responsibilities of all parties in manufacturing, packaging, testing, holding, and/or distributing product to the marketplace:** SOP's and Quality (Service) Agreements
- Supplier risk and reliability:** Establishing an internal and pharma supplier audit program
- Growing Biotech industry in Canada:** Establishing supply chain operations for biotechs and small pharma
- Traceability and visibility:** Air-freight real-time monitoring
- Small shipments:** Cost effective solutions for LTL Room Temperature Shipments

- Pre-Qualified Packout compliance:** The gap between qualified & pre-qualified packouts performance qualification protocol
- Cost control:** Containing increased costs associated to CRT & ambient temperature products and increased monitoring requirements
- Organizational requirements:** Impact on cold chain packaging design, performance, and cost
- Clinical supply chains:** Developing cost effective and quality supply chains
- Canada - an import nation:** Reducing/eliminating import delays

## 2015 SUMMIT HIGHLIGHTS:



- Network and Share Best Practices with **300+** Industry Colleagues and Supply Chain Stakeholders
- Meet **35+** Exhibitors Offering the Latest Solutions Available in Canada for Distribution of Quality Control Life Science Products
- Learn from **40+** industry thought leaders

## TOP INDUSTRY TRENDS ADDRESSED IN 2015 CONTENT

- Shift Towards Supply Chain Integrity
- Alternate Modes Of Transportation – Ocean Freight
- Increased Visibility And Understanding Of The "Last Mile"
- Increase In International Operations & Shipments
- Increased Data Management Focus
- Pressure To Prove ROI
- Continuous Improvement – Supply Chain & Process Optimization
- Green/Reusable Packaging

## BACK TO MONTREAL!



### Why Montreal?

- Quebec represents Canada's leading biotech cluster
- Access to new supply chain stakeholders in world-class companies operating in pharmaceuticals, health technologies, biotechnology and contract manufacturing/research
- Easy access to global markets: 2 international airports and one of the world's busiest ports, connected by 2 national railways to Toronto, Detroit, New York and Chicago with daily services



# It's The People Who Make This Event Possible.

Your Speakers, Advisory Board Members, Topic Champions & Event Team



**SPECIAL THANKS TO OUR  
DEDICATED ADVISORY BOARD**

## 2015 Speaker Faculty: Keynotes, Industry Experts & Your Peers

Sarah Skuce  
Compliance Specialist  
**Health Canada**

Sarvang Mishra  
Associate Director- Global Operations  
**Biogen Idec**

Wilf Meschwitz  
Senior Supply Chain Specialist  
**BioVectra Inc.**

Lisa Barbieri Moher  
Head of Distribution Packaging  
**Sanofi**

Rob Mancuso  
Associate Director, AGO-QA-Quality  
Systems & Compliance  
**Apotex Inc.**

Ronald Schaefer  
Manager, Cargo Business Process and  
Standards  
**International Air Transport  
Association (IATA)**

Jim Bacon  
Senior Director, Grifols Demand  
Planning & International Customer  
Operations - US Office  
**Grifols, Inc.**

Mary Foster  
Chair, Packaging and Storage  
Expert Committee  
**United States Pharmacopeia**

Eric A. Newman  
Vice President, Loss Prevention  
**Falvey Cargo Underwriting**

Claude Jolicoeur  
Director Regulatory Affairs, Corporate  
GMP officer, Legal Services,  
Compliance and GMP  
**McKesson Canada**

Kevin O'Donnell  
Senior Partner  
**Exelsius Cold Chain Management**

Moataz Mostafa  
Procurement & Supply Chain Division  
Manager  
**EBN Sina Medical**

Tony Wright  
CEO  
**Exelsius Cold Chain Management**

Sean D. Benedik, B.Sc.  
Spécialiste en validation et conformité /  
Validation and Compliance Specialist  
**Aliquo Pharma Inc.**

Melissa Iddison  
Quality Assurance Coordinator  
**World Courier of Canada Ltd.**

Marilda Bezerra  
Quality Manager for GDP  
**Bayer**

Natasha Harper  
Transport and Customs Specialist  
**Sandoz Canada Inc.**

Shirley Feld  
End to End Supply Chain Deputy Director  
**Sanofi-Aventis**

Ed Downey  
Senior Director - Risk Management  
**Cubist Pharmaceuticals**

Jim Bacon  
Senior Director, Global Demand Planning and  
Customer Operations  
**Grifols**

Rafik H. Bishara, PhD  
Technical Advisor and Chair PCCIG  
USA Branch  
**PDA**

Veronique Dameme  
Vice President, Pharma/Healthcare  
**Kuehne + Nagel, Inc.**

Eric Malouin, Eng., B.Sc, CCS  
Manager, International Customs & Traffic  
**Abbott Canada**

Rich Ellinger  
CEO  
**Intelligent Thermal Solutions**

Claude Jolicoeur  
Director, Regulatory Affairs,  
Corporate GMP Officer  
**McKesson Canada**

Paul Saratsiotis  
Business Development Manager  
**World Courier Canada**

Mary Foster  
Chair, Packaging and Storage Expert Committee  
**United States Pharmacopeia**

## MEET THE EVENT TEAM

Claudia Rubino  
Content Curator & Divisional  
Director, Cold Chain Portfolio  
**IQPC**

Cassandra Fernandez  
Operations Manager  
**IQPC**

Hae Rim Lee  
Sponsorship Manager  
**IQPC**

Stephanie Gonzalez  
Jr. Divisional Marketing Director –  
Cold Chain Portfolio  
**IQPC**

Simon Copcutt  
Sponsorship Director  
**IQPC**

Michael Ringo  
Registration Manager  
**IQPC**

Kathleen McKay  
Operations Director  
**IQPC**

Teneyke Smith  
Sponsorship Director  
**IQPC**

Shawn Siegel  
Online Content Director  
**IQPC**

Todd Smith  
Sponsorship Director  
**IQPC**

Colby Shine  
Sponsorship Marketing Manager  
**IQPC**

**POWERED BY** **ColdChainIQ**  
Temperature Control Logistics  
& Quality Network

Website: [www.coldchainiq.com](http://www.coldchainiq.com)

An international resource center for the temperature control life science professional, Cold Chain IQ delivers insightful, unbiased information about today's 'hot topics'. Our 13,000+ members benefit by reading expert analysis, trend-setting articles, listening to interviews, watching video features and top-rated presentations from IQPC's global temperature control supply chain event series.

Cold Chain IQ focuses on all areas of temperature controlled logistics, distribution and quality in pharmaceuticals and biotechnology. Cold Chain IQ, part of IQPC, maintains the largest cool chain pharmaceutical international database, offering strategic partners, members and contributors an unparalleled opportunity to network, share ideas and disseminate best practice information across the globe with peers.

To receive our newsletter and download our latest whitepapers articles and interviews please visit [www.ColdChainIQ.com](http://www.ColdChainIQ.com).



# Pre-Conference Training Master Classes

Monday, February 23rd, 2015  
9:00am – 5:00pm

Get a head start on your learning experience by signing up for one of these full day master classes. Master classes provide skill development and best practice sharing in a casual interactive group setting. Both master classes have been carefully developed to provide an in-depth review of all you need to know regarding temperature-sensitive packaging as well as GDP essentials.

8:15am **Registration**

9:00am

## TRAINING A

### Temperature-Sensitive Packaging Essentials: An Introduction to Thermodynamics, Packaging Systems & Temperature Monitoring Device Technologies and Applications

#### INTERACTIVE EXERCISE

##### An Introduction to Thermodynamics

Understand the methods and implications of heat transfer and how it is exploited in the design of insulated packaging systems

- Defining heat
- Heat vs. temperature. No, they are not the same thing!
- Types of heat transfer
- The critical importance of phase changes: solid, liquid, gas, and plasma
- How frozen is frozen?
  - How long does it take to freeze a gel pack?
  - Economics of freezing gel packs?
- Important principles of heat transfer in insulated packaging systems

##### Active, Passive and Hybrid Insulated Packaging Systems

Identifying the differences between types of packaging materials, systems, their costs, performance and applications

- Defining insulation materials
- Active systems and technologies explained and applied
- Passive packaging technology explained and applied
- What are hybrid systems?
- Why package qualification is necessary and important
- My package is qualified but fails in the field. Why?
- Air temperature vs. Product temperature: how to maintain compliance

#### INTERACTIVE EXERCISE

##### Refrigerants

Understanding how specific temperature ranges are maintained using temperature stabilizers

- Types of refrigerants and their applications
- What are PCM's and how do they work?
- Everything you need to know about Dry Ice but were afraid to ask
- How product stability affects package design

## TRAINING B

### GDP Essentials: An introduction to GDP Regulation & Guidance, Transport Qualification, Air Cargo Processes, Fundamentals of SOP's and Quality Agreements

#### GDP and the regulatory environment

An examination of current GDP regulations and their application

- Organizations, regulations and impact
- Examining the key areas of compliance
- New EU GDP regulations
- Revised USP1079
- What regulators focus upon in GDP compliance in the transportation environment

#### Supply Chain Mapping & Transport Qualification

Team Exercise Map a typical logistics supply chain and examine the benefits of Transport Qualification

- What's my responsibility?
- How Transport Performance Qualification (PQ) works
- Analyzing the right supply chain data
- Risk Management in the supply chain through Critical Control Point analysis, mitigation and contingency planning

#### CASE STUDY - REAL PRODUCTS FOR REAL PATIENTS

##### The Essentials of Good Temperature Management & Storage

Identifying the key aspects of good temperature management

- What is 'temperature sensitive'?
- The 6 'P's' of Good Temperature management
- Storage & Handling temperature Vs. Product temperature
- Common temperature ranges
- Temperature deviations and their impact
- Fundamentals of 'packaging types'

#### Meeting temperature-sensitive requirements in air cargo

- Air cargo in practice – user video
- What information do airlines need from shippers?
- Correct use of the IATA Time & Temperature label
- Checklists used by airlines and handlers
- Managing and auditing carriers

**SPACE IS LIMITED**  
and they always sell out – **Register early** to secure your spot



9:00am

## TRAINING A

## INTERACTIVE EXERCISE

## Temperature Monitoring Device Technology

Exploring the benefits and drawbacks of various technologies, comparing costs and applications

- Chemical indicators & integrators
- Electronic Indicators
- Electronic Data Logging Monitors (EDLM's)
- Electronic Integrators
- The boon in data management
  - How it improves quality and lowers cost

## Putting it All Together

An interactive exercise evaluating actual shipments of active, passive and hybrid systems

- Disassembling shipments of each packaging type
- Downloading, evaluating and interpreting the temperature monitoring devices

Trainer: Kevin O'Donnell is Senior Partner at Exelsius Cold Chain Management

[Read complete Master Class leader bio here](#)



## TRAINING B

## The role of Quality Management Systems, Quality Service Agreements and SOP's in cGDP

Building Quality Agreements and SOP's to ensure correct handling practices within your organization and your suppliers

- Roles & Responsibilities within a Quality (service) Agreement
- EU Guidance on supplier management
- Developing key performance indicators (KPI's)
- Improving performance of your suppliers

An interactive Team Exercise - Creating SOP's – how do I write them? What should I include? How can I make it work?

## INTERACTIVE EXERCISE

## CAPA – A case study looking at what went wrong and how to avoid repetition of temperature excursions



Trainer: Tony Wright, CEO of Exelsius Cold Chain Management

[Read complete Master Class leader bio here](#)

*"Presentations from regulatory authorities were informative & very helpful."*  
- Amerisource Bergen Specialty Canada

*"Very good speakers and subject matter and was filled with information rather than basic concepts"*

- Bilcare Inc.



# Pre-Conference Workshops

Tuesday, February 24th 2015



8:00am

## Registration Workshop A

8:30am -  
10:30am

### WORKSHOP A: A Look at Public & Private Partnerships

For years IATA has been collaborating with supply chain stakeholders to understand and define industry-wide standard requirements for temperature sensitive pharmaceutical products via air. Transporting healthcare products by air needs the establishment of complex logistical methods to maintain shipment's integrity. It requires specific equipment, storage facilities, harmonized handling procedures and, above all, strong cooperation among the cold chain partners. IATA's newly created CEIV Pharma program aims at addressing these challenges experienced by airlines, ground handlers and airports, pharmaceutical companies and freight forwarders. The program is a concerted effort to improve the level of competency, operational and technical preparedness. It focuses on assessing and validating knowledge, facilities, and processes, as well as training stakeholders and recognizing compliance.

- What are the risks and the potential gaps along the cold chain
- How IATA's standards can improve the handling of pharmaceutical cargo
- Practical solutions IATA proposed to the industry by means of certification

- How they will improve the handling of pharmaceuticals in the air cargo environment in compliance with the regulations
- Understand the benefits for organizations that would volunteer for such validations.
- Provide your input and constructive feedback on the solution that IATA is proposing and implementing
- How to be recognized in the pharmaceutical environment of being a key player in the industry
- Experience the process of a simplified audit solution against clear standard criteria developed by the industry
- Understand the establishment of a complete cool chain logistical process to maintain shipment integrity



Ronald Schaefer

Project Lead, Center Of Excellence for Independent Validators  
**International Air Transport Association (IATA)**

10:45am

## Registration Workshop B or C: Lunch will be served during this workshop

11:00pm -  
1:00pm

### WORKSHOP B: Creating Value through Designing and Implementing a Shipping Lane Qualification for High-Value Pharmaceutical Products

Qualifying shipping lanes for high value products scheduled to travel the same routes multiple times has significant benefits and is a common industry practice. Manufacturers often opt to design packaging for specific products traveling in specific lanes. The benefits from this practice typically results in reduced excursion rate for the shipments, reduced loss of product, fewer delays, and more predictable delivery.

#### What you will learn:

- Analyzing of your temperature controlled products and their requirements
- Considering off-the-shelf packaging solutions for products with little stability data
- Offset investment requirements for a shipping lane qualification through high volume and frequency of commercial products shipments
- Considering lane qualification for low volume of shipments – Depending on the drugs development stage, lost shipment can be detrimental to the launch of a new product
- Best practices and tools to help organizations realize improvements with easy implementation processes
- Security risk assessment process and risk mitigation
- Security enhancements
- High volume and frequency of commercial products
- Case study: Compare passive versus active container qualification
- Designing your packaging for specific products traveling in specific lanes
- Design Qualification – Scope document & user requirements

### WORKSHOP C: Quality Assurance Systems and Statistical Process Controls for Good Distribution Practices (GDP)

In the past few years, GDP guidelines from a variety of authorities have been published. From the World Health Organization Annex 5, the European Union 2013/C 68/01, the USP <1083> and <1079> to the Health Canada GUIDE-0001, these guidelines have many common elements with respect to Quality Assurance Systems. Despite these guidelines, the design of organizational structures, quality policies, and compliance strategies are left entirely up to the stakeholders. This workshop will focus on commonalities in the guidelines and will serve as a participant's roadmap toward compliance. The workshop will also highlight key differences between the guidelines. The participants will come away from the workshop with an in-depth understanding of Quality Systems, Key Performance Indicators (KPI) and Statistical Process Controls for Good Distribution Practices that will satisfy their clients' expectations and withstand the scrutiny of regulatory agencies worldwide.

#### What you will learn:

- QUALITY MANAGEMENT: Using a risk-based approach
- PERSONNEL: The responsible person, training
- PREMISES and EQUIPMENT: Qualification and validation
- DOCUMENTATION: Valid and approved procedures & records
- OPERATIONS: Receiving, storage, destruction, picking, shipping
- GUIDELINES FOR HANDLING COMPLAINTS, RETURNS,
- SUSPECTED COUNTERFEIT, RECALLS
- OUTSOURCED ACTIVITIES: Managing subcontractors
- TRANSPORTATION: Containers, special conditions



- Operational Qualification – Chamber and distribution testing
- Performance Qualification – Size, maximum/minimum load, winter/summer
- Choosing a test profile that is appropriate for your shipping channels as part of the overall qualification process



Alan J. Davis  
Chief Operating Officer  
**K.L. Herring Transportation LLC**

- KEY PERFORMANCE INDICATORS: Tools for measuring quality using statistical process controls

Sean D. Benedik, B.Sc.

Spécialiste en validation et conformité / Validation and Compliance Specialist

**Aliquo Pharma Inc.**

1:15 pm

## Registration Workshop D or E

1:30pm  
4:00pm

### WORKSHOP D: Establishing a Best Practice Approach for Risk Assessment & Management for your Temperature Controlled Supply Chain and Products

Through appropriate management of the risks involved in temperature control distribution, organizations are now able to make risk-based decisions. This approach can have a direct impact on the quality, safety and efficacy of products as well as reduce risk and provide better insight to the distribution process.

Join us to gain a best practice approach to risk assessment and management.

#### What you will learn:

- Maintain product quality, safety and efficacy by preventing product adulteration, counterfeiting, theft, and diversion
- Identifying risk sources for your supply chain and products
- Identifying the critical stages in temperature controlled distribution management
- Risk management for Temperature Controlled Distribution - Technical Report 58
- Adapting a best practice approach to mitigate the lack of industry standards to execute a risk assessment for temperature controlled distribution
- Control risks in temperature controlled distribution for shipper, LSP, carrier and customer
- Risk Control
- Understanding residual risk
- Improving the effectiveness of your current processes



### WORKSHOP E: Shipping Container Qualification Process

This workshop will explore best practices for qualifying a shipping container. Processes for both thermal qualification as well as distribution qualification will be examined with an emphasis on specifying and conducting the testing. Industry standards will be explored and the associated reporting documentation. Finally cases studies will be used to show the entire process from start to finish.

#### What you will learn:

- What shipping container features need to be tested during qualification.
- How to design a qualification process to meet industry standards.
- What the pitfalls are putting together a proper study plan.
- How laboratory results compare to actual shipments.

#### How you will benefit:

- Proper shipping container qualification can save money and time, both in the lab and the field.
- Conducting this process directly will directly improve product safety and customer satisfaction.
- Gain a broader knowledge of package testing methods.
- Learn from examples of successful qualification studies.



Anthony Alleva  
Technical Director  
**Cryopak, a TCP Reliable Company**

4:15pm

## Registration Workshop F

4:30pm  
6:30pm

### WORKSHOP F: Collaboration in the Cold Chain – The Core Team Approach

In this workshop we'll discuss the barriers that create indecision in your Cold Chain Strategy and review a proven best practice to create coordination and consensus in your program. Balancing your requirements and the capabilities of the supplier or service provider with the increasing regulatory requirements requires focus, alignment and engagement. We'll use success factors to develop a custom strategy that encourages innovation and generates an environment of continuous improvement.

#### What you will learn:

- Develop collaborative relationships, both internal and external
- Determine capability by understanding the compliance, quality, and business aspects of a partner relationship
- Take a lead role in the decision process by incorporating this into contractual agreements

- 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

#### How you will benefit:

- Become a Client of Choice – drive the success that you define
- How to assess risk and indifference in potential solutions and relationships
- Using the Core Team to jointly develop and create solutions
- Develop meaningful KPI's that drive innovation and continuous improvement



Jim Bacon  
Senior Director, Grifols Demand Planning & International Customer Operations - US Office  
**Grifols, Inc.**



# Site Tour: ATS Healthcare

Tuesday, February 24, 2015 • 9:00AM – 12:00PM



ATS Healthcare is the most dedicated and reputable provider in Canada's temperature controlled healthcare transportation industry. Healthcare and cosmetic manufacturers, wholesalers and their customers appreciate our reliable end-to-end solutions to their temperature management, security and other shipping requirements. Our standards are the highest, complying with Health Canada guidelines for the transportation of temperature sensitive products such as pharmaceuticals, cosmetics, medical devices and over-the-counter products. SNC Lavalin Pharma has recognized and can attest to our high standards through the qualification of our systems and procedures. In combination with 24/7 tracking, data capture and retention, our nationwide network of temperature managed facilities and the highest level of security, ATS provides shippers a clean, efficient and committed healthcare

## Facility Highlights

- State-of-the-art, 125,000 square foot temperature controlled warehouse is monitored and controlled 24 / 7 ensuring products are kept between 15-25° Celsius.
- Highly secure facility is TAPA (Transported Asset Protection Association) certified and compliant with Health Canada GUIDE-0069 and the Good Manufacturing Practices for Drugs and Health products.
- Fully integrated transportation HUB featuring wide-ranging fleet of vehicles and innovative conveyor system for energy efficient sorting capabilities.
- Trucks, trailers and temperature management equipment that is customized, qualified, calibrated and monitored.

## Case Study

- Customer details regarding the integration process between ATS Healthcare and its customers. Whether shipping to the distributor, wholesaler, retailer, pharmacy or hospital, ATS Healthcare provides the most efficient, convenient and cost effective solutions for the dedicated services our customers require.

## Process Review

- A growing area of ATS Healthcare's business is its **reverse logistics process**. This closed-loop logistics system provides an opportunity to ship highly sensitive products in reusable thermal packaging units designed to withstand even the harshest conditions. This system is managed through a highly proficient return process ensuring units have a fast turnaround for re-use once returned and refurbished. Witness this process at the on-site refurbishment centre.



## WHAT YOUR TICKET INCLUDES:

Roundtrip transportation picking up and dropping off at the Hilton Montreal Bonaventure

- An exclusive tour through the ATS Healthcare facilities
- A Q&A session with the ATS Healthcare executives
- Lunch and light refreshments

Price  
Per Person:  
**\$599\***

**BOOK YOUR TICKET TODAY BY EMAILING [ENQUIRY@IQPC.COM](mailto:ENQUIRY@IQPC.COM).**

\*Not included in any Cold Chain Canada packages



# For The Best ROI, Attend As A Team

- Split up and meet different topic champions during our meet-ups
- Collaborate and develop take-away action plans
- Spend 4 days bonding and sharing ideas
- Meet with the vendors in our expo hall – and “tag team” them with your questions
- Attend different track sessions, compare notes and maximize your learning experience
- Listen to sessions focused on team projects and leadership and get new ideas for your own teams
- Take advantage of the 2 master-classes and 6 workshops – attend the same one, or split up – you can't go wrong either way



## Technology Demo Drive

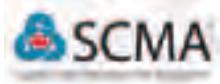
MAIN CONFERENCE DAY TWO: THURSDAY FEBRUARY 26TH AT 10:30AM

### Take the time to learn about the latest and most innovative technologies available to the industry.

These presentations will showcase participating sponsor products/services.

Each delegate will be given a map of the Exhibit booths running a live demo of their products for the first 15 minutes of the networking break. Select a booth and gather around to hear about the participating sponsor products/services. The demos that will run are staggered across two groups, the first group will have 7 minutes before handing over to the second group. Get the most out of the world's largest exhibition of solutions for temperature controlled life science products!

### Media Partners:



**60%**  
of Attendees  
joined with  
multiple team  
members in  
2014!



**Group  
discounts  
applicable to  
END USERS  
ONLY**  
(Life Science  
Manufacturer)





# Main Conference Day One

Wednesday February 25th, 2015



8:00	<b>Registration – Exhibit Hall</b>
8:40	<b>Welcome Remarks by IQPC</b>
8:45	<b>Opening Remarks by Chairman</b>  Rafik H. Bishara, PhD Technical Advisor & Leader, PCCIG PDA
9:00	<b>KEYNOTE: A Regulator's Perspective - Health Canada's Update on GUIDE-0069</b> <ul style="list-style-type: none"> <li>What's new and Health Canada's thoughts on potential future GDP alignment</li> <li>Lessons learned from implementation of 0069</li> <li>Recent inspections trends</li> <li>Concerns about the Supply Chain Security</li> <li>Last mile focus – processes allowing compliance with regulations</li> <li>Stability data and evidence to support excursion</li> <li>Industry tips to remaining compliant</li> </ul>  Sarah Skuce Compliance Specialist <b>Health Canada</b>
9:45	<b>USP MEGA CHAPTER - Update on Next Sub-Chapters Plus an Overview of Current FDA Input on the Pharma/Biotech Supply Chain</b> <ul style="list-style-type: none"> <li>Clinical Trial Materials - Learn about the subjects the USP Expert Panel are writing about right now as CTM specific</li> <li>Is there any concern with extractables &amp; leachable effects during the distribution process?</li> <li>Current agency objectionable observations on distribution</li> <li>Next steps for a global GDP document - Is this a realistic goal? No more 40+ documents to read and understand</li> </ul>  Mary Foster Chair, Packaging and Storage Expert Committee <b>United States Pharmacopeia</b>

10:30	<b>Morning Networking Break In The Exhibit Hall</b> Join your peers to browse the 2015 Solution Hall where you'll be able to find all the latest in technology, implementation, advisory and analytics solutions. The ideal place to meet existing and new partners.
11:15	<b>Convergence in the Supply Chain – Process and Information Sharing Put in Practice</b> <ul style="list-style-type: none"> <li>Open, none proprietary exchange and implementation of standards and processes</li> <li>New, robust and standardizes interfaces for all parties in the industry</li> <li>"Data driven" and near real-time knowledge of the supply chain</li> <li>The "Russian doll" effect</li> </ul>  Gabriel Andersson COO <b>Envirotainer</b>
12:00	<b>Risk Management Principles in Designing the Cost Effective Shipment Solutions for Packaging and Various Transportation Modes</b> <ul style="list-style-type: none"> <li>A strategic approach to analyzing all associated risk</li> <li>Key considerations and common pitfalls</li> <li>Utilizing the latest technology developments in packaging and monitoring</li> <li>Understanding the impact of various innovations to your risk factors</li> <li>Analyzing the cost implications of your decisions</li> <li>Benefits of a quality risk management system</li> </ul>  Marc Constant Director, GMP Compliance <b>Sanofi Pasteur</b>
12:45	<b>Networking Lunch</b>



1:50

## TRACK A: SUSTAINABLE PACKAGING

**PANEL DISCUSSION: Control Room Temperature - A Cost Effective Transportation Methodology**

Regulatory organizations have shown considerable focus on Control Room Temperature (CRT) products over the past year. A number of regulatory authorities have expressed the expectation that all members of the pharmaceutical supply chain comply with label claim temperature requirements. The discussion panel will present on cost effective methods for analyzing and implementing strategies to manage and document proper storage, handling, and distribution of products with a CRT label claim. The panel will debate a number of relevant topics including existing stability data, developing new stability data, collecting route temperature data, and developing appropriate strategies to cost effectively address this increased regulatory expectation and ensure product quality and patient safety.

**Mark Maurice**

Senior Project Manager / Sales Engineer

**Sensitech Temperature Sensitive Supply Chain Advisors****Michael Lopez**

Former Head of Quality Operations

**Merck/EMD**

## TRACK B: PERFORMANCE QUALIFICATION

**2 Part Case Study:****① Packaging systems Performance Qualification Case Study with Shoppers Drug Mart**

- Shoppers Drug Mart transportation process analysis
- Performance Qualification methodology
- Discussion on Performance Qualification results

**② Data Sharing – Complete Mapping of the Canadian Territory for Temperature Profiles for all Transportation Modes**

- Sharing 12 years of temperature data in transport in Canada
- Per transportation modes
- Origins and destinations
- Duration
- Temperature ranges
- Discussion on temperature profiles to be used when shipping products in Canada

**Jean Bédard**

MBA, President &amp; CEO

**Infitrak Inc.**

## TRACK A: SHIFTING FROM CLINICAL TO COMMERCIAL SUPPLY CHAINS

2:45

**Setting up your Temperature Controlled Supply Chain for Success – Moving from Clinical to Commercial in a Compliant and Cost Effective Manner**

- Product launch case studies to help analyze the transformation process
- Brining in the 3Cs:
  - Clarify
  - Control
  - Compliance
- Cost impact and considerations
- Establishing the right partnerships with clear expectations

**Dan Bell**

Vice President, Regulatory Compliance and Technical Affairs

**Marken****Paddy Hanlon**

Senior Director, Business Development

**Marken**

## TRACK B: CRT/AMBIENT OCEAN FRIEGHT AS A COST EFFECTIVE SOLUTIONS

**Making the Switch from Air to Ocean Freight Transportation Mode for your Ambient Products**

- Implementing a step by step process to analyze your products and current shipping modes to select the best products for ocean freight
- Impact on ambient shipping costs and key considerations
- Best practices in making the switch – what to consider and pitfalls to avoid
- Assessing your risks for a cost effective solution
- Mindset change – A big hurdle to overcome

**Natasha Harper, APFF, CCS, CTCS**

Transport and Customs Specialist

**Sandoz Canada Inc.**

3:25

**Afternoon Networking & Networking Break In The Exhibit Hall**

4:10

## TRACK A: AIR FREIGHT TRANSPORTATION

**CASE STUDY: You Do Not Have to Sacrifice Economics for Sustainable Packaging**

Life science manufacturers are facing growing internal and external pressures to reduce their environmental footprints and increase the use of sustainable and green packaging. Join us for a case study example highlighting the implementation of sustainable packaging at Sanofi and the positive impact it has had with its external partners and on the organization's bottom line.

- How to save \$2M+ while being green
- Tools and techniques on how you and your customers can be green
- Projected material cost savings, sustainability, reduction to landfill
- Educate your customer and know your packaging



**Lisa Barbieri Moher**  
Head of Distribution Packaging  
**Sanofi**

4:55

**Troubleshooting Tips & Best Practices for Validation/Mapping**

- Calibration Risk Assessment: Where to Start
- Sensor placement: where, how many, and for how long?
- Validation Master Plan checklist
- Develop a "risked based" common / best practice for validation/mapping
- A temperature mapping study should be designed to assess temperature uniformity and stability over time and across a three-dimensional space
- Key considerations and common pitfalls



**Sarvang Mishra**  
Associate Director- Global Operations  
**Biogen Idec**



## TRACK B: LAST MILE – PHARMACY PERSPECTIVE

**Gaining Competitive Advantage by Applying Data Analytics to Your Cold Chain**

- Examining data to identify optimization opportunities in cold chain transportation leading to:
  - Operational efficiency
  - Improved customer satisfaction
  - Optimized business models
- In depth portfolio analysis on your shipping processes enables:
  - Performance metrics assessing financial, marketing, regulatory, and environmental aspects
  - Gap identification and trends
  - Risk assessment for the cold chain transportation model
  - Cost Savings Analysis
  - Identifying approaches for optimization and problem solving
- Data analytics can assist in innovation and optimization for shipping vaccines and pharmaceuticals including selection of a profitable mode, profitable route, and labor planning



**Boriana Cavicchia**  
Program Analyst, Office of Research & Development  
US Department of Veterans Affairs

5:40

**End of Conference Day 1**

5:45

**Evening Cocktail Reception – Exhibit Hall**

Join us in the Exhibit Hall for our annual networking cocktail reception. The perfect place to unwind and meet our speaking faculty, attending industry delegates, sponsors and advisory board members.



*"Provided me with an in-depth understanding of temperature product management throughout design and transportation within a temperature controlled environment. - Baxter*



# Main Conference Day Two

Thursday February 26th, 2015



8:00 **Coffee and Networking and Networking in Exhibition Hall**

8:50 **Opening Remarks by Chairman**



Rafik H. Bishara, PhD  
Technical Advisor & Leader, PCCIG  
**PDA**

9:00 **An Industry Perspective - Update & Interpretation of European GDP Guidelines**

- Changes on transportation - Impact for distribution logistics
- How can organizations fulfill new requirements?
- A deeper dive into new risk assessment section
- Brokers and contracts
- Wholesaler license for products stored for more than 24-48hrs



Shirley Feld  
Global Manufacturing Quality Organization, End to End Supply Chain, Deputy Director, **Sanofi-Aventis**

9:45

**Quality Agreements: Securing the Transportation and Storage Supply Chain While Fulfilling Regulatory Requirements**

- Importance of establishing Quality Agreements with transportation providers
- Highlighting the 5 W's of Quality Agreements
- Defining roles and responsibilities of each party
- Case study highlighting best practices and an effective quality agreement



Melissa Iddison  
Quality Assurance Coordinator  
**World Courier of Canada Ltd.**

10:30

**Morning Networking Demo Drives & Networking Break In The Exhibit Hall**

Join your peers to browse the 2015 Solution Hall where you'll be able to find all the latest in technology, implementation, advisory and analytics solutions. The ideal place to meet existing and new partners.

## INTERACTIVE IN-DEPTH DISCUSSION LOUNGES

Choose from the listed roundtables and participate in a lively discussion. Select your discussion topic and join in to hear from leading industry experts

11:15 -  
12:05

### COLD CHAIN MANAGEMENT

#### Defining Success in your Cold Chain Management Program

- Clearly defining priorities internally – knowing what you want
- Establishing a relationship and creating a solution with your provider
- Key Drivers that define success
- Your next steps



Jim Bacon  
Senior Director, Grifols  
Demand Planning &  
International Customer  
Operations - US Office  
**Grifols, Inc.**

### CRT PRODUCTS

#### CRT: Ensuring Compliance Doesn't Have to Mean High Cost

- What can be done about unavoidable heavy costs



Claude Jolicoeur  
Director Regulatory Affairs,  
Corporate GMP officer, Legal  
Services, Compliance and GMP  
**McKesson Canada**

### EXTERNAL & INTERNAL AUDITS

#### Ensuring Internal and External Audit Compliance

- Implementing a formal internal audits process
- Utilize employees not directly involved in the distribution processes to help identify the smaller details
- List of corrected items (i.e. pest control, pipes, dust...) and checklist for details identified

### LANE QUALIFICATION

#### Filing for Lane Qualification – Working Towards an Industry Consensus

- Standardization of "risked based controls" / requirements based on 4 criteria categories;
- 1. temperature robustness
- 2. shipping program
- 3. freight forwarder controls/ transportation provider controls
- 4. shipping mode

## INTERACTIVE IN-DEPTH DISCUSSION LOUNGES CONTINUED

Choose from the listed roundtables and participate in a lively discussion. Select your discussion topic and join in to hear from leading industry experts

12:10-  
1:00

### IMPORTS COMPLEXITIES

#### Tips to Effectively Navigate Customs for your International Imports Arriving Via Air, Truck and Sea Shipments

- Considerations for custom imports
- Health Canada's impact on customs imports and why they are doing things the way they are



Natasha Harper,  
APFF, CCS, CTCS  
Transport and Customs  
Specialist  
**Sandoz Canada Inc.**

### COLD CHAIN MANAGEMENT

#### Compliant Cold Chain Management

- Process validation and problem resolution
- Robustness of pack-out configurations and transportation



Rob Mancuso  
Associate Director,  
AGO-QA-Quality Systems &  
Compliance  
**Apotex Inc.**

### CLINICAL TRIALS

#### Maintaining Good Distribution Practices in the Transition from Clinical to Commercial

### RISK MANAGEMENT

#### Risk Assessments of Delivery Routes to Identify When Temperature Control is Needed

- Room temperature products - How can we assess when temperature control is required
- The last mile – delivery to customers



Shirley Feld  
Global Manufacturing Quality  
Organization, End to End  
Supply Chain, Deputy Director  
**Sanofi-Aventis**

1:00

### Networking Lunch in the Exhibit Hall & Annual Prize Drawing

2:00

### MAIN SESSION TRACK

#### PANEL DISCUSSION: Shipping Temperature-Sensitive Pharma Products Via Ocean Container

During this session all parties involved in the ocean transportation of temperature sensitive pharmaceutical products will discuss their roles, responsibilities and how teaming up can allow sea transportation to be a consistent and efficient mode of transportation. Panelists will address the benefits and challenges that can be encountered when choosing ocean transportation. Risk management, insurability, new technologies, logistics, and port procedures will be covered.

Exploring and appreciating the unique complexities involved in shipping their regulated pharma products via ocean container (as compared to other modes of conveyance), including shipboard and terminal operational considerations. The concept of equipment and shipping lane qualification will also be explored as a critical step in order for shippers to achieve GDP compliance.

- Industry trends and statistics
- Current limitations/impediments faced by shippers preventing them from shipping via ocean container

### INTERACTIVE LOUNGE - BIOTECH & SMALL PHARMACEUTICAL COMPANY

2:00 – 3:00pm

#### 2 PART CASE STUDY

##### ① CASE STUDY #1: SHIPPING VALIDATION STRATEGY USING ESTABLISHED PRODUCTS AND SERVICES (PEI CANADA TO EASTERN EUROPE)

- Define the validation scope
- Research routing options
- Risk and regulatory considerations
- Assess solutions and define methods
- Leveraging equipment and service provider expertise
- The validation process
- Results



Wilf Meschwitz  
Senior Supply Chain Specialist  
**BioVectra Inc.**

**Group Discounts are Available!  
See Page 910 for more details.**

- Risk factors and exposures
- Common causes of loss/damage
- Best practices and GDP compliance
- Current and future technologies
- Proper equipment qualification



**Eric A. Newman**  
Vice President, Loss Prevention  
**Falvey Cargo Underwriting**



**Jean Vezina**  
President  
**Salvus Inc.**



**Ed Downey**  
Senior Director - Risk Management  
**Cubist Pharmaceuticals**

②

## CASE STUDY #2: SHIPPING VALIDATION STRATEGY EMPLOYING A CUSTOM SOLUTION (PEI CANADA TO INDIA)

- Why a customs solution?
- Understanding routing options
- Risk and regulatory considerations
- Identifying the right pack-out qualification service providers
- The validation process
- Results



**Wilf Meschwitz**  
Senior Supply Chain Specialist  
**BioVectra Inc.**

2:45

### Afternoon Networking & Networking Break In The Exhibit Hall

3:10

### A Paradigm Shift in GCC Pharmaceutical Distribution Challenges & Opportunities

- A regional view of the current state of affairs for Pharma healthcare setup in GCC Countries including:
  - Regulations
  - Infrastructure challenges
  - Risks
  - Regional challenges and possible solutions in line with New EU GDP guidelines
- Steps towards insuring product supply security to GCC



**Moataz Mostafa**  
Procurement & Supply Chain Division Manager  
**Ebn Sina Medical**

### 2 PART CASE STUDY CONTINUED



3:55

### Pharmaceutical Shipper Perspective - Lane Qualification Vs. Continuous Temperature Monitoring

- Managing temperature data globally
- A systematic analysis - Is it worth the risk?
- Key considerations and risks to be assessed
- Using product stability data and supply chain risk assessment to justify shipping without either continuous monitoring or qualification of the shipping system



**Marilda Bezerra**  
Quality Manager for GDP  
**Bayer**



*"Roundtable discussions – great opportunity to meet people face-to-face."*

**- NFI Canada**

4:25

### Close of Conference



# We Take Pride In Connecting You With The Latest Technologies And Services For Temperature Controlled Life Science Products



*"Great topics!  
Great Exhibitors!"*  
-Valeo Pharma

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Contact Colby Shine at 212-885-2744 or by email at [Colby.Shine@iqpc.com](mailto:Colby.Shine@iqpc.com).

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information, well organized  
and great interaction."*  
- Sonoco Thermosafe

*"Excellent presentations on  
Supply Chain involving 3rd  
party transportation carriers."*  
- Bristol Myers Squibb

*"Networking with key  
suppliers & clients in a very  
organized environment"*  
- UTi Worldwide

*"Exhibit space and setup  
was great. Easy to connect  
with suppliers."*  
- Amgen Canada

*"Very informative. Enjoyed  
having time to meet with  
vendors."*  
- Abbott Vascular



# Thank You to Our Sponsors



## American Aerogel Website: [www.american aerogel.com](http://www.american aerogel.com)

American Aerogel provides life science companies with insulated shipping solutions for the protection of temperature-sensitive payloads. Our patented product, Aerocore VIP, allows customers to ship larger payloads, with less coolant, in smaller containers, and over a longer period of time. We also operate ISTA-certified and authorized testing equipment, allowing us to pre-qualify shipping solutions for our customers and to offer testing services for other shipping solutions. We are proud to say that our life science customers have shipped thousands of products in Aerocore insulated shippers with no product loss due to temperature variations.



## ATS Healthcare [www.atshealthcare.ca](http://www.atshealthcare.ca)

ATS Healthcare is the most dedicated and reputable provider in Canada's temperature controlled healthcare transportation industry. Healthcare and cosmetic manufacturers, wholesalers and their customers appreciate our reliable end-to-end solutions to their temperature management, security and other shipping requirements. Our standards are the highest, complying with Health Canada guidelines for the transportation of temperature sensitive products such as pharmaceuticals, cosmetics, medical devices and over-the-counter products. SNC Lavalin Pharma has recognized and can attest to our high standards through the qualification of our systems and procedures. In combination with 24/7 tracking, data capture and retention, our nationwide network of temperature managed facilities and the highest level of security, ATS provides shippers a clean, efficient and committed healthcare



## Berlinger Website: [www.berlinger.com](http://www.berlinger.com)

Innovation has propelled the Berlinger Company through the past 150 years. Our team has been helping customers around the world create greater visibility into their cold chain, reduce risk and drive process improvements. Berlinger proudly offers a family of products that are designed to validate pharmaceutical cold chain shipments. Through intelligent design, the Q-tag® CLm doc continuously monitors temperatures in transit, providing the user with more information when excursions occur than the typical data logger on the market. It's also the most economical product for a 3 day or 40+ day shipment. Avoid software validation and up-grades through our PDF report and SmartView information management system. SmartView uniquely enables users to achieve two goals: 1) store information in a central network that is 21 CFR part 11 compliant & 2) analyze the data through unique report writing software embedded in the system. Or ask us how to use the device within your own centralized data base. When you are ready to automate cold chain information and reporting processes, seek out Berlinger: [www.berlinger.com](http://www.berlinger.com)



## Cedarlane Website: [www.cedarlane.ca](http://www.cedarlane.ca)

CEDARLANE is an ISO 9001:2008 and ISO 13485:2003 registered privately held Canadian Corporation. CEDARLANE SHIPPING SUPPLIES was established as a response to the growing need for temperature sensitive shipping supplies and transportation of perishable and time sensitive goods. Specialties are gel & foam ice packs, Styrofoam insulated shipping cartons and expanded polystyrene (EPS) insulated shipping cartons, offering you everything you need to make sure your important shipments arrive in good standing, every time. Cedarlane Shipping Supplies – Got Your Temperature Under Control?



## Coldbox Builders Website: [www.coldboxbuilders.ca](http://www.coldboxbuilders.ca)

Linking design and construction through accountability and single sourcing, Coldbox Builders' approach to building design and construction eliminates the stresses you may experience when managing multiple parties, complying with various regulation requirements and GMP standards, and working within a set budget and time frame. Our in-house design and construction management team will work with you throughout the entire building process from design to construction to commissioning and validating the facility, ensuring the spaces meet regulations and GMP standards. We specialize in Pharmaceutical manufacturing and logistics facilities to your users' requirement specifications for greenfield, additions, interior fit-ups, and retrofitting.



## Cryopak Website: [www.cryopak.com](http://www.cryopak.com)

Cryopak (a TCP Reliable Company), specializes in the field of temperature controlled packaging and services including package design, qualification, testing manufacturing insulated shippers, refrigerants, phase change materials and temperature monitors. All services are provided in strict conformance with ISO 9001:2000, ISTA and ASTM test methodology, and FDA good manufacturing practices. TCP maintains facilities in Quebec, British Columbia, New Jersey and France.



## Tyvek. air cargo covers

Covers for Pharmaceuticals are specifically engineered to address the threat of cold chain breaks during air transit. They provide excellent protection against temperature excursions by shielding your products from the damaging effects of solar radiation and extreme ambient temperatures. Validated in a wide variety of applications by pharmaceutical manufacturers worldwide, including applications subject to the newly revised EU GDP guidelines, DuPont™ Tyvek® Air Cargo Covers are ideal for "cold room temperature" products and will strengthen a 2C-8C cold chain solution. The DuPont™ Tyvek® Air Cargo Covers also offer a "breathable" barrier that helps reduce the probability of condensation damage while protecting against the physical hazards such as rain and airborne contaminants.



## ELPRO Services, Inc. Website: [www.elpro.com](http://www.elpro.com)

ELPRO Services, Inc. is a leading manufacturer of high quality temperature, humidity, and CO2 data loggers, providing recording and monitoring solutions while observing regulatory compliances (GMP/GLP/FDA 21 CFR Part 11). LAN/W-LAN solutions are fully scalable to meet your central monitoring requirements and future growth. Our new LIBERO PDF Logger (no software required) provides simple cold chain monitoring of temperature sensitive pharmaceuticals. This ground-breaking concept of producing the report in a PDF file eliminates the need to install, qualify and validate any specific software at destination. Available in 100 and 400 day models, our LIBERO PDF Logger also supports compliance with the standard FDA 21 CFR Part 11.

## Envirotainer®

The Active Cold Chain

## Envirotainer Website: [www.envirotainer.com](http://www.envirotainer.com)

Envirotainer is the world-leader in secure cold chain logistics solutions, primarily within the life science industries. The company manufactures and leases active temperature-controlled container solutions for air transportation, including validation, support and service. Envirotainer operates in over 50 countries around the world with headquarters in Upplands Väsby just outside of Stockholm, Sweden. Envirotainer is a registered trademark of the company Envirotainer AB.



## GMD PharmaSolutions Website: [www.gmdpharma.ca](http://www.gmdpharma.ca)

GMD PharmaSolutions - Your Cold Chain Distribution Partner in Canada: At GMD PharmaSolutions we bring new drugs to Canada. We offer our clients a Complete Canadian Solution. We can fully incubate your cold chain needs in Canada. We can facilitate your regulatory needs, and provide market access, and specialized warehouse and distribution services for your cold chain product, including refrigerated, frozen or deep freeze products. For our international clients, we can act as your Importer and distributor.



## Infitrak Website: [www.infitrak.com](http://www.infitrak.com)

For 15 years Infitrak has been a unique one-stop resource for developing and executing plans to meet Good Distribution Practices (GDPs) and cold chain management requirements. Using current regulations and guidance, the company evaluates current methods where risk may be present, identifies deficiencies, and proposes remediation. It is an integrated approach that provides cost-effective enhancements to customer quality systems. As a pioneer in environmental monitoring platforms, packaging, and compliance consulting, the company has successfully delivered solutions to a loyal customer base that includes pharmaceutical manufacturers, wholesalers, laboratories, logistics and storage companies, hospitals, food manufacturers and data centers. Learn more about Infitrak and their services at [www.infitrak.com](http://www.infitrak.com).



**Lufthansa Cargo**  
Website: [www.lufthansa-cargo.com](http://www.lufthansa-cargo.com)

Lufthansa Cargo ranks among the world's leading cargo carriers. In the 2012 business year, the airline transported around 1.9 million tonnes of freight and mail and sold 8.7 billion revenue tonne-kilometres. The company currently employs about 4,600 people, worldwide. Lufthansa Cargo focuses on the airport-to-airport business. The cargo carrier serves more than 300 destinations in some 100 countries with its own fleet of freighters, the belly capacities of passenger aircraft operated by Lufthansa and Austrian Airlines, and an extensive road feeder service network. The bulk of the cargo business is routed through Frankfurt Airport. The company's other hubs are in Munich, Leipzig-Halle and Vienna. Lufthansa Cargo is allied with other cargo carriers and companies affiliated to the freight business, which enhance one another's products, services and network in the Lufthansa Cargo Group. Lufthansa Cargo is a wholly owned Lufthansa subsidiary of Deutsche Lufthansa AG.



**Pelican BioThermal**  
Website: [www.pelicanbiothermal.com](http://www.pelicanbiothermal.com)

Minnesota Thermal Science, now Pelican BioThermal, is the global leader in delivering temperature control packaging solutions through a comprehensive range of advanced temperature control product shippers, services, software and asset management tools enabling clients to reduce payload risk, total distribution costs and lessen environmental impact. The new Pelican BioThermal brand integrates Minnesota Thermal Science (MTS) and Cool Logistics, into an international powerhouse with the broadest range of temperature controlled packaging options including a rapidly expanding global network of asset management service solutions. The new division boasts the largest global sales, distribution and customer service support capability in the life science industry. It also provides the highest concentration of talent, resources and customizable solutions to accommodate any thermal shipper requirements.



**Marken**  
Website: [www.marken.com](http://www.marken.com)

Marken is the leading global clinical supply chain solutions provider dedicated to the pharmaceutical and life sciences industries, supporting over 49,000 investigators in more than 150 countries. Marken integrates Depot and Logistics services into solutions that extend the reach of clinical trials to even the most remote treatment naïve geographies, leveraging decades of experience in the logistics, transport and distribution of temperature sensitive life saving pharmaceuticals, clinical trial supplies and specimen collection. Our team members, technologies and network of facilities bridge the distance between patients and the essential resources of life science companies.



**Robert**  
Website: [www.robert.ca](http://www.robert.ca)

Founded in 1946, Robert proudly upholds a tradition of excellence that has made it a leader in the North American asset based supply chain management sector. We owe our success to our 3,300 dedicated employees and our expertise in delivering state-of-the-art logistics, distribution and transportation solutions. Multiple times in its history Robert has chosen to take on new challenges. The keys remain constant, education, quality and dedication. As we evolve we will strive to continue to do what we have always done, create serious solutions for serious people.



**Sensitech**  
Website: [www.sensitech.com](http://www.sensitech.com)

Sensitech Inc. is a leading provider of supply and cold chain visibility solutions that enable our customers – global leaders in the life sciences, food, and industrial markets – to track, monitor and protect the quality and integrity of their temperature-sensitive products across complex supply chains. Through its logistics security division, FreightWatch International, Sensitech also offers origin-to-destination services that provide customers with real-time cargo transparency, helping them to mitigate such risks as theft, diversion, counterfeiting, and chain of custody. Sensitech Inc. is an ISO 9001:2008 company based in Beverly, Mass., with more than 30 sales, service and distribution locations around the world. Sensitech is a part of UTC Building & Industrial Systems, a unit of United Technologies Corp., a leading provider to the aerospace and building systems industries worldwide. Visit [www.sensitech.com](http://www.sensitech.com) for additional information.



**Skelton Truck Lines**  
Website: [www.skeltontruck.com](http://www.skeltontruck.com)

Skelton has provided refrigerated services for 28 years to Pharmaceutical/Biological companies. We partner with customers to ensure we maintain product integrity through out the cold chain link. Our Critical Care Division validated trailers are devoted for products that require 2°C to 8°C with double reefers units to ensure the safety of the products. Our investment in assets, people and training have provided our customers with a Tried, Tested and Proven solution that meets and exceeds Health Canada 0069 regulations.



**Testo, Inc.**  
Website: [www.testo.com](http://www.testo.com)

Testo, Inc. is a world leader in the design, development and manufacturing of portable test and measurement instrumentation. Backed by over 50 years of innovation, our mission is to provide the best quality, service and value in the industry. Specifically for the Pharma and Biotech markets, Testo has an extensive line of product and environmental monitoring solutions. From simple-to-use data loggers, to multi-function reference loggers, to the multi-point, facility-wide Saveris Monitoring System, Testo has you covered with a number of fully compliant solutions. For more information, visit us at [www.testo.com](http://www.testo.com).



**ThermoSafe Brands**  
Website: [www.thermosafe.com](http://www.thermosafe.com)

ThermoSafe, a Sonoco Protective Solutions™ brand, is the leading global provider of temperature assurance packaging for the safe and efficient transport of pharmaceuticals, biologics, vaccines and other temperature sensitive products. Our shipping solutions mitigate risk for our customers and ensure product efficacy throughout the extremes of a supply chain. ThermoSafe has operations in North America, Europe, Asia and South America to assure close proximity to our customers. Our vast product offering features industry leading technology that encompasses refrigerated, frozen or controlled room temperature applications. In addition, 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.



**Tripar Transportation**  
Website: [www.tripartrans.com](http://www.tripartrans.com)

Since our start in 1981, we have continued to build our company around three principles: offer clients advantageous transportation programs; provide responsive customer service; maintain competitive pricing. Our customers have been served well, and we will continue to meet the challenge of following these principles. We lead the industry in LTL overnight service from the north east USA to Ontario. We pride ourselves on offering the best service in the industry to our customers. We also understand that the market changes each year, so we are now adapting to our clients needs by offering validated temperature control trailers. Our new trailers will be validated to Health Canada 0069 standards. We will continue to offer our overnight LTL service from the north east USA to Ontario with our validated equipment. We at Tripar continually further our ability to accommodate our customer needs.



**va-Q-tec AG**  
Website: [www.va-q-tec.com](http://www.va-q-tec.com)

va-Q-tec AG develops and produces vacuum insulation panels (VIPs) and phase change materials (PCM) high performance thermal packaging products and other applications. In most cases these packaging solutions comprise both, VIPs and PCM. This leads to the most reliable and temperature stable system solutions used to transport valuable and temperature sensitive products for up to 6 days and even longer. va-Q-tec's all season solutions do not allow any temperature excursions even at the most challenging ambient conditions. The va-Q-tec solutions range from one-way shippers to air freight containers. va-Q-tec offers small quantities from the standard portfolio to large quantity custom tailored series production. The applications range from pharma and biotec products to food and fine arts. The va-Q-tec headquarters in Würzburg / Germany (ca. 100 km from Frankfurt) with its more than 4 500 m<sup>2</sup> high tech production area offers excellent facilities for testing and official validation run by our experts in thermal physics. va-Q-tec has won several national and international awards for the advanced technology of saving and storing energy efficiently.



**World Courier of Canada Ltd.**  
Website: [www.worldcourier.com](http://www.worldcourier.com)

World Courier has set the benchmark for worldwide time & temperature sensitive transportation. We remain the only specialist courier company with its own global company network. Each office ISO 9001 certified with the same operating standards dedicated to treating every shipment on an individual, priority basis. World Courier is utilized in approximately 80% of the world's clinical trials requiring the use of a specialty courier. With experience in managing the logistics of over 7,500 clinical trials worldwide, we are the acknowledged experts in handling temperature sensitive specimen and drug shipments.