

SOFRIGAM will be attending Cool Chain Europe in January. We would really like you to join us there and it is our pleasure to be able to offer you a **15% discount** for the event. Please contact a representative at Pharma IQ via the channels below quoting **CCE/SOFR**, who will facilitate this for you.



presents the 10th annual

COOLCHAIN EUROPE 2011

24 - 26 January, 2011
World Trade Centre,
Rotterdam, The Netherlands

Network with 400 professionals at Europe's largest Cool Chain event



Ensuring Cost-Effective, Quality-Driven Temperature-Controlled Transportation and Logistics

Solve your cool chain logistics challenges and shape ideas for the future by discussing how to:

- **Establish effective operational procedures for ocean freight** - hear how **AstraZeneca**, **Merck**, **PCCIG** and **APL** are defining processes for temperature monitoring in a reefer, developing contract and quality agreements and consolidating shipments
- **Ship perishable pharmaceuticals effectively by air** - **WHO**, **Abbott**, **Schiphol Airport** and **Amgen** show you how to overcome air capacity challenges and ensure compliance in the air and on the ground
- **Demonstrate temperature control and regulatory compliance** - join **Janssen**, **Pfizer** and **Sentipharm** as they discuss best practice approaches to collecting sufficient stability data and developing effective agreements with customers and partners
- **Minimise risk in your cool chain** - learn how **Abbott**, **MSD**, **Novo Nordisk** and **ActoGeniX** are conducting FMEA and risk analyses and integrating risk management into the QMS
- **Develop distribution strategies for all temperature ranges** - **Pliva** and **Vitrolife** discuss thermal mapping routes, optimal air transport processes for CRT and working with supply stakeholders to implement quality processes

www.coolchaineurope.com/sofrigam

PLUS, 10 more reasons why you can't afford to miss this event:

- **Tour of the Port of Rotterdam** - a one off networking and educational opportunity!
- **LOGISTICS LEADERS** focus day - no presentations, 100% high level discussion
- **OCEAN REEFER DEPOT SITE VISIT** - get 'hands on' with reefer technology
- **COOL CHAIN AWARDS** - YOU have the say
- **IATA Ch. 17 Training** - become certified in perishable air freight logistics
- The brand new **SURVEY SESSION** - real-time results on burning questions
- Four **TAILORED STREAMS** focusing on your key areas of concern
- **THREE INTERACTIVE WORKSHOPS** focused on clinical supply, sustainable packaging and risk assessment
- The **LARGEST EXHIBITION** of cool chain solutions in Europe
- And **20+ HOURS** worth of interactive discussion and debate with industry leaders

Attend the industry's most recognised cold chain event and engage with 35+ forward-thinking speakers including:

-  **Rafik H. Bishara**, PhD, Technical Advisor and Chair PCCIG USA Branch, **PDA**
-  **Dr. Mary Foster**, Chair, Packaging and Storage Expert Committee, **US Pharmacopeia (USP)**
-  **Ian Holloway**, Manager, Defective Medicines Reporting Centre, **MHRA**
-  **Cornelia Nopitsch-Mai**, Scientist, Federal Institute for Drugs and Medical Devices Germany, **BFARM**
-  **Umit Kartoglu**, Technical Officer and Scientist, **World Health Organisation**
-  **David A Ulrich**, QA Director - Distribution, Global Pharmaceutical Operations, Strategic Quality Initiative, Distribution QA, **Abbott Laboratories**
-  **Lisa Mazzoni**, Project Lead, Temperature Controlled Supply Chain, **F. Hoffmann-La Roche**
-  **Anna Hallgren**, Senior Logistics Specialist, **Vitrolife Sweden AB**
-  **Saddam Huq**, Cold Chain Technology Lead, **Pfizer Pharmaceuticals**
-  **Steve McCarney**, Cold Chain Technologies Specialist - Project Optimize, **PATH**
-  **Ian King**, Global Logistics Regional Leader, Middle East and Africa, **Pfizer**
-  **Jon E. Ross**, Senior Manager, Supply Chain Operations, **Seattle Genetics**
-  **Jens Lamberth**, Global Category Manager, **AstraZeneca**
-  **Erik Van Asselt**, Cold Chain Improvement Manager, Vaccines, **Merck Sharp & Dohme BV**
-  **Søren Kåre Nielsen**, Quality and Projects, Shipping and Customer Service, **Novo Nordisk A/S**
-  **Eric Eng**, Vice President, Global Reefer Trade, **APL Co Pte Ltd**
-  **Sam Corveleyn**, Director CMC & QP, **ActoGeniX N.V.**
-  **Robert-Jan van den Bos**, Senior Distribution Manager, **Amgen**
-  **Rikke Ulslev Degn**, Project Manager, CMC Clinical Supplies, **Novo Nordisk**
-  **Bart Pouwels**, Director Business Development, **Amsterdam Airport Schiphol**

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10th Anniversary

COOLCHAIN EUROPE 2011



Dear Colleague,

We've been sitting on the edge of our seats for months waiting to bring you Cool Chain Europe's Anniversary edition!

Ten years on from our first ever conference on the subject and business for temperature controlled shipping is booming. According to Pharmaceutical Commerce's first ever study into the area, the North American market is projected to continue to grow by 5% a year, while *"the global market will show a growth rate of double that"*.

Indeed, *"based on projected market growth rates, seven of the top ten global pharma products in 2014 will require cold chain handling"*.

With this type of growth on the horizon, the need for sharing best practice solutions and processes in handling these products is paramount. As the longest running event in this area, we have pulled out all the stops in 2011 to bring you a host of new formats and sessions to give you the tools you need to succeed in this competitive market space including:

- A brand new Focus Day designed specifically for Logistics Leaders
- A tour of the Port of Rotterdam
- A visit to an ocean reefer depot
- 2 day intensive training for IATA Chapter 17
- "Open microphone" regulatory discussions with the US Pharmacopeia (USP), BFARM and the MHRA
- Interactive survey sessions: Instant results from hand-held devices will provide you with the opportunity to bench mark against your peers on the industry's most important issues

In addition, we will be providing everything you've come to expect from the largest Cool Chain event in Europe – hours of networking opportunities, two solid days of industry case-studies, streamed content on the industry's hottest issues and the long awaited Cool Chain awards ceremony that will pay homage to the biggest and best achievements in the industry.

Join us at Cool Chain Europe 2011 as we bring you strategies for dealing with the TOP 5 CONCERNS facing the industry today including:

- Overcoming tightening air capacity
- Ensuring cost control of expensive cool chain logistics
- Fixing the leaks with air freight and closing the gaps when working with carriers, cargo handlers and airports
- Maintaining security and visibility in the cool chain
- Attaining regulatory readiness and compliance with international cool chain regulations

Don't miss Europe's largest, most comprehensive learning and networking forum. Sign up today!

The speakers, sponsors and Advisory Board look forward to seeing you next January for the 10th Annual Anniversary Cool Chain event.

Sincerely,

Courtney Becker-James
Event Director
Cool Chain Europe
IQPC

With great thanks to the 2011 Executive Advisory Board for their time, expert insight and continuing support

Gert-Jan van Diest, QA Project Manager,
Abbott Logistics BV

Robert-Jan van den Bos, Senior Distribution Manager, **Amgen**

Jens Lamberth, Global Category Manager,
AstraZeneca

Martin Peter, Director, Cold Chain Operations,
ELPRO

Lisa Mazzoni, Project Lead, Temperature Controlled Supply Chain, **F. Hoffmann-La Roche**

Erik Van Asselt, Cold Chain Improvement Manager, Vaccines, **Merck Sharpe and Dohme and Chair PCCIG EU**

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

Richard Peck, Head of Technical Systems,
Softbox

Henry Ames, Director Strategic Marketing,
Sensitech

Ian Buck, Director European Sales, **Thermosafe**

Meet Your Respected Peers and Supply Chain Partners at the Industry's Leading Temperature Control Logistics Event

Cool Chain Europe 2010 was attended by 369 people from 181 different organisations including:

Industry Breakdown



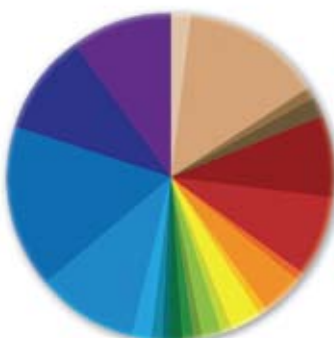
- Pharmaceutical and Medicine Manufacturing
- Pharmaceutical Preparation Manufacturing
- Bio-Technology
- Food and Beverage
- Veterinary Services and Products
- Medical Equipment and Supplies Manufacturing
- Air Transportation
- Logistics, Cargo and Storage Providers
- Other Transportation
- General Freight Trucking
- Airport Operations
- Marine Cargo Handling
- Couriers
- Supply Chain Management Solutions
- Management Consulting Services
- Semiconductor Machinery Manufacturing
- Business Support Services
- Packaging and Labeling Services
- Health Care and Social Assistance

Job Function Breakdown



- Logistics Head/Director/Manager
- Distribution/Warehousing Head/Director/Manager
- Transport Head/Director/Manager
- Supply Chain Engineer/Manager/Director
- Purchasing/Procurement/Buyers Director/Manager
- Export Manager
- Operations Head/Director/Manager
- Facility Head/Director/Manager
- CEO/MD/VP/Exec Dir/Chief Exec, President
- Strategic Development Manager
- Management Services Director/Manager/Head
- Quality Head/Director/Manager
- Six Sigma/Champion
- Business Development Director/Manager
- Sales/Marketing
- Production/Process/Manufacturing

Region Breakdown



- Austria
- Belgium
- Croatia
- Denmark
- France
- Germany
- Hungary
- Ireland
- Israel
- Italy
- Lithuania
- Luxembourg
- New Zealand
- Norway
- Slovenia
- South Africa
- Spain
- Sweden
- Switzerland
- Netherlands
- United Kingdom
- United States

- AAC Capital Partners
- Abbott France S.A
- Abbott Healthcare Products B.V.
- Abbott Laboratories
- Abbott Logistics BV
- Actavis UK Ltd.
- ActoGenix NV
- Air Cargo Transportation
- Security Administration
- Air France – KLM Cargo
- AirBridgeCargo Airlines, LLC
- Airforwarders Association
- Alcon Couvreur NV
- ALK-Abelló
- Allergan Services International Ltd.
- Almac Group Ltd.
- Ambient Systems
- American Airlines Cargo
- Amgen
- Amsterdam Airport Schiphol
- APRC General Hospital
- Aptuit Inc
- Cold Chain Technologies
- Coldpack
- Continental Airlines Cargo
- Cooltrans TDL Group
- Crucell Holland B.V.
- Cryopak
- CSafe, LLC
- DACHSER GmbH & Co. KG
- Delta Cargo delta T
- DEPOLABO
- DGP Group
- DHL Logistics Switzerland Ltd
- Domestic Sarl
- Dryce Italia S.r.l.
- DSM Biologics
- Dutch Health Care Inspectorate
- ELPRO
- Emballiso SA
- Entropy Solutions
- Envirotainer
- Escort Data Loggers
- Esoterix Clinical Trials
- Services BVBA
- Eurofins
- Exam Packaging
- Exelsius Ltd
- F. Hoffmann-La Roche Ltd
- Fairbridge Technologies
- Federal Ministry of Health, Austria
- FedEx
- FedEx Custom Critical
- Fermentas UAB
- Fisher Clinical Services UK Ltd.
- Fisher Scientific
- Genzyme
- Genzyme Ireland Ltd.
- Geodis Wilson
- GlaxoSmithKline
- Globex Couriers GmbH
- Globopharm AG
- GSK Biologicals
- H. Lundbeck A/S
- Hospira
- IATA Time & Temperature
- Task Force
- Panalpina World Transport
- PATH
- Pauwels Consulting/Genzyme
- PDA
- Penn Pharmaceuticals
- Pfizer
- Pfizer Manufacturing Belgium
- Power ID
- Salviae d.o.o.
- Samedan Ltd.
- Sanofi Pasteur
- Sanofi-Aventis Deutschland GmbH
- Sanquin
- Savsu
- SCA Cool Logistics
- Schering Plough SpA
- Schering-Plough Labo NV
- Sensitech
- Sofrigram
- Softbox Systems Ltd.
- Solvay Biologicals BV
- Spedition Kautetzky GmbH & Co. KG
- SPMSD
- Swiss International Air Lines Ltd.
- Tabriz Consulting Limited
- Talecris Biotherapeutics
- Talecris Biotherapeutics GmbH
- Arvato Distribution GmbH
- AstraZeneca
- Austrian Airlines
- AviaPartner Cargo BV
- B & C Group
- Bavarian Nordic AS
- Baxter SA
- Bayer Diagnostics
- Bayer Schering Pharma
- Beckman Coulter Inc
- Berlinger & co AG
- Bio-Bottle New Zealand Ltd
- Biocair International Ltd
- Biogen Idec
- Biotest AG
- Boehringer Ingelheim GmbH
- Bristol Myers Squibb
- CAEN RFID s.r.l.
- CAPPI
- Cargologic Ltd.
- Celgene International Sárl
- Intervet International B.V.
- J. van de Put Fresh Cargo Handling
- Jan de Rijk Logistics
- Janssen Pharmaceutica
- Johnson & Johnson
- Kales Airline Services
- Kalibox SAS
- Kern Frio
- Kerry Logistics
- Knauf Industries
- Kryotrans International
- Kuehne + Nagel S.a.r.l.
- Kuehne and Nagel Ireland Ltd.
- Laminar Medica
- LifeConEx
- Lindt & Sprüngli (International) AG
- Logesta
- Logica Management Consulting
- Lundbeck
- Marken Ltd.
- Maxim Integrated Products Ltd
- Maya Deutschland GmbH
- MAYA Simulation
- MBI Aero
- Medicines and Healthcare products Regulatory Agency
- Merck Sharp & Dohme BV
- MHRA
- Midwest Clinical Supplies Group, Inc
- Minnesota Thermal Science
- Movianto Belgium
- Movianto UK Ltd.
- MSF Logistique
- MSF Supply
- Nederlands Vaccin Instituut
- Nomeco A/S
- Norwegian Institute of Public Health
- Novartis
- Novartis Vaccines & Diagnostics
- Novo Nordisk A/S
- NXP Semiconductors Austria GmbH Styria
- Ole
- Omxix Biopharmaceuticals
- Oriola OY Reform-Keskus
- OSI Pharmaceuticals, Inc
- TCP
- TDL Group
- Tegrant
- Teva Pharmaceutical Works Ltd.
- Thermosafe
- TNT Express
- Topa Instituut
- Topa Packaging
- Topa Verpakking B.V.,
- Topo Target
- TSA/TSNM
- UCB
- UCB Pharma SA
- United Cargo
- UTI Pharma
- UTI USA Inc
- UTI Worldwide
- Va-Q-Tec AG
- Viessmann Technologies GmbH
- Vitrolife Sweden AB
- VTS H.Verdijk Int. Transport b.v.
- WABCO
- Wockhardt UK Ltd.
- World Courier
- World Health Organization

“Very valuable, as always.”

Bristol-Myers Squibb

“Good opportunity to meet peers and gain understanding of new regulations – very valuable.”

Amgen Europe BV

“Great ‘state of the art’ update on temperature sensitive clinical trial suppliers!”

Actogenix Belgium

Pre-Conference 'Discussion Only' LOGISTICS LEADERS Focus Day: 24th January 2011

No presentations - just discussions. This Focus Day will provide logistics leaders with the opportunity to share ideas, challenges and strategies with other logistics leaders in an informal, 'no holds barred', open dialogue forum. Join your senior logistics, supply chain and QA peers for leader-to-leader debates of today's most critical challenges in setting up effective global processes for shipping temperature sensitive products internationally.

Participants will generally be manager level or higher, have responsibility for P&L of a distribution centre or cost control of distribution operations, report to senior management and/or have a global role in an organisation.

No presentations, no self-publicity – strictly business to business knowledge sharing only.

You can submit your key challenges and requests for discussion to the group ahead of time by sending them to courtney.becker@iqpc.co.uk

08.00 Registration and Coffee

08.30 Opening Remarks Chairperson

09.05 Creating an Effective Distribution and Warehousing Strategy

- Direct-to-Pharmacy (DTP) distribution: Maintaining the temperature control supply chain
- Home-delivery of medicines
- Adapting cold chain operations to deliver quicker and at smaller volumes DTC
- Distribution and warehousing strategy for a multi-national/global company: Evaluating outsourcing options, cost-drivers and impact of distribution channels
- Lessons learned from the volcano ash chaos

Discussion Leader: Alan J. Davis, Supply Chain Temperature Control Leader, **Johnson & Johnson**

10.05 Morning Coffee

10.35 A Global Quality Cool Chain System

- Defining a Global Quality Management System for the cool chain
- Examining the drivers for centralisation and standardisation of global cool chain processes
- Qualifying transport partners
- Standardising the qualification process
- Temperature excursion management
- Applying international cold chain best practices to help enter new markets by using sufficient communication and guidance documents
- Best practice quality and technical agreements: Integrating QA into logistic operations

Discussion Leader: Gert-Jan van Diest, QA Project Manager, **Abbott Logistics BV**

11.35 Lunch

12.20 Good Distribution Practices

- How can the organisation be structured in a way that embeds QA into the logistics operations?
- Risk based approach versus 100% risk averse: What level of risk can we take and how do we assess/control it?
- Linking security standards into the operations as much as quality
- Logistics challenges growing into emerging markets (quality, local reg. bodies /requirements, security)

Discussion Leaders: Robert-Jan van den Bos, Senior Distribution Manager, **Amgen**
Martine Nolan, Senior Manager, Quality Assurance, **Amgen**

13.20 Afternoon Coffee

13.45 Working with and Shipping to Affiliates

- Communication and collaboration with affiliates for emergencies such as volcano ash incidences
- Affiliates in distant regions or new markets: Discussions on transportation method, mode and plan
- Barriers to rolling out a fully qualified global solution

Discussion Leader: Lisa Mazzoni, Project Lead, Temperature Controlled Supply Chain, **F. Hoffmann-La Roche**

14.45 Finding Local Partners in New Markets

- Identifying, sourcing and qualifying local transportation suppliers
- Working with regional and local teams to assess risk and conduct market intelligence
- Shortfalls of working with global suppliers
- Understanding the current economic, environmental and petrol usage issues
- Qualifying best temp monitors, decide best metrics to track excursions and how to track cumulative excursions

Discussion Leader: Jens Lamberth, Global Category Manager, **AstraZeneca**

15.45 Close of Focus Day

Pre-Conference Practical Learning Workshops: 24th January 2011

12.30 - 15.30

A) Shipping Temperature Sensitive Clinical Supplies Internationally

The clinical trial supply chain is unique with a huge number of destinations, smaller packaging and added pressure to mitigate risks that could have a severe impact on expensive clinical trials. This workshop will focus on the operating challenges related to clinical trial supply of temperature sensitive IMPs and materials and how companies can establish achievable goals, select the proper tools and leverage cross-functional supply chain capabilities. Key topics include:

- Qualifying insulated boxes and packaging for international studies
- Choosing the right shipping material and solution in regard to route and IMP type
- Temperature monitoring of temperature sensitive IMP shipments with various temperature ranges and stability data
- Evaluation of temperature deviations and decision on action plan following temperature deviation to time-sensitive clinical drugs
- Use of local depots – is it necessary, why and how?
- Develop SOPs with freight forwarders for new distribution routes
- Enforcing strict KPIs and quarterly review meetings with forwarder



Workshop Leader: Rikke Ulslev Degn, Project Manager, CMC Clinical Supplies, **Novo Nordisk**

12.30 - 15.30

B) Managing End to End Transportation Processes to Prevent Loss and Minimise Risk

How do you control your cold chain? "Control" means, to check, monitor and verify by evidence. It should eliminate, prevent, minimise the risk of, and adjust to a requirement. In this three hour session, learn how active intervention management can prevent loss. Indeed, find out how you can answer vital questions such as, 'What is happening? Where it's happening? When it's happening? What is the resolution?' This session will provide you with the tools you need to:

- Prevent loss using proactive alerts
- Utilise historical data for continuous improvement
- Run thorough risk assessments of transportation service providers
- Conduct on-site audits, assessing the where, why and to whom
- Develop contractual agreements (SLA, TA, etc.)
- Create functional SOPs
- Run constructive review meetings

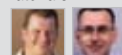
Workshop Leaders: Federico Lupp, Head of Sales Europe and Latin America, **LifeConEx, LLC**

16.00 - 19.00

C) Re-Usability, Return-ability and the Realities of Sustainable Packaging Initiatives

- An overview of the regulatory guidance
- Lifecycle analysis and risk assessment
- Return and reverse logistics
- Re-using passive shipping systems
- Recycling of materials / carbon footprint and the use of environmentally friendly materials

Workshop Leaders: Richard Peck, Head of Technical Systems, **Softbox**
Gert-Jan van Diest, QA Project Manager, **Abbott Logistics BV**



15.45 - 18.30

D) Reefer Depot Site Visit: Understanding the Technology Advancement of Reefers and Temperature Monitoring Capabilities of Ocean Freight

15.45 Registration 16.00 Coaches depart WTC for Port Depot

18.30 Coaches return to WTC

This 'site visit' will take participants to a reefer depot in the Port of Rotterdam to get 'up close and personal' to reefer containers. You will learn from reefer manufacturers and users what the capabilities, technological advancements and in-practice use of reefer technology are. If you are currently running pilots for sending temperature sensitive pharmaceutical via ocean, or are even considering it, you will not want to miss this unique opportunity to understand the key challenges, concerns and abilities of today's reefer technology to handle your life science products.

Why is ocean transport a viable, sustainable and cost effective alternative for pharma companies?

- There are close to a million refrigerated containers in operation today providing unparalleled connectivity across the globe
- Shipping by sea in refrigerated containers is the most carbon-efficient mode of transportation
- Reefer container technology has advanced in recent years to be able to achieve very precise temperature control and back-up sensor protection and fail safe logic ensures that your cargo is always protected
- Reefer containers are also able to achieve very low relative humidity environments that are beneficial while transporting certain types of pharmaceutical goods
- Real-time remote data monitoring provides visibility to your cargo to assure you that it's being carried the way you want it

Site Visit Hosts: **Carrier Transicold** and **Sensitech**

Day One Conference: 25th January 2011

08.00 Registration and Coffee

09.00 Welcome Remarks Pharma IQ

09.05 Opening Remarks Chairperson

Maintaining Critical Temperatures during International Transportation

09.15 Exploring Opportunities for Consolidation of Shipments to Improve Asset Utilisation and Decrease Transportation Cost

- Balancing cost with quality: Quality as a determining factor for deciding which transportation mode, lane and partner to use
- Assessing LTL and LCL opportunities
- Results of an FMEA analysis on LCL
- Use of combi-trucks (2-8C + 15-25C)
- Understanding the effect of loading CRT products in cool trucks



David A Ulrich, QA Director - Distribution, Global Pharmaceutical Operations, Strategic Quality Initiative, Distribution QA, **Abbott Laboratories**

09.50 Air Cargo Capacity: The Future of Transporting Vaccines to Developing Countries

This presentation will give an evaluation of the airline industry's ability and challenges in meeting the future transport demands of the World Health Organisation (WHO), including:

- Key drivers for increased cubic volume of vaccines, pharmaceutical and biologics
- An overview of the state of the airline / air cargo industry
- Current and future survival scenarios
- Understanding fleet, routes and consolidation factors
- Analysing the regions/airports that are of most concern
- The domino effect
- Effective approaches to overcoming the challenges



Umit Kartoglu, Technical Officer and Scientist, **World Health Organisation**

10.25 Ensuring That Airport Facilities and Infrastructure Maintain Required Temperatures

- The airport authority's role in ensuring product quality, working with airlines and having an influence on the cold chain process
- Examining the infrastructure challenges at some large international airports
- Quality measures and accountable action plans that airlines have in place with airports to ensure temperature control
- Establishing a collaborative approach between the shipper, freight forwarder, airline and airport authority



Bart Pouwels, Director Business Development, **Amsterdam Airport Schiphol**

10.55 Morning Networking Break in Exhibition Arena

Join your peers to browse the 2011 Solution Hall. Open across the 2 days this is where you'll be able to find all the latest packaging/container, transportation, logistics, temperature monitoring and data management solutions. The ideal place to meet existing and new partners!

13.15 Networking Lunch

Discuss the morning's presentations and current concerns with like-minded colleagues by joining the networking lunch with peers in QA, logistics, technology development or packaging.

Track A: Improving the Performance of your Cool Chain Packaging

14.30 Assessing Cost-Effective "Last Mile" Packaging Solutions that Ensure Patient Safety and Product Efficacy

- Identifying the needs of the product and the needs of the patient
- Defining a solution: Finding a portable, small, 2-8C 'user-friendly' packaging solution
- A global solution that may easily be implemented by affiliates and their pharmacy partners
- Understanding the qualification process
- Completing the cold chain process by ensuring temperature control in the very last mile - from pharmacy to patient



Lisa Mazzoni, Project Lead, Temperature Controlled Supply Chain, **F. Hoffmann-La Roche**

15.05 How to Implement Cost-Containment and 'Green' Improvements in your Cold Chain Logistics

After several years of testing, Sofrigram has worked with pharmaceutical clients to develop a solid understanding and capabilities for a successful and cost-effective implementation of 'green' logistics. This presentation will be based on practical case study results and discuss:

- What does "green" mean in a logistics strategy?
- When, where and how you have to act
- How to evaluate results and benefits



Gilles Labranque, Managing Director, **Sofrigram**

15.40 Case Study: Designing a High Performance Cold Chain Shipping Systems

- Utilising both vacuum panel insulation and custom phase change materials
- Assessing materials cost vs. reusability benefits
- Integrating new packaging systems into day to day operations

Fabian Eschenbach, Manager, **va-Q-tec AG**

15.55 Afternoon Networking Break

11.25 Novel Technologies Shaping the Future of Vaccine Transport, Storage and Logistics

Project Optimize, a collaboration of WHO and PATH, has been given a unique mandate to identify, develop and test solutions to help supply chains keep up with rapidly advancing vaccine and delivery device technologies needed to safely and effectively deliver needed vaccines to middle and low income countries. This presentation will examine in-progress collaborative demonstration projects to assess the impact of technology innovations on the efficiency and sustainability of supply chain and logistics systems and the availability and quality of products that move through the system. Points include:

- Thermos table vaccines stored out of the traditional cold chain yet in a "controlled temperature chain"
- Longer term passive storage containers
- Solar "battery free" vaccine refrigerators
- "Zero energy" cold chain including electric vehicles
- Further examples from demonstration projects in Albania, Guatemala, Senegal, South Africa, Tunisia and Vietnam



Steve McCorney, Cold Chain Technologies Specialist - Project Optimize, **PATH**

12.00 Panel Discussion: Temperature Monitoring Methodologies for Different Stages of the Drug Supply Chain

This panel will review the risk-based decision process and criteria that led to different monitoring methodologies employed for different stages of the drug supply chain - while ensuring the goal of product quality and patient safety. An explanation of when full time/temperature data loggers are used, as well as, when temperature indicators are employed for later stage (direct-to-site) shipments will be given. Points for discussion include:

- Regulatory pressures and requirements to monitor to the patient
- The impact of mail order and home delivery care distribution methods
- Temperature monitoring and deviation training methods
- Product release/quarantine processes
- Reduction in excursion trends
- Workload and QA staffing required
- Utilisation of stability data



Moderator: Henry Ames, Director, Strategic Marketing, **Sensitech**

12.35 Survey Session

The purpose of Cool Chain Europe is to share best practice and benchmark practices with other companies. This survey session will ask several questions examining the 'state of play' within the temperature control logistics industry. 400+ conference participants will enter their answer into a hand-held device. The information will be calculated 'live' and shown in graph format on the conference screen within minutes. Sample survey questions include:

- What % of your shipments are ambient 15-25C?
- What mode of transport is currently increasing for the distribution of your temperature sensitive finished products?
- What are your key geographic growth markets you're shipping to/from?

For sponsorship opportunities, contact Gal Cohen +44 (0)20 7368 9300 or sponsorship@iqpc.co.uk

Track B: Understand Industry Approaches to CRT and Ambient Temperature Strategies

14.30 Controlled Room Temperature (CRT) Case Study: Temperature Studies and Quality Issues

- Overview on current and future logistic operators roles and responsibilities
- Working with stakeholders to implement quality processes
- Thermal blankets validation
- Temperature monitoring: Friend or foe?
- Thermal mapping transport routes
- Improving air transport processes for CRT products



Zvonimir Majic, Manager Distribution, Croatia Operations, Supply Chain, **PLIVA**

15.05 Cost-Effective Shipment and Supply of Medical Devices World-Wide

- The temperature control distribution challenges of a small, global medical device company
- Overcoming limited economical and personal resources
- Assessment and implementation of cost-effective packaging
- Working closely with freight forwarders to ensure cost-effective distribution
- Distribution challenges due to the 'Ash Cloud 2010'



Anna Hallgren, Senior Logistics Specialist, **Vitrolife Sweden AB**

15.40 Afternoon Networking Break

Track A: Improving the Performance of your Cool Chain Packaging**16.25 Case Study: Cold Chain Shipping Validation of a Complex Global Pharmaceutical**

- Seattle Genetic's supply chain structure and challenges
- Temperature requirements of complex antibody products
- Assessing and selecting active and passive systems most suitable for the products
- Setting validation design parameters and expectations
- Sharing validation results



Jon E. Ross, Senior Manager, Supply Chain Operations, **Seattle Genetics**

17.00 Meeting Future Challenges in Global Temperature Controlled Shipping

- A case study of Pharmerging markets: Demonstrating effective operational procedures for shipping to new markets
- Fit for purpose: Designing packaging solutions to meet specific criteria and certain temperature ranges
- Total cost of ownership: Calculating the packaging cost per liter volume shipped
- Assessing sustainability initiatives for today's temperature control shipping of pharmaceuticals



Steve Healy, Sales and Marketing Manager, **SCA Cool Logistics**

17.35 Phase Change Materials (PCMs) Test Results: Assessing How Product Integrity is Maintained Whilst Enhancing Performance, Increasing Operational Efficiency and Ensuring a Company's Sustainability Profile

- Maintaining product integrity at <-20, 2-8, 15-25C
- Can materials be combined to increase stability / enhance a package's performance?
- Are reductions in size, weight and volume of packages achievable with PCMs?
- Can the use of PCMs simplify your packing operations and increase efficiency in a high pressure warehouse environment?
- Recycle, re-use or retain? Which fits your distribution / business model?



Prakash Mahesh, Vice President, Marketing and Business Development,



ThermoSafe

Ken Maltas, Vice President, Engineering, **ThermoSafe**

18.10 Closing Remarks**18.15 Networking Drinks Reception****19.30 Cool Chain Europe Gal Dinner and Excellence Awards 2011**

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- **Best Temperature Control Logistics Project**
- **Best Quality, Qualification or Risk Management Project**

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**Day Two Conference: 26th January 2011****08.00 Morning Coffee****08.50 Opening Remarks Chairperson**

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

Regulatory Readiness and Preparedness**09.00 United States Pharmacopeia (USP) <1079> Regulations and Future Supply Chain and Packaging Initiatives**

- Agenda and timelines for the USP Packaging and Storage Expert Committee: How industry can get involved
- Final edits to <1079> including:
 - Quality Management System (QMS)
 - Storage Management System (SMS)
 - Transportation Management System (TMS)
 - Environmental Management System (EMS)
- New Chapters for discussion including Anti-Counterfeiting and Supply Chain Best Practices



Dr. Mary Foster, Chair, Packaging and Storage Expert Committee,
US Pharmacopeia (USP)

Track B: Integrating and Utilising Temperature, Stability and Supply Chain Data**16.25 Pfizer Operational View: Developing Best Practice Company Guidelines for Global Shipment Tracking and Release**

- Retrieval, storing, tracking of temperature sensitive data
- Trending of temperature data for individual lanes
- Excursion management



Saddam Huq, Cold Chain Technology Lead, **Pfizer Pharmaceuticals**

17.00 Pfizer QA View: Temperature Excursion Management During Transport and Integrating Temperature Data

- Definition of the product transportation temperature range vs. label claim
- Evaluation of temperature excursions relative to the quality and compliance impact
- Perspectives on the evaluation/ investigation of excursions including MKT and stability data



Ian King, Global Logistics Regional Leader, Europe, Middle East and Africa, **Pfizer**

17.35 PCCIG Panel Discussion Stability Data Generation and Sharing of that Data

- Discussing the current gap in international guidance and developing a consensus for industry best practices
- Collecting the appropriate stability data to support wider shipping ranges
- The possibilities and risks of shipping outside label claim
- Sharing data with customers and partners for licenses, quality agreements and stability testing
- Flat data or mean kinetic temperatures?
- Russia's new requirement: The shipping condition has to be part of the case label and the shipping documents



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



Panellists:

Ian King, Global Logistics Regional Leader, Middle East and Africa, **Pfizer**



David A. Ulrich, QA Director - Distribution, Global Pharmaceutical Operations, Strategic Quality Initiative, Distribution QA, **Abbott Laboratories**

10.50 German National and European Requirements for GDP and Cold Chain Processes

- An overview of the guidelines which refer to GDP
- Requirements for GDP and cold chain processes
- Stability data for API and drug products requiring cold chain storage
- Stability issues relating to pharmaceutical bulk products



Cornelia Nopitsch-Mai, Scientist, Federal Institute for Drugs and Medical Devices Germany, **BFARM**

11.30 "Open Microphone" Regulatory Discussion: What are Realistic GDP Regulations for Temperature Control Distribution?

- Reviewing the regulatory trend moving from GMP to GDP: A focus on the supply chain
- Practical realities vs. regulatory expectations
- To what extent should shipping conditions and transport conditions be included into the documentation?



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

Panellists: Ian Holloway, Manager, Defective Medicines Reporting Centre, **MHRA**

Cornelia Nopitsch-Mai, Scientist, Federal Institute for Drugs and Medical Devices Germany, **BFARM**

Dr. Mary Foster, Chair, Packaging and Storage Expert Committee, **US Pharmacopeia (USP)**

**12.30 Networking Lunch**

Discuss the morning's presentations and current concerns with like-minded colleagues by joining the networking lunch with peers in QA, logistics, technology development or packaging.

Track A: Establishing Effective Operational Procedure for Temperature Sensitive Ocean Freight**13.30 Case Study: Assessing the Benefits of Shipping High-Value Pharma via Ocean**

- Pharma consolidation opportunities: Examining the financial benefits of shipping by ocean
- Perceived risks and actual risks: Changeover in ports, on the quay while loading, arrival and delivery
- Security in the port
- Liability - Who's responsible for shipments and temperature deviations?
- Temperature alarms functionalities out at sea and while on the quay



Jens Lamberth, Global Category Manager, **AstraZeneca**

14.10 Case Study: Temperature Monitoring of Ocean Freight and Security in Port: Case Study

- Contract with carrier/ship
- Insurance considerations
- Container flow in the supply chain
- Security in port



Sonja Roeper, Senior Manager South East Asia & China, Distribution Logistics, **Merck KGaA**

14.50 Afternoon Networking Break**15.20 Understanding the Business of a Reefer Ocean Carrier and How Critical Temperatures are Maintained from Origin to Destination**

- Day to day volumes and commodities being shipped by ocean reefer
- Challenges of handling high value and temperature-sensitive products
- Advantages of shipping temperature-sensitive products via reefer containers
- Handling processes for high value and temperature-sensitive cargo
- SMARTemp™: Continuous temperature and humidity monitoring, real-time data and temperature alarms



Case examples: Shipping pharmaceutical and high value products with SMARTemp™
Eric Eng, Vice President, Global Reefer Trade, **APL Co Pte Ltd**

16.00 Panel Discussion: Defining Best Practice Operational Procedures with Ocean Freight Stakeholders

- PCCIG Working Group initiative on ocean shipping: Qualifying equipment and qualifying the process
- Positioning of temperature monitors
- Measuring humidity
- Decreasing condensation
- Dealing with the reefer 'lottery': Not knowing type, age or manufacturer of container will be used for your product
- Contract and quality agreements
- Insurance cost considerations



Panelists:
Jens Lamberth, Global Category Manager, **AstraZeneca**

Sonja Roeper, Senior Manager South East Asia & China, Distribution Logistics,

Merck KGaA

Eric Eng, Vice President, Global Reefer Trade, **APL Co Pte Ltd**

16.40 Closing Remarks from Chairperson and End of Conference

"Very practical and lots of new knowledge. Excellent interaction with Exhibitors."

Galapagos NV

Track B: Developing a Regulatory Compliant Cool Chain Quality System**13.30 Development of a Methodology to Review Global Regulations on Good Distribution Practices to Determine Acceptable Shipping Practices for a Given Country/Region**

Since the various global regulatory authorities have not yet harmonized requirements for the distribution of temperature sensitive products, it is difficult for the industry to develop global solutions. This presentation will provide

- A risk management approach to evaluating shipping practices
- The methodology utilized to assess Global GDP Regulations & Climate Conditions by Country/Region for determining acceptance of alternative shipping conditions based on the products stability data, which is a key element in the risk management model



Gwyn Murdoch, Director of the Materials/Packaging Quality System, **Eli Lilly and Company**

14.10 Novo Nordisk Case Study: Risk Analysis in Shipping

- Risk analysis according to the text book
- What they don't write in the text book
- Sharing firsthand experience



Søren Kåre Nielsen, Quality & Projects, Shipping & Customer Service, **Novo Nordisk A/S**



Morten Duus Eriksen, International Freight Manager, **Novo Nordisk A/S**

14.50 Afternoon Networking Break**15.20 Cold Chain Risk Mitigation: Where to Start?**

- Update on the PCCIG project Risk Management for Temperature Controlled Distribution
- Application of FMEA
- Risks in ocean, road and air transport
- Detecting and analysing potential risks throughout the cold chain
- Integration of cold chain risk management into the QMS



Erik Van Asselt, Cold Chain Improvement Manager, Vaccines, **Merck Sharp & Dohme BV**

16.00 Case Study: Managing External Contractors to Ensure Effective Transfer of Investigational Medicinal Products

- Assessing and selecting sub-contractors for packaging, labelling and clinical "cold chain" supply
- Setting up packaging and distribution processes, KPIs and metrics with partners
- Audit frequency and schedule
- Deciding best practice for packaging temperature sensitive IMPs, temperature monitoring and reporting procedures
- A QP point of view: Assessing temperature excursions and while keeping partners accountable and IMPs safe for administration
- Implementing continuous long-term improvements with partners



Sam Corveleyn, Director CMC & QP, **ActoGeniX N.V.**

"Great event to understand temperature control industry concerns and need – definitely valuable"

Continental Airlines Cargo

IATA Chapter 17 Certified Training: 27 & 28 January 2011

Air Transport Logistics for Time and Temperature-Sensitive Healthcare Products



This two day course provides interactive, competency-based learning and provides the skills and knowledge required to understand the needs of the healthcare industry and be able to successfully handle their temperature-sensitive products in the air cargo logistics process.

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- The globalisation of the healthcare industry and its logistical needs
- Healthcare product distribution in air cargo and the procedures required for handling time and temperature-sensitive shipments
- Correct temperature management and critical control points in the healthcare supply chain
- The role of packaging technology in the distribution process
- The importance and use of Standard Operating Procedures, Service Level Agreements
- The correct use of the new IATA Time and Temperature Sensitive handling label
- Intensify your study of time and temperature-sensitive cargos and the value-added service they require
- Gain understanding of best practices when handling healthcare products
- Gain the skills required to develop operations procedures supporting the handling and transport of healthcare products

The course is designed for:

- Healthcare product manufacturers and shippers
- Ground handlers
- Cargo operations managers
- Cargo agents
- Freight forwarders
- Operational staff of airlines
- Cargo export/import specialists
- Cargo training specialists
- Cargo sales

Course Syllabus

1.	Introduction: The New Perishable Cargo Regulations Chapter 17; Overview of the Global Healthcare Industry	<ul style="list-style-type: none"> • Product types • Increased global regulatory scrutiny 	<ul style="list-style-type: none"> • Globalisation of healthcare production
2.	Understanding Healthcare Logistics	<ul style="list-style-type: none"> • Meeting supply chain challenges • Service level agreements 	<ul style="list-style-type: none"> • Standard Operating procedures • Good Distribution Practice (GDP)
3.	Temperature Management in the Healthcare Supply Chain	<ul style="list-style-type: none"> • Product temperature ranges 	<ul style="list-style-type: none"> • Storage & handling temperature versus product temperature
4.	Packaging Technology	<ul style="list-style-type: none"> • Packaging and thermodynamics • Active /Passive Packaging technologies 	<ul style="list-style-type: none"> • Seasonal configurations • Interactive exercises
5.	Distribution Processes & Procedures: Acceptance and Handling	<ul style="list-style-type: none"> • Critical Control Points (CCP) in the distribution process 	<ul style="list-style-type: none"> • Recommended procedures for acceptance • Preparing and using a checklist exercise
6.	Package Labeling for Healthcare Products	<ul style="list-style-type: none"> • Labeling responsibilities • Proper use of the label 	<ul style="list-style-type: none"> • Temperature indications • Interactive exercises
7.	Quality Management Systems	<ul style="list-style-type: none"> • The role of a Quality Management System • Roles and responsibilities 	<ul style="list-style-type: none"> • CAPA • Training
8.	Review of Healthcare Logistics Best Practice	<ul style="list-style-type: none"> • Course content review 	<ul style="list-style-type: none"> • Interactive exercise
9.	Course Examination	<ul style="list-style-type: none"> • Accreditation process 	

About your Trainers:

Kevin O'Donnell is Director & Chief Technical Advisor to Industry for Tegrant Corporation, ThermoSafe Brands & the Chair of International Air Transport Association (IATA) Live Animals & Perishables Board Time & Temperature Task Force. Recently revised, the IATA's Perishable Cargo Regulations Chapter 17 "Air Transport Logistics for Temperature-Sensitive Healthcare Products," is being used to establish Quality Management System for airlines and their partners, and developing a standardized handling label specific to time- and temperature-sensitive healthcare products. Mr. O'Donnell is retired in 2005 from Abbott Laboratories, as Principle Packaging Engineer, and was responsible for the design, development, qualification and implementation of all temperature controlled distribution packaging for the Abbott Global Pharmaceutical Division. His 26 year career at Abbott included more than 20 years of temperature assurance packaging experience in the Diagnostics Division, the International Division, and Global Pharmaceutical Operations Logistics and Supply Chain. Mr. O'Donnell is a member of the World Health Organization (WHO) Task Force on Regulatory Oversight on Pharmaceutical Cold Chain Management; a member of the USP Expert Committee on Packaging, Storage and Distribution; a founding member of the Parenteral Drug Association Pharmaceutical Cold Chain Discussion Group (PDA-PCCDG, now the PCCIG); Co-author of PDA Technical Report #39.

Tony Wright is Managing Director of Exelsius Cold Chain Management Consultancy in the UK. With over 30 years experience in the air cargo logistics and distribution sector and a further six years leading and developing specific solutions for some key global companies, Tony is a prominent figure in the rapidly growing global temperature controlled airfreight business. Formerly with British Airways World Cargo, Tony initiated the development and building of London Heathrow distribution centre, starting a revolution in air cargo temperature controlled logistics. In 2001, he joined Envirotainer as Senior Vice President and continued to develop ways of improving the air cargo cold chain for companies such as Marks & Spencer, P&O Cruise Lines, CSL/ZLB, British Airways and Emirates Airline. Tony is a founding committee member of the Cool Chain Association and is an active participant inside the IATA temperature sensitive cargo structure.

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2011 Award Categories:

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Please read the information listed below as each booking is subject to IQPC Ltd standard terms and conditions.

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IQPC Cancellation, Postponement and Substitution Policy: You may substitute delegates at any time by providing reasonable advance notice to IQPC. For any cancellations received in writing not less than eight (8) days prior to the conference, you will receive a 90% credit to be used at another IQPC conference which must occur within one year from the date of issuance of such credit. An administration fee of 10% of the contract fee will be retained by IQPC for all permitted cancellations. No credit will be issued for any cancellations occurring within seven (7) days (inclusive) of the conference. In the event that IQPC cancels an event for any reason, you will receive a credit for 100% of the contract fee paid. You may use this credit for another IQPC event to be mutually agreed with IQPC, which must occur within one year from the date of cancellation.

In the event that IQPC postpones an event for any reason and the delegate is unable or unwilling to attend in on the rescheduled date, you will receive a credit for 100% of the contract fee paid. You may use this credit for another IQPC event to be mutually agreed with IQPC, which must occur within one year from the date of postponement. Except as specified above, no credits will be issued for cancellations. There are no refunds given under any circumstances.

IQPC is not responsible for any loss or damage as a result of a substitution, alteration or cancellation/postponement of an event. IQPC shall assume no liability whatsoever in the event this conference is cancelled, rescheduled or postponed due to a fortuitous event, Act of God, unforeseen occurrence or any other event that renders performance of this conference impracticable, illegal or impossible. For purposes of this clause, a fortuitous event shall include, but not be limited to: war, fire, labour strike, extreme weather or other emergency.

Please note that while speakers and topics were confirmed at the time of publishing, circumstances beyond the control of the organizers may necessitate substitutions, alterations or cancellations of the speakers and/or topics. As such, IQPC reserves the right to alter or modify the advertised speakers and/or topics if necessary without any liability to you whatsoever. Any substitutions or alterations will be updated on our web page as soon as possible.

Discounts: All 'Early Bird' Discounts require payment at time of registration and before the cut-off date in order to receive any discount. Any discounts offered whether by IQPC (including team discounts) must also require payment at the time of registration. All discount offers cannot be combined with any other offer

Please do not pass my information to any third party