SMi Presents the 11th Annual Conference on...

Cold Chain Distribution

12th - 13th DEC 2016

Park Plaza Victoria, London, UK

The Big Chill – Delivering Quality Products to Your Customers through Fail-Proof Cold Chain Logistics and Tightened Collaboration with Your 3PLs

Highlights in 2016:
• Regulatory expectations? Answers from PIC/S and Danish Medicines Agency
• Evaluate your GDP implementation journey to ensure compliance
• Assess new transportation options for cold chain – air vs sea vs railway?
• Pushing the limit? What is the acceptance level for stability requirement and temperature range?
• Join our Executive Boardroom Discussions – meet and hear other senior colleagues’ views and benchmark your best practice!

2016 Chairmen:
David Spillett,
Key Account Director,
World Courier

Tony Wright,
CEO,
Exelsius

KEYNOTE SPEAKERS INCLUDE:
• Yoram Eshel, Senior Director, Global Transportation and Logistics, Teva Pharmaceuticals
• Didier Basseras, Vice President, Global Head of Clinical Supplies, Sanofi R&D
• Saddam Huq, Global QA Senior Manager, Distribution & Cold Chain, GSK
• Gino Vleugels, Senior Manager EMEA Temperature Control, Johnson & Johnson
• Thomas Vestergaard Pedersen, Medicines Inspector, Danish Medicines Agency
• Andrea Gruber, Senior Manager, Special Cargo, IATA
• Stephen Todd, Chair of GDP Expert Circle, PIC/S; Senior GDP Inspector, MHRA

GALA DINNER
HOSTED BY LEAD SPONSOR ON 12 DECEMBER BY INVITATION ONLY

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#ColdChainSMI
Cold Chain Distribution
Day One | Monday 12th December 2016

08.30  Registration & Coffee

09.00  Chairman’s Opening Remarks
Tony Wright, CEO, Exelsius

09.10  OPENING ADDRESS: The Role of PIC/S in the International Harmonisation of Regulatory Inspections across 6 Continents
• Who is PIC/S? Role and responsibilities
• Challenges of international harmonisation of regulatory inspections
Stephen Todd, Chair of GDP Expert Circle, PIC/S; Senior GDP Inspector, MHRA

09.50  Authority Inspection of GDP, With Focus on Cold Chain Issues
• Authority focus during GDP/ cold chain inspection, in relation to new GDP guidelines
• Examples of common authority observations from GDP inspections
Thomas Vestergaard Pedersen, Medicines Inspector, Danish Medicines Agency

10.30  Myth Buster – Regulatory Quick Fire
In this session delegates will get the chance to ask regional regulators questions to clear any GDP and cold chain distribution compliance concerns.
Panellists:
Thomas Vestergaard Pedersen, Medicines Inspector, Danish Medicines Agency
Stephen Todd, Senior GDP Inspector, MHRA

10.50  Morning Coffee & Networking Break

11.20  IATA’s Initiatives in Supporting Temperature-Controlled Distribution for Pharma
• How to ensure compliance with regulatory requirements?
• How is the industry responding to IATA’s Certification (CEIV) programme?
• How will this impact on the routing of temperature-controlled supply chain?
• What are the next steps to ensure the future of air cargo?
Andrea Gruber, Senior Manager, Special Cargo, IATA

12.00  Enhanced Expectations – The Evolution of Temperature Control
• Speciality products necessitate specialist solutions
• More than a box – the development of temperature controlled packaging systems
• Data driven decision making and risk mitigation
David Spillett, Key Account Director, World Courier

12.40  Networking Lunch

13.30  How Much Control Do You Have? Maintaining the Chill throughout the Supply Chain
• From first mile to last – determining points of transfer and defining a risk mitigation plan to avoid temperature glitch
• Real time temperature surveillance and monitoring
• New approach – from Means to Processes
• How to tackle temperature-sensitive shipment?
Yoram Eshel, Senior Director, Global Transportation and Logistics, Teva Pharmaceuticals

14.10  Remote QP Assessment of ATMPs and Supply Chain Controls
• Introduction to ATMPs
• Special requirements for ATMP supply chains
• QP oversight of the ATMP supply chain
• Challenges presented by remote assessment
Tim Holliday, Qualified Person, PCI Pharma Services

14.50  Afternoon Tea & Networking Break

15.20  Future Challenges for the Cell-and Gene Therapy Supply Chain
• Summary of the current supply chain
• Future growth as an operational pressure
• Enabling a viable cell and gene therapy supply chain at commercial volumes
Simon Ellis, Head of Commercial, Cell Therapy Catapult

16.00  Cold Chain Board Room – Roundtable Discussion Part 1
Take advantage of this Executive Roundtable session to engage in interactive and open dialogue with industry colleagues to seek common solutions to your CCD problems!
• How to interpret and translate GDP regulations into everyday practice?
• Quality assurance and validation – how to mitigate risks and what measures should we take to enhance QA study?
• 3PL engagement – due diligence and collaboration: Challenges with contractors and sub-contractors
Moderated by:
Mark Edwards, Managing Director, Modalis Ltd
Stephen Mitchell, Quality & Compliance Manager, Global Logistics, GSK

16.40  Chairman’s Closing Remarks and Close of Day One

17.00  Drinks Reception  Hosted by World Courier

Register online at: www.coldchain-distribution.com
**Cold Chain Distribution**  
**Day Two**  
<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>08.30</td>
<td>Registration &amp; Coffee</td>
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| 09.00 | Chairman’s Opening Remarks  
David Spillett, Key Account Director, World Courier |
| 09.10 | OPENING ADDRESS: Exploring the Optimal Temperature-Controlled Freight Options  
• Is air freight still the best solution?  
• Experience so far on ocean freight: Quality of supply chain  
• Constraints and scheduling considerations  
• What if things go wrong? Defining responsibilities and insurance strategy upfront  
• Looking beyond – other options  
Saddam Huq, Senior Manager, Quality for Distribution & Cold Chain Management, GSK |
| 09.50 | An Evaluation of Transport Modes for Pharmaceutical Shipments  
• Characteristics of each freight mode  
• Risks and benefits of the varying modes  
• Analysis of speciality (pharmaceutical) services  
Mark Edwards, Managing Director, Modalis Ltd |
| 10.30 | Morning Coffee & Networking Break |
| 11.00 | What can the pharmaceutical industry learn from the food cold chain?  
• What technologies developed for the food cold chain are directly applicable for pharmaceutical industry  
• Discovering cost-reduction strategies without jeopardising product quality  
• How to manage risks  
Stephen James, Director, Food Refrigeration & Process Engineering Research Centre (FRPERC), The Grimsby Institute |
| 11.40 | Blood Supply Temperature Control Chain  
• Protecting donations  
• Regulatory and safety environment  
• Effective, low cost solutions  
Dave Edmondson, Head of Manufacturing and Product Development, NHS Blood & Transplant |
| 12.00 | Reliability in Cold Chain Air Transports  
• Understanding your customer needs  
• Improved transparency in pharma air cargo transports  
• Value through customer collaboration  
Fredrik Wildtgrube, Head of Global Sales, Finnair |
| 12.50 | Networking Lunch |
| 13.50 | Direct-to-Patients: Translating Thoughts into Actions  
• Why would last mile distribution be different and more challenging?  
• It’s not just about technology but ethics  
• Developing a pioneering customer-centric distribution strategy and supporting activities  
Didier Basseras, Vice President, Clinical Supply Chain Operations Head, Sanofi R&D |
| 14.30 | KEYNOTE ADDRESS: Inspired by Supply Chain in Africa  
• Supply chain set-up in an epidemical region  
• Cultural differences and how to cope with it  
• How we all can make a difference  
Gino Vleugels, Senior Manager Temperature Control EMEA, Johnson & Johnson |
| 15.10 | Afternoon Tea & Networking Break |
| 15.40 | Selecting Your Long-Lasting Partners  
• Partner qualification – screening of your contractors and sub-contractors for their competencies  
• Understanding local compliance and clearing potential risks  
• On-going partner management  
Robert Potts, Director, International Quality, Vertex Pharmaceuticals (Europe) Ltd |
| 16.20 | Cold Chain Board Room  
– Roundtable Discussion Part 2  
Take advantage of this Executive Roundtable session to engage in interactive and open dialogue with industry colleagues to seek common solutions to your CCD problems!  
• Streamlining your cold chain operations while adapting to the increasingly complex supply chain requirements  
• How to work with your suppliers and 3rd parties in a compliant manner – defining liabilities and responsibilities  
• What do you need most for a temperature-controlled distribution operation? Technologies or protocols?  
**Moderated by:**  
David Spillett, Key Account Director, World Courier  
Mark Edwards, Managing Director, Modalis Ltd |
| 17.00 | Chairman’s Closing Remarks and Close of Day Two |

**HOW DO YOU SHIP?**

**EMERGING MARKETS – ARE THEY STILL EMERGING?**

**KEYNOTE ADDRESS: Inspired by Supply Chain in Africa**

**Selecting Your Long-Lasting Partners**

**Cold Chain Board Room**  
– Roundtable Discussion Part 2  
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David Spillett, Key Account Director, World Courier  
Mark Edwards, Managing Director, Modalis Ltd
Cold Chain Distribution
12th - 13th December 2016

**Who should attend this conference:**
You should attend this event if you work in the Pharmaceutical Industry with responsibilities in supply chain, cold chain, logistics, distribution, packaging, operations, production, manufacturing, quality assurance and compliance.

**Audience include:**
Directors, VPs, Chiefs, Heads, Principals, Managers of:
- Cold Chain
- Logistics
- Distribution
- GMP Compliance/ Inspection
- Packaging
- Clinical Logistics
- International Supplies
- Quality Assurance & Compliance
- Operations
- Manufacturing
- Demand Planning & Customer Operations

**Cold Chain Distribution Attendees 2014 and 2015 by Industry Sector**

- Pharmaceutical 56%
- Suppliers 35%
- Regulatory 7%
- Academia 2%

**Cold Chain Distribution Attendees 2014 and 2015 by Region**

- UK 45%
- USA 13%
- APAC 7%
- Europe 35% (excluding UK)

**Cold Chain Distribution 2015 Attending Organisations Included:**
- Abbott
- Actelion Pharmaceuticals UK Ltd.
- Baxalta
- Cell Therapy Catapult
- Genzyme Corporation
- GlaxoSmithKline
- GW Pharmaceuticals Ltd
- GlaxoSmithKline
- Hexal AG
- MHRA
- Mundipharma International
- Norgine Ltd
- Pfizer
- Roche
- Sandoz International GmbH
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