

SMi Presents the 10th Annual Conference on...

Cold Chain Distribution

Enhance Temperature Management for
an Efficient Supply Chain

Victoria Park Plaza Hotel, London, UK

3rd - 4th
DEC
2015

CHAIRS FOR 2015:

 **Tony Wright**, Managing Director, **Exelsius Cold Chain Management**

 **David Spillett**, Key Account Director, **World Courier**

KEY SPEAKERS INCLUDE:

- **Cheryl Blake**, GDP Inspector, **MHRA**
- **Michelle Arnot-Kruger**, Health Specialist, Health Programmes, **UNICEF**
- **Hasan A. Jabarti**, Quality Assurance Head, **Novartis Pharma AG** (Saudi Arabia)
- **Marc Sotly**, Clinical Supplies – Studies and Distribution Unit Head, **Sanofi R&D**
- **Henry Moran**, UK and International Supplies Manager, Pharmaceuticals, **NAPP Pharmaceuticals**
- **Bev Nicol**, Senior Manager, Clinical Supply Logistics, **Pfizer**
- **Claire Armstrong**, Distribution Specialist, Clinical Supply Logistics, **Pfizer**
- **Thomas Grubb**, Manager, Cold Chain Strategy, **American Airlines**

BUSINESS BENEFITS FOR 2015:



LISTEN to case study scenario based presentations assessing the challenges faced in cold chain distribution and what strategies are being implemented in the attempt to secure better practices in the pharma distribution environment



HEAR the latest on the advances in real time temperature monitoring and direct to patient distribution strategies
REVIEW the GDP compliance regulations and lessons learned from audits to maintain standards



DISCUSS bridging the gap between pharma and logistics companies and managing expectation and requirements from one another in the partnership

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NEW FOR 2015 - TWO NETWORKING DRINKS RECEPTIONS AND A DINNER!

Thursday 3rd December 2015:

End of Day One drinks reception and
dinner sponsored by World Courier

Friday 4th December 2015:

End of Day Two drinks reception
sponsored by American Airlines Cargo

www.coldchain-distribution.com

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#ColdChainSMi

Cold Chain Distribution

Day One | Thursday 3rd December 2015

8.30 Registration & Coffee

9.00 Chair's Opening Remarks

Tony Wright, Managing Director, **Exelsius Cold Chain Management**



GDP COMPLIANCE

OPENING ADDRESS

9.10 Reviewing the implementation of the GDP regulatory requirements

- Where we are now in terms of the latest GDP developments and what can we learn?
 - Bridging the gap between the pharma company and the logistics provider from a GDP perspective
 - Developing emerging markets- what actions can be taken...
- Session Reserved for: **Reikert Bruinink**, Member of the GDP drafting Group of the EMA, **Dutch Healthcare Inspectorate**

9.50 REVIEW: Demonstrating how to meet the needs of the EU GDP

- Discussing EU GDP with an update on the findings specific to the extension of GDP of APIs
 - What are the expectations from the MHRA?
 - Reviewing what differentiation between companies is being noticed regarding compliance with the regulations
- Cheryl Blake**, GDP Inspector, Inspection, Enforcement and Standards, **MHRA**



10.30 Morning Coffee

11.00 Assessing the practical implementation of cold chain distribution

- The RP Gold Standard - history and development
 - Requirements of the RP defined by the Gold Standard
 - The RP Training Standard
 - The role of Cogent Skills - The Sector Skills Council for the Pharmaceutical Industry
- Bob Hayes**, Director, **SeerPharma (UK)**



TEMPERATURE MONITORING & BEST PRACTISES IN PHARMA DISTRIBUTION

PART ONE

11.40 The End-User Perspective - Case Study: Temperature Control

- Focusing on the importance of the end user - what can be done?
- Evaluating what happens through tracking the whole distribution cycle

Michelle Arnot-Kruger, Health Specialist, Health Programmes, **UNICEF**



12.20 Networking Lunch

1.30 Case Study: Enhancing the handling, storage and distribution within cold chain distribution

- Evaluating how the increased importance of temperature control and monitoring has affected the supply chain
 - Addressing how we can ensure that product quality and integrity aren't compromised
 - Brainstorming over the capacity for handling medicinal products
- Henry Moran**, UK and International Supplies Manager, Pharmaceuticals, **NAPP Pharmaceuticals**



2.10 Patient-Centricity "We will move the mountain"

- An introduction to Home Trail Support and Direct To Patient distribution
 - An evolving supply chain model
 - Challenges and solutions for maintaining temperature control
- David Spilleit**, Key Account Director, **World Courier**



2.50 Afternoon Tea

EMERGING MARKETS

3.20 Assessing the supply chain in Emerging Markets - focus on the Middle East and Russia

- Understanding the differences among countries - standards, rules and regulations, methods etc.
- What strategies are being utilised to support and enhance supply chain development in these regions
- What can we learn from the Emerging Markets and apply elsewhere?

Chris will share the Genzyme experience and describe some of the specific challenges in emerging markets and how to overcome them

Chris Wallace, Distribution Director, **Genzyme**



4.00 THE INTERNATIONAL DEBATE: Emerging Markets

- Assessing the emerging markets - How can we instil the same standards and basic requirements from one country to another?
- How does cold chain in the Middle East differentiate from Europe?
- How can industry experts and policy-makers work together in tandem to grow the business?
- Eliminating barriers to grow cold chain in emerging markets

Hasan A. Jabarti, Quality Assurance Head, **Novartis Pharma AG (Saudi Arabia)**



4.40 Chair's Closing Remarks and Close of Day One

5.30 - 6.30 Drinks Reception sponsored by



6.30 Depart for Dinner The Goring Hotel

Day One Drinks Reception Thursday 3rd December 2015

World Courier would like to invite you to join the drinks reception taking place between 5.30pm - 6.30pm on Thursday 3rd December 2015 at the Victoria Park Plaza Hotel

Sponsored by



Day Two Drinks Reception Friday 4th December 2015

American Airlines Cargo would like to invite you to join the drinks reception taking place between 3.30pm - 4.30pm on Friday 4th December 2015 at the Victoria Park Plaza Hotel

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8.30 Registration & Coffee

9.00 Chair's Opening Remarks

David Spillett, Key Account Director, **World Courier**

TEMPERATURE MONITORING & BEST PRACTISES IN PHARMA DISTRIBUTION

PART TWO

OPENING ADDRESS

9.10 JOINT PRESENTATION: Managing Clinical Supplies to Patients

- Patient focused initiatives within Global Clinical Supply
- System based temperature monitoring functionality
- Controlled room temperature monitoring strategy
- The importance of vendor relationships

Bev Nicol, Senior Manager, Clinical Supply Logistics, **Pfizer**

Claire Armstrong, Distribution Specialist, Clinical Supply Logistics, **Pfizer**

JOINT PRESENTATION



9.50 Case Study: Direct To Patient Home Delivery

- Concerns about traditional distribution
 - Sanofi's global process overview
 - Reasons to consider a Direct To Patient solution
- Marc Sothy**, Clinical Supplies - Studies and Distribution Unit Head, **Sanofi R&D**



10.30 Morning Coffee

11.00 Reviewing GDP and legislation to ensure compliance

- Risk Management, change control and quality agreements - pre-qualification activities involving specification, obtaining and assessing data, and supplier audits.
- Assessing how to establish and optimise good quality and operational systems - being answerable to auditors on validating processes
- If temperature excursions arise, how can we avoid repetition of this happening again?

Session Reserved for: **Simona Vatzova**, Associate Director, International Freight & Compliance, **Actavis**

INSIGHT INTO PACKAGING

11.40 Case Study: Sustainable CO2-neutral shipping packaging for maintenance of cold chain for E-commerce

- Studies to compensate for real-life temperature variations within the distribution chain of single packaging
- How to go green with carbon-neutral shipping?
- Reviewing an alternative active shipping packaging concept to implement temperature-controlled evaporative cooling inside an air-spaced double-wall corrugated cardboard box

Alexander Bardenstein, Technical Manager, R&D Coordinator, Packaging section, **Danish Technological Institute**



12.20 Networking Lunch

SHIPMENTS AND ADVANCES IN DATA LOGGING

1.30 PANEL DISCUSSION: Risk Mitigation of Air Shipments - Meeting temperature sensitive requirements

- Air shipments of pharmaceutical products - where are we now?
- Airport is a black hole and I don't know what happens to my product;
- Airline handling is a low-wage environment so how can you ensure staff are appropriately skilled and trained to handle my product;
- There are many agencies involved in airfreight - how can these be best co-ordinated;
- What happens to my product when it transfers from one flight to another?
- Managing and auditing carriers - what's done and what could be done differently when challenges are faced

Moderator: Alan Dorling, Global Head

- Pharmaceutical & Life Sciences, **IAG Cargo**

Panellists:

Mark Edwards, Managing Director, **Modalis**

Thomas Grubb, Manager, Cold Chain Strategy, **American Airlines**

Didier Basseras, Vice President Global Head of Clinical Supplies and Supply Chain, **Sanofi R&D**

Tim Wood, Technical Services Manager, **GlaxoSmithKline**



2.10 Case Study: Shipping temperature-sensitive products via airfreight

- An overview into how the ground and warehouse staff deal with handling pharmaceutical products
- Mitigating risk when transporting products via airfreight
- Reviewing the challenges surrounding air freight and the procedures to overcome the hurdles
- An insight into the development of airfreight procedures

Thomas Grubb, Manager, Cold Chain Strategy, **American Airlines**



2.50 Analysing Air Shipments - Are they the future?

- Assessing challenging
- Active solutions
- Passive solutions
- Airline solutions

Mark Edwards, Managing Director, **Modalis**



3.30 Chair's Closing Remarks and Close of Day Two

3.30 - 4.30 Drinks Reception sponsored by **American Airlines Cargo**

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Cold Chain Distribution

Thursday 3rd and Friday 4th December 2015

Lead Sponsor:



World Courier Incorporated in 1969, World Courier is the leader in specialty logistics for global clinical trials delivering fully-integrated GxP-compliant temperature-controlled transport, storage and distribution solutions worldwide in over 10,000 clinical studies. World Courier has a network of over 150 company offices operating in more than 50 countries plus a network of 13 x GMP compliant storage depots in strategic locations. Through its company-owned network of offices World Courier provides door-to-door, customs-cleared service to more than 220 countries and territories and sets the benchmark for temperature controlled, time sensitive transportation. As Cold Chain shipments face increased scrutiny from internal bodies and international agencies alike, strict adherence to temperature control is critical for compliance with international regulatory, manufacturing and safety standards. With our proven track record in Cold Chain Management, World Courier is the only specialty logistics provider that offers comprehensive and customized temperature-controlled transportation services 24/7/365 worldwide. www.worldcourier.com

Day One Dinner
Thursday 3rd December 2015
Sponsored by World Courier

World Courier will be hosting a unique and exciting evening dinner at the end of Day One. This event will be hosted at The Goring Hotel, leaving from the Victoria Park Plaza at 6.30pm. It promises to be a fantastic experience. Places are strictly limited for pharmaceutical companies only, visit our website for further details.

www.coldchain-distribution.com



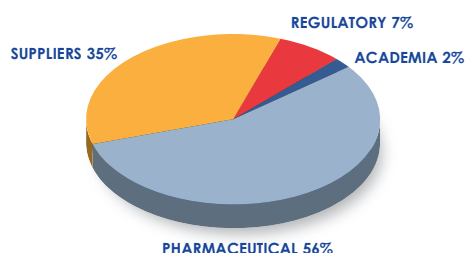
Who should attend this conference:

You should attend this event if you work in the Pharmaceutical Industry with responsibilities in Quality Assurance, Quality Compliance, Regulatory, Supply Chain, Manufacturing, Packaging, Distribution, Operations.

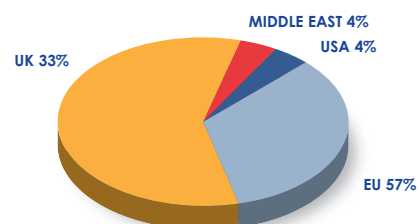
Job titles include:

- GMP Compliance Specialist
- GMP Inspector
- Director, Global Demand Planning & Customer Operations
- Director, Purchasing and Distribution
- General Manager, Distribution and Logistics
- Director, Regulatory Affairs, Corporate GMP Officer
- Head of Packaging
- VP, Clinical Logistics
- International Supplies Manager
- Quality Assurance and Quality Compliance Manager
- Head of Corporate Supply Chain Operations

**Cold Chain Distribution Attendees
2013-2014 by Industry Sector**



**Cold Chain Distribution Attendees
2013-2014 by Region**



Cold Chain Distribution

Thursday 3rd and Friday 4th December 2015

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Peli Bio Thermal

Peli BioThermal Limited offers the widest range of temperature controlled transport solutions in the world. Their products ensure that delicate biological materials arrive intact and effective, despite exterior environments. Peli BioThermal is dedicated to fulfilling the complex needs of the global healthcare industry. The company's customers benefit from their extensive expertise in ensuring that temperature stability is maintained throughout the distribution chain. Peli BioThermal also offers a complete range of services and software to support end-to-end temperature controlled packaging asset management. Peli Products, S.L.U. is the European arm of Pelican Products, Inc. www.pelibiothermal.com



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COLD CHAIN DISTRIBUTION

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First 20 Pharmaceutical Companies			
☐ Conference only LIMITED AVAILABILITY	£899.00	+ VAT	£1078.80

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- ☐ End of Day One Evening Dinner at The Goring Hotel
(Pharma only, subject to availability)

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