

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**

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# Cold Chain Distribution

Day One | Monday 12th December 2016

08.30 Registration & Coffee

09.00 **Chairman's Opening Remarks**  
Tony Wright, CEO, Exelsius



## ARE YOU GDP COMPLIANT?

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**

## HOW COLD SHOULD IT BE? OVERCOMING TECHNICAL COLD CHAIN CHALLENGES

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
- 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**

## COLD CHAIN DISTRIBUTION PLANNING

15.20 **Future Challenges for the Cell-and Gene Therapy Supply Chain**

- Background of the Cell and Gene Therapy Catapult and how we enable companies to move forwards?
- 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 Ellison**, Head of Commercial, **Cell and Gene 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**



### Leading Media Partners



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### 08.30 Registration & Coffee

### 09.00 Chairman's Opening Remarks



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

### HOW DO YOU SHIP?

### 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 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**

### 11.40 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**

### 12.20 Networking Lunch

### 13.30 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**

### EMERGING MARKETS – ARE THEY STILL EMERGING?

### 14.10 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**

### 14.50 Afternoon Tea & Networking Break

### 15.20 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**

### 16.00 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**

### 16.40 Chairman's Closing Remarks and Close of Day Two

\*Session details subject to final confirmation

Want to know how you can get involved? Interested in promoting your services to this market?

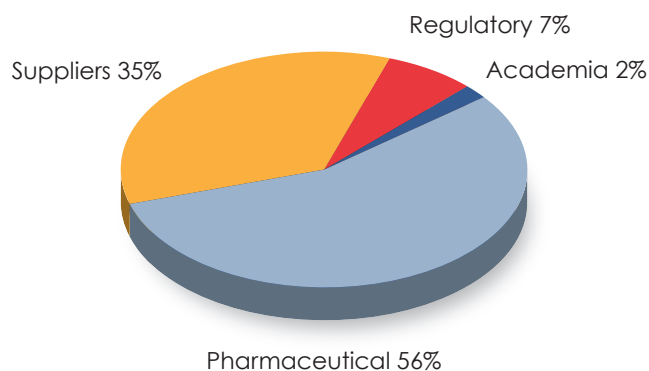
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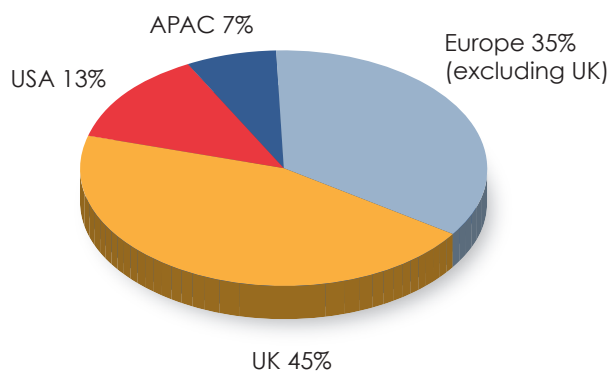
# Cold Chain Distribution

12th - 13th December 2016

Cold Chain Distribution Attendees  
2014 and 2015 by Industry Sector



Cold Chain Distribution Attendees  
2014 and 2015 by Region



## 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 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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  - Napp Pharmaceuticals
- and many more...

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# COLD CHAIN DISTRIBUTION

Conference: Monday 12th & Tuesday 13th December 2016, Park Plaza Victoria, London, UK

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